Juul Labs®

JLI Submission to the consultation on the Tobacco and Related Products Regulations 2016

About Juul Labs

Juul Labs Inc. (JLI) was founded and is based in the United States. Our products are sold in countries around the world, including the United States, Canada, and the United Kingdom. JLI's mission is to transition the world's one billion adult smokers away from combustible cigarettes, eliminate their use, and combat underage use of its products. To accomplish that mission, JLI is committed to working with governments, regulators, and other stakeholders to create a responsibly regulated and adequately safeguarded vapour category.

JLI supports risk-proportionate regulation for vapour and other non-combustible alternative products. Such a policy framework, at its core, applies the most stringent regulations to the riskiest products (e.g., combustible cigarettes) and encourages current adult users to switch to potentially less harmful non-combustible alternatives. A comprehensive, risk-proportionate regulatory approach can put the end of the age of cigarettes within reach.

JLI is pleased to provide our submission to the Department for Health & Social Care's consultation on the Tobacco and Related Products Regulations 2016 and the Standardised Packaging of Tobacco Products Regulations 2015.

Question 6: How far do you agree or disagree that the current regulations on e-cigarettes have been proportionate in protecting young people from taking up use of these products?

Response:

Juul Labs Inc. (JLI) strongly believes that those who are underage should not have access to or use any tobacco or nicotine-containing product. Public Health England's 2021 Vaping in England evidence update highlighted data from the ASH-Youth survey, which found, "little change in levels of vaping over the last few years with current vaping (at least once per month) prevalence being 4.8% in March 2020, the same as in March 2019."[1]

These stable prevalence rates, as well as the fact that most youth currently using vaping products were former or current smokers,[2] suggest that the regulations the UK has in place – as well as its focus on positioning vaping as an alternative to smoking amongst adults – is working to protect young people from taking up these products.

However, more can and should be done. Regulators, policymakers, and industry all have roles to play to

[1] Public Health England, Vaping in England: an evidence update including vaping for smoking cessation, February 2021, https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021
[2] Ibid.

proactively prevent underage use of tobacco and nicotine-containing products.

JLI takes a comprehensive, data-driven approach to underage use prevention focused on two pillars: limiting the appeal of and restricting access to our products for those underage.

Limiting Appeal

The first pillar of JLI's comprehensive approach to preventing underage use involves limiting the appeal of products to those who are underage.

We adhere to strict guidelines to ensure that our marketing and commercial communications are directed toward existing adult smokers.

For example, strict guidelines ensure that advertising materials and packaging are carefully designed to target and appeal to adult smokers. These guidelines include assuring that our marketing is clear that JUUL products are alternatives to cigarettes for adult smokers.

Additional steps to limit the appeal of JUUL products to those who are underage include:

- Limiting the ways and channels in which products are advertised to ensure that they appeal to adult smokers and limit the potential for unintended exposure among nonusers, especially youth;
- Requiring all media partners working with JLI to establish, maintain, and monitor the use of competent and reliable data sources, methodologies, and technologies to track and measure actual delivery of all advertising impressions, by channel, by product, and by audience demographics, including a breakout by age-group.
- Placing marketing media only where we can ensure that a minimum of 85% of the audience is over the age of 18;
- Strictly prohibiting the use of labelling that resembles kid-friendly foods and drinks or resembles other non-ENDS products:
    - This includes, for example, labelling and/or advertising that results in the product resembling juice boxes, candy, or child-friendly cereal; and/or
    - Products marketed with youth-appealing cartoon or animated characters, such as those that depict or resemble popular children's characters.
- Not using social media for product advertising or promotional purposes. JLI maintains a single social media account for corporate communications use only;
- Not engaging in lifestyle influencer marketing, including on Facebook, Instagram, and similar social media platforms; and
- Actively monitoring social media platforms for inappropriate content, including content that depicts or encourages underage use of JUUL products, and seeking its removal.

Restricting Access

The second pillar of JLI's comprehensive approach to preventing underage use involves measures to restrict underage access, including:

- Restricting underage purchases on owned e-commerce platforms by implementing advanced age-verification technology that requires a purchaser to age verify by uploading a government-issued identification and providing a "selfie" photo that is matched to the picture

on the identification;
- Enforcing strict product quantity limits on purchases to limit the potential for proxy purchasing of devices and pods that could end up used by those underage;
- Enforcing retailer terms that include monitoring and penalties for non-compliance with underage restrictions; and
- Monitoring non-age-gated e-commerce platforms (e.g., eBay) for JUUL product listings and seeking their removal.

In retail settings where JUUL products are available for sale, we enforce 'Challenge 25' age verification methods, which require retailers to check the government-issued identification of anyone who appears to be under the age of 25 prior to completing a sale of tobacco or nicotine-containing products.

JLI also conducts random compliance checks of independent retail stores using a mystery shopper programme. Failures identified through this programme can result in sanctions up to and including retailers being placed on a “no-supply” list and being unable to sell JUUL products.

Reforming the TRPR

The TRPR review presents an opportunity to explore additional measures to further prevent underage use of e-cigarettes.

Product presentation regulations (Section 38), as well as advertising regulations (Part 7) within the TRPR could be updated to include requirements that packaging and advertising be targeted to adults who smoke.

We note that the UK Vaping Industry Association, of which we are a member, has drawn up suggested packaging and labelling guidelines that could be imposed upon the whole industry via new regulations. These regulations would seek to substantially limit youth appeal (e.g., by banning the use youth-oriented content on packaging or in advertising and mandating responsible flavour naming conventions).

Enforcement efforts should also be increased, with tougher penalties for retailers who are found to take insufficient steps to prevent underage sales or who are found to have been selling to underage customers. We welcome cross-industry dialogue about how to enhance enforcement.

Question 7: How far do you agree or disagree that the current regulations have ensured that e-cigarettes are available for those smokers who wish to switch to these products?

While JLI agrees that the current regulations have ensured that e-cigarettes are available to adult smokers, current regulations also act as a barrier to entry to certain e-cigarettes that may help adult smokers who will not quit switch completely away from combustible cigarettes.

Professor John Britton, former chair of the Tobacco Advisory Group of the Royal College of Physicians, emphasised the enormous public health potential:

> *"If all the smokers in Britain stopped smoking cigarettes and started (vaping) e-cigarettes we would save 5 million deaths in people who are alive today. It's a massive potential public health prize."*

While the headline number of e-cigarette users appears to tell a positive story – there are about 2.7 million vapers in the UK according to the Smoking Toolkit Study[3] – the uptake of vaping among smokers is beginning to stall.

According to ASH survey data[4], when the TRPR was implemented in 2016, there were roughly 2.8 million e-cigarette users – an increase of 2.1 million during the previous four years. In the four years following TRPR's implementation, only 400,000 more smokers overall have been added to the total. Of course, these numbers may not account for former smokers becoming former vapers, but the data strongly suggest that the pace of adoption of e-cigarettes has slowed significantly.

Recent ASH data suggests that the overall number of e-cigarette users is now beginning to contract year-on-year for the first time since e-cigarettes came to market.

Key questions for HM Government, as it seeks to set the right policy mix to achieve its 2030 Smoke-Free ambition include:

- Have elements of the regulations simultaneously restricted the availability of emerging products that could have produced more rapid and complete switching of smokers to potentially less-harmful alternatives?
- Might those rules now be reviewed to encourage innovative new products – with mass appeal for adult smokers who may not have tried, or have tried and rejected e-cigarettes – to come to market in time to help power the UK's drive towards a smoke-free society?

Accelerating Adult Smoker Switching to Non-Combustible Products

To compete with cigarettes, a highly effective nicotine-delivery product that smokers have used for years, if not decades, alternative products must provide sufficient appeal and nicotine delivery to those adult smokers. Abrams et al.[5] proposed a Three-Dimensional Framework for Harm Minimization that ranks cigarette alternatives based on relative: "(a) harmfulness; (b) appeal; and (c) satisfaction including dependence." Products which are potentially low in toxicity/harmfulness but also low in appeal and nicotine satisfaction are unlikely to be satisfying alternatives for large numbers of smokers. For example, Nicotine Replacement Therapy (NRT) products have proven efficacy in a smoking cessation setting but have not displaced smoking at the population level.

[3] Public Health England, Vaping in England: an evidence update including vaping for smoking cessation, February 2021, https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021
[4] Action on Smoking Health (ASH), Use of e-cigarettes among adults in Great Britain, October 2020, https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf
[5] Abrams DB, Glasser AM, Villanti AC, Pearson JL, Rose S, Niaura RS. Managing nicotine without smoke to save lives now: Evidence for harm minimization. Prev Med. Dec 2018;117:88-97. doi:10.1016/j.ypmed.2018.06.010

To optimise their potential benefit for adult smokers, alternatives to cigarettes must occupy the "Sweet Spot" of the framework with lower potential toxicity/harmfulness but also sufficient appeal and nicotine satisfaction.

Similarly, the US Food and Drug Administration (FDA) acknowledges that nicotine satisfaction – and ultimately abuse liability – can be a positive feature in products that are designed to compete with cigarettes for adults who smoke, better enabling the non-combustible alternative to pull smokers away. When granting marketing authorisation to IQOS, a non-combustible heated tobacco product, the FDA stated, "*The data indicate that [IQOS] has addictive potential and abuse liability similar to [combustible cigarettes]. This is important as it signifies [IQOS] can provide an adequate nicotine source for dependent populations, including current [combustible] smokers."*[6]

Lack of Satisfaction is Limiting Adult Smoker Switching Away from Combustible Cigarettes

Data suggest that one of the main reasons adult smokers switching to e-cigarettes has stalled is lack of nicotine satisfaction.

Even amongst ex-smokers who vape – those who have switched completely away from combustible cigarettes – 31% still find e-cigarettes less satisfying than smoking a cigarette,[7] putting them at risk for returning to smoking.

Nearly two-in-five current e-cigarette users (38.3%) are 'dual users' – smokers still using combustible cigarettes while using an e-cigarette. Almost two thirds of dual users report being less satisfied by e-cigarettes than combustible cigarettes[8]. Approximately 750,000 e-cigarette users are still smoking and struggling to find satisfaction from their alternative product[9].

To achieve the Smoke-Free 2030 ambition, approximately two-thirds of the current seven million adult smokers will need to either quit or switch to non-combustible alternatives. Yet for millions of smokers, these products do not appear to be sufficiently satisfying alternatives. According to ASH data, 47% of current smokers have tried e-cigarettes but then stopped. This translates to approximately 3.2 million smokers who could have switched, and yet many returned to exclusive smoking[10]. Satisfaction levels for this group are lowest of all – 80% say they found e-cigarettes less satisfying, commonly citing that they did not feel like a cigarette (22%) and did not help with cravings (16%).

Taken together, these data show there are likely as many current vapers in the UK as there are smokers who were dissatisfied with the e-cigarettes they tried.

Current Nicotine Regulation does not allow for Products that Could Enable Large-Scale Switching

The TRPR, implemented pursuant to the EU Tobacco Products Directive, restricts the nicotine concentration of an e-liquid to 20 mg/mL, intending to achieve parity in delivery with a cigarette:

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[6] United States Food and Drug Administration. Premarket Tobacco Product Marketing Orders Decision Summary - IQOS System Holder and Charger 2019. Accessed 01/26/2021.
[7] Action on Smoking Health (ASH), Use of e-cigarettes among adults in Great Britain, October 2020, https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf
[8] Ibid.
[9] Ibid.
[10] Ibid.

> "*Nicotine-containing liquid should only be allowed to be placed on the market under this Directive, where the nicotine concentration does not exceed 20 mg/ml. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette.*" Recital 38 (page 6)[11].

However, there is evidence that suggests the EU regulatory approach fails to achieve its stated objective. This is because the amount of nicotine delivered by an e-cigarette and absorbed by the user is the result of multiple variables[12], including:

- User behaviour;
- The nicotine content of the liquid; and
- Product characteristics, including:
  - ➢ Ingredients;
  - ➢ The temperature at which the liquid is heated.

Therefore, regulating a highly varied category of products based on nicotine content alone is unlikely to ensure consistency with respect to nicotine exposure of the end user.

While certain types of e-cigarettes can provide sufficient nicotine satisfaction to enable some smokers to switch completely away from cigarettes, studies demonstrate that the 20 mg/mL nicotine concentration limit actually prevents many e-cigarettes, particularly innovative closed system pod-based products, from delivering nicotine at levels sufficient to move smokers away from cigarettes[13][14][15]. The result: combustible cigarettes – the deadliest form of nicotine delivery – have a competitive advantage over many e-cigarettes among adult smokers.

Need for A More Risk-Proportionate Regulatory Framework to Further Advance Harm Reduction

JLI is committed to advance the harm reduction potential of non-combustible alternatives. Since coming into force in the UK in 2016 through the TRPR, a new class of products has come to market: closed, temperature-controlled systems that are smaller, produce less aerosol, operate at lower-power, and are simpler for adult smokers to use than other types of e-cigarettes.

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[11] DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Recital 38 (page 6) https://ec.europa.eu/health/sites/health/files/tobacco/docs/dir_201440_en.pdf

[12] Talih, S., Salman, R., El-Hage, R., Karam, E., Karaoghlanian, N., El-Hellani, A., . . . Shihadeh, A. (2020). Might limiting liquid nicotine concentration result in more toxic electronic cigarette aerosols? *Tob Control*. https://doi.org/10.1136/tobaccocontrol-2019-055523

[13] Goldenson NI, Fearon IM, Buchhalter AR, Henningfield JE. An Open-Label, Randomised, Controlled, Crossover Study to Assess Nicotine Pharmacokinetics and Subjective Effects of the JUUL System with Three Nicotine Concentrations Relative to Combustible Cigarettes in Adult Smokers. Nicotine Tob Res. Jan 25 2021; https://doi.org/10.1093/ntr/ntab001

[14] Hajek, P., Przulj, D., Phillips, A., Anderson, R., & McRobbie, H. (2017). Nicotine delivery to users from cigarettes and from different types of e-cigarettes. *Psychopharmacology*, *234*(5), 773–779. https://doi.org/10.1007/s00213-016-4512-6

[15] Phillips-Waller, A., Przulj, D., Smith, K.M. et al. Nicotine delivery and user reactions to Juul EU (20 mg/ml) compared with Juul US (59 mg/ml), cigarettes and other e-cigarette products. Psychopharmacology 238, 825–831 (2021). https://doi.org/10.1007/s00213-020-05734-2

These products show tremendous potential as alternatives to cigarettes, with studies in the US showing more than 50% of adult smokers who purchase these products switching completely away from cigarettes (no smoking within the past 30-days, not even a puff) within a year, including those with longer smoking histories and those who are more dependent on cigarettes[16].

The EU TPD, however, has prevented these products from reaching the U.K. market and reducing the potential they hold for adult smokers looking to switch. This is because these closed-system e-cigarettes typically operate at lower temperatures and produce less aerosol than open tank systems. As a result, they typically require higher concentrations of nicotine in e-liquids (above 20 mg/mL) to deliver sufficient nicotine to compete with cigarettes.

Research shows significantly lower rates of switching away from cigarettes in the UK, with a 20 mg/mL nicotine concentration limit, than in countries where products with higher nicotine concentrations are available[17].

By retaining the EU regulatory framework, cigarettes will be unintentionally protected – reinforcing their position as the most efficient, simple, appealing, and lethal nicotine delivery product on the UK market, and hindering progress towards the Smoke-Free 2030 target.

A Purpose-Built Approach to Regulating Nicotine

The Royal College of Physicians highlights:

> "*the ideal harm-reduction device should deliver nicotine in a manner as similar as possible to cigarettes, while at the same time maximising palatability and nicotine delivery to approximate the experience of cigarette smoking more closely.*"[18]

This principle – that e-cigarettes should be able to deliver nicotine competitively with a combustible cigarette to provide a satisfying experience for adult smokers – should underpin the Government's approach to nicotine regulation.

The Government committed to review the 20 mg/mL nicotine concentration limit in its response to the Science and Technology Committee[19]. We recommend that DHSC now undertake a specific review of this regulation. This process should be informed by the latest science and evidence to examine the best

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[16] Goldenson, N.I., Le, G.M., Augustson, E.M. *Switching Away from Cigarettes Among Adult Smokers who Purchased the JUUL System: 12-Month Follow-Up Results from Two Large Longitudinal Studies* https://www.juullabsscience.com/wp-content/uploads/sites/8/2020/09/Switching-Away-from-Cigarettes-Among-Adult-Smokers-who-Purchased-the-JUUL-System-12-Month-Follow-Up-Results-from-Two-Large-Longitudinal-Studies.pdf

[17] Shiffman, S., Goldenson, N. I., Ding, Y., Prakash, S., Hatcher, C., & Augustson, E. M. (2020). *Differences in Rates of Adult Smokers Switching Away from Smoking using JUUL System Products, Across Jurisdictions with Different Maximum Nicotine Concentrations (North America and the United Kingdom)*. https://www.juullabsscience.com/wp-content/uploads/sites/8/2020/09/Differences-in-Rates-of-Adult-Smokers-Switching-Away-from-Smoking-Using-JUUL-System-Products-Across-Jurisdictions-with-Different-Maximum-Nicotine-Concentrations.pdf

[18] Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction, April 2016, https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction

[19] The Government's Response to the Science and Technology Committee's Seventh Report of the Session 2017-2019 on E-cigarettes, Recommendation 5, page 10 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762847/government-response-to-science-and-technology-committee_s-report-on-e-cig.pdf

way to ensure that e-cigarettes can better compete with combustible cigarettes and switch the maximum number of smokers.

Learnings from other countries that have embraced an evidence-based and pragmatic approach to e-cigarette adoption and harm reduction could provide valuable insight into such a review.

For example, New Zealand is currently consulting on regulations that would set a broader range of nicotine levels for vaping products so that adult smokers have access to satisfying alternatives to cigarettes[20].

The United States, on the other hand, imposes no restriction on nicotine concentration in e-liquids. Instead, the US Food and Drug Administration (FDA), assesses nicotine delivery of cigarette alternatives and uptake by users on a case-by-case basis through its Premarket Tobacco Product Application process.

The appropriate regulatory framework will require a delicate balance to ensure product safety and quality while enabling market access for a broad range of products and ensuring smokers have access to products that can compete effectively with cigarettes.

As always, a critical element of any framework is ensuring appropriate regulatory safeguards are in place to prevent underage use of all tobacco and nicotine-containing products, and additional scrutiny and safeguards against underage use for certain products or categories of products. We would welcome the opportunity to share our views with regulators and policymakers as the regulatory framework is reviewed.

Expanding the Scope of TRPR to Cover Adjacent Products

We support Public Health England's recommendation[21] that non-nicotine vapor products, as well as non-tobacco nicotine products such as nicotine pouches, are brought within the scope of the regulation.

Question 8: What effect do you think the regulations have had on smokers considering switching to e-cigarettes?

Significant progress has been made in reducing smoking prevalence over the last two decades – the result of sustained focus from regulators and policymakers to prevent smoking initiation and encourage cessation.

[20] New Zealand Government Ministry of Health, Smokefree Environments and Regulated Products Act 1990 Proposals for regulations, 2021, https://www.health.govt.nz/system/files/documents/publications/smokefree-environments-regulated-products-act-1990-proposals-regulations-public-consultation-document_21dec2020.pdf

[21] Public Health England, Vaping in England: an evidence update including vaping for smoking cessation, February 2021, https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021

E-cigarettes have played an increasingly important role in that framework. In 2019 an estimated 3.6 million adults in Great Britain were current e-cigarette users[22], with over half of those former cigarette smokers. However, 2020 saw the first decline in e-cigarette use since their survey began in 2012, with a fall to an estimated 3.2 million adult e-cigarette users.

In addition to the important role that nicotine satisfaction plays in encouraging adult smokers to switch completely to e-cigarettes, discussed in detail in the response to Question 7, worsening of public misperceptions around the risks of different tobacco and nicotine-containing products may also play a role.

Data from around the world show that smokers who understand the relative risk of non-combustible products are more likely to switch completely away from cigarettes[23]. Since 2013, the proportion of the adult population thinking that e-cigarettes are more or equally harmful as combustible cigarettes has increased by five times, from 7% in 2013 to 37% in 2020[24]. Among smokers, misperceptions have also worsened. In 2020, 14.8% of smokers thought vaping was more harmful than smoking, and 38% of smokers thought vaping was equally harmful as smoking.

These misperceptions are at odds with the conclusions of public health and scientific experts – including Public Health England[25], the Royal College of Physicians[26], the US' National Academies of Science, Engineering and Medicine[27], and as evidenced in a recent Cochrane Review[28] – that e-cigarettes are likely substantially less harmful than combustible cigarettes, and can play a positive role in tobacco harm reduction.

Experts have expressed concern about the effect of these growing misperceptions on adult smoker switching. According to Professor John Newton, Director of Health Improvement at PHE[29]:

> "*Thousands more could have quit except for unfounded safety fears about e-cigarettes. The evidence has been clear for some time that, while not risk-free vaping is far less harmful than smoking.*"

[22] Action on Smoking Health (ASH), Use of e-cigarettes among adults in Great Britain, October 2020, https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf
[23] Persoskie A, O'Brien EK, Poonai K. Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users. Addiction. 2019;114(12):2197-2205.
[24] Action on Smoking Health (ASH), Use of e-cigarettes among adults in Great Britain, October 2020, https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf
[25] Public Health England, E-cigarettes and heated tobacco products: evidence review, February 2018, https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review
[26] Royal College of Physicians, Nicotine without smoke: Tobacco harm reduction, April 2016, https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction
[27] National Academies of Sciences, Engineering, and Medicine. 2018. Public Health Consequences of E-Cigarettes. Washington, DC: The National Academies Press. https://doi.org/10.17226/24952
[28] Cochrane Database of Systematic Reviews, Electronic cigarettes for smoking cessation, October 2020, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full
[29] Public Health England, Vaping better than nicotine replacement therapy for stopping smoking, evidence suggests, February 2021, https://www.gov.uk/government/news/vaping-better-than-nicotine-replacement-therapy-for-stopping-smoking-evidence-suggests

Similarly, according to Professor Ann McNeill, Professor of Tobacco Addiction at King's College London, and lead author of PHE's recent evidence update said[30]:

> "*What is concerning is that smokers, particularly those from disadvantaged groups, incorrectly and increasingly believe that vaping is as harmful as smoking. This is not true and means fewer smokers try vaping.*"

Adult smokers should have access to accurate, science-based information about the risks, including relative risks, of all tobacco and nicotine-containing products in order to enable them to make informed decisions for their health. Under the appropriate regulatory framework, government, public health, and industry can play important roles in ensuring adult smokers have access to accurate, science-based information.

While TRPR's current restrictions on advertising channels are appropriate, the Government should consider undertaking a broader review of means by which information could be communicated to adult smokers. This review should study the opportunities and potential effect of category-wide and product-specific messaging.

New Zealand provides a ready example of category-wide messaging. The government has established a website entitled Vaping Facts, which provides the public with harm reduction messaging with respect to e-cigarettes[31]. New Zealand is also consulting on proposed regulations[32] that would allow approved public health messages to be displayed at retail or online. The messages include, "*If you are a smoker, switching completely to vaping is a much less harmful option*" and "*Switching completely from smoking to e-cigarettes will reduce harms to your health*."

The Government has committed to review the standardised packaging regulations in relation to the impact of the ban on inserts in cigarette packs[33], while at the same time suggesting, in the *Advancing our Health* green paper, that pack inserts could carry harm reduction messaging encouraging smokers to switch away from cigarettes[34]. Such pack inserts could provide a well-targeted and effective approach to providing science-based information to current smokers. These pack inserts should contain public health information about the category of products rather than any brand-specific promotion.

Question 9: Do you consider the restrictions on e-cigarette advertising to be an effective way to

[30] Ibid.
[31] Health Promotion Agency, https://vapingfacts.health.nz
[32] New Zealand Government Ministry of Health, Smokefree Environments and Regulated Products Act 1990 Proposals for regulations, 2021, https://www.health.govt.nz/system/files/documents/publications/smokefree-environments-regulated-products-act-1990-proposals-regulations-public-consultation-document_21dec2020.pdf
[33] The Government's Response to the Science and Technology Committee's Seventh Report of the Session 2017-2019 on E-cigarettes, Recommendation 5, page 11 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/762847/government-response-to-science-and-technology-committee_s-report-on-e-cig.pdf
[34] Advancing our Health: Prevention in the 2020s, HM Government, July 2019 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753688/Prevention_is_better_than_cure_5-11.pdf

discourage young people and non-smokers from using e-cigarettes?

As discussed in our answer to Question 6, we believe that the regulations intended to limit the appeal of e-cigarettes to those underage have a role to play in preventing underage use.

Question 13: Is there anything else you would like to share on negative or positive impacts the regulations have had on topics not covered above? If so, please explain and include any evidence and research you may have to back your response.

Smoking remains the single largest preventable cause of death in the UK, causing more than 200 deaths per day in 2018-19[35]. Nearly two-thirds of smokers in UK want to quit, but fewer than 1 in 20 will succeed[36].

The UK has been a global leader in the area of tobacco harm reduction as it works towards achieving its ambition to deliver a smoke-free future by 2030. Its intellectual and scientific leadership in this space has been instrumental in fostering the debate around nicotine without smoke worldwide.

JLI fully supports the government's Smoke-Free 2030 ambition. Yet we fear that the goal may not be met without changes to the status quo. Cancer Research UK's February 2020 report projects that adult smoking prevalence in England is not expected to reach the 5% smoking prevalence target until 2037[37].

One strategy to accelerate the decline in smoking is to maximize the potential of e-cigarettes and other non-combustible products. The UK can do this by encouraging innovation in the non-combustible tobacco and nicotine sectors; providing smokers with potentially less harmful alternatives that can deliver satisfying levels of nicotine to compete with cigarettes and transition smokers; and ensuring those smokers who will not quit using nicotine know about the harm reduction potential in non-combustible alternatives.

This is consistent with the aims of the Government's current Tobacco Control Plan[38] (2017-2022), which committed to evidence-based policy making to:

- "*Help people to quit smoking by permitting innovative technologies that minimise the risk of harm*;" and
- "*Maximise the availability of safer alternatives to smoking*."

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[35] NHS England, Statistics on Smoking, England, 2020, https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-smoking/statistics-on-smoking-england-2020

[36] Simonavicius, E., McNeill, A., & Brose, L. S. (2020). Transitions in smoking and nicotine use from 2016 to 2017 among a UK cohort of adult smokers and ex‐smokers. *Drug and alcohol review*, *39*(7), 994-1005

[37] Cancer Research UK, Smoking Prevalence Projections for England, Scotland, Wales and Northern Ireland, February 2020 https://www.cancerresearchuk.org/sites/default/files/cancer_research_uk_smoking_prevalence_projections_february_2020_final.pdf

[38] Gov.uk, Towards a smoke-free generation: a tobacco control plan for England, July 2017, https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england

The current review of the TRPR and SPoT, and the upcoming update to the Tobacco Control Plan, present an opportunity to craft regulation and implement policy measures to put the UK on track to reach the Smoke-Free 2030 goal. In leaving the European Union, the Government has the opportunity to adopt regulation that may be more effective in supporting UK public health objectives, something the Government itself has committed to examine[39]:

> "*Over the course of this Tobacco Control Plan, the government will review where the UK's exit from the EU offers us opportunities to reappraise current regulation to ensure this continues to protect the nation's health. We will look to identify where we can sensibly deregulate without harming public health or where EU regulations limit our ability to deal with tobacco*.
>
> "*In particular the government will assess recent legislation such as the Tobacco Products Directive, including as it applies to e-cigarettes, and consider where the UK's exit provides opportunity to alter the legislative provisions to provide for improved health outcomes within the UK context.*
>
> "*The government will continue to embrace developments that have the potential to reduce the harm caused by tobacco use and as such we will consider if the current regulatory framework strikes the right balance and whether there is more we can do to help people to stop smoking. We remain committed to a comprehensive and robust tobacco control strategy which protects the population of England*."

These commitments should sit at the heart of the Government's next Tobacco Control Plan, due to be published later this year. The Government should meet its commitment to review where the UK's exit from the EU offers opportunities to further improve public health. This could include legislation that allows for the commercialization of potentially less harmful alternatives with the ability to better compete with cigarettes and creates an environment that more effectively supports adult smokers as they switch away from combustible products.

Regulatory and non-regulatory measures to advance progress towards the Smoke-Free 2030 goal should include:

1. **Ensuring that e-cigarettes can provide nicotine satisfaction sufficient to enable adult smokers to switch completely away from cigarettes.**

   To successfully transition completely away from cigarettes, adult smokers need a product that delivers sufficient nicotine to compete effectively with the cigarettes they know and use. While existing e-cigarettes have been sufficient for many smokers – including the roughly 1.9 million e-cigarette users who are ex-smokers – we know that 47% of current smokers who have tried e-cigarettes stopped vaping, and that the most frequent reasons given were that e-cigarettes did not feel like a cigarette (22%) and did not help with cravings (16%)[40].

   Reviewing the nicotine concentration limit set in TRPR, as well as the manner in which

[39] Ibid.
[40] Action on Smoking Health (ASH), Use of e-cigarettes among adults in Great Britain, October 2020, https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf

nicotine in e-cigarettes is regulated, provides the opportunity to consider how best to enable e-cigarettes to compete effectively with cigarettes and accelerate switching away from smoking at the population-level.

2. **Ensuring adult smokers have the information they need to make better decisions for their health.**

   In order to encourage more adult smokers to switch completely to potentially less harmful products, they need accurate, science-based reasons to switch. Current misperceptions of the relative risks of different tobacco and nicotine-containing products must be corrected. This information can and should come from a variety of sources, including Government, scientists, clinicians, public health experts, and industry.

   Comprehensive public awareness campaigns commissioned by the Department for Health and Social Care and informed by opinion research may have particular resonance with adult smokers.

   Medical professionals also have a role to play. Despite Public Health England's advice that smokers who will not quit should switch to e-cigarettes, CRUK found[41], "*Over 1 in 3 clinicians are unsure if e-cigarettes are safe enough to recommend as a quit tool to patients who smoke*," and that 3 in 5 clinicians said "*we do not know enough about them so I don't endorse them*." The government should help ensure accurate clinical guidance for medical professionals.

   Local Authority stop smoking services provide a key channel to reach adult smokers. However, only 11% of local authority stop smoking services offered vaping products to some or all people making a quit attempt[42]. The guidance of Public Health England is particularly salient here: "*Local authorities should continue to fund and provide stop smoking services and all stop smoking services should have a consistent approach to using vaping products*."[43]

   At the same time, it is important to meet adult smokers where they are. Public health messages encouraging switching from cigarettes to non-combustible products at retail, in advertising, and on or in product packaging may be effective means of encouraging switching. We encourage the Government to review the various options and enact regulatory pathways that ensure accurate, scientifically-substantiated information can be communicated to adult smokers as it sets the path to a Smoke-Free 2030.

3. **Continuing research into non-combustible alternatives and dissemination of the results**

   Over the past decade, Public Health England has played a seminal, global role in leading the tobacco harm reduction debate by conducting, commissioning, and publishing scientific research and evidence updates on non-combustible products, in particular e-cigarettes. The recently announced changes in public health provide an opportunity to ensure that the research, monitoring, and reporting of the evidence continues following the replacement of PHE later

[41] Cancer Research UK, E-cigarettes and primary care: a cross-sectional survey of nurses and GPs across the UK, October 2019, https://www.cancerresearchuk.org/sites/default/files/cancer-stats/full_report/full_report_0.pdf
[42] Public Health England, Vaping in England: an evidence update including vaping for smoking cessation, February 2021, https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021
[43] Ibid.

this year. Continuing this world-leading research program is essential for advancing global tobacco harm reduction, and will play a critical role in informing policy to support the Government's Smoke-Free 2030 ambitions.

The first annual decline in vaping threatens to put the Smoke-Free 2030 target out of reach. It is increasingly urgent that the Government take action to seize the opportunity presented by non-combustible products, such as e-cigarettes. The review of the TRPR and forthcoming Tobacco Control Plan provide the opportunity for the Government to take decisive action in support of tobacco harm reduction. Taking the steps outlined above, and working with all stakeholders, can help deliver substantial increases in the number of smokers switching completely away from cigarettes and, in turn, deliver a Smoke-Free 2030.