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# Reactie van Imperial Brands Nederland[1] op de internetconsultatie van het Ministerie van Volksgezondheid, Welzijn en Sport m.b.t. het concept Besluit van Staatssecretaris van Volksgezondheid, Welzijn en Sport houdende de regulering van smaken voor e-sigaretten

18 januari 2021

[1] Van Nelle Tabak Nederland B.V.

# Inhoudsopgave

# 1.Introductie

Imperial Brands Nederland verwelkomt de mogelijkheid om te reageren op het voorstel van het Ministerie van Volksgezondheid, Welzijn en Sport om het Tabaks- en Rookwarenbesluit te wijzigen door wetgeving in te voeren voor een limitatieve lijst van additieven die zouden toegestaan zijn in nicotinehoudende en nicotinevrije e-sigaretten - waardoor het Ministerie in feite een verbod op gearomatiseerde vape producten op de Nederlandse markt voorstelt.

Imperial Brands Nederland is van mening dat het Ministerie niet in deze richting moet gaan, gezien het grote aantal bestaande wetenschappelijke gegevens waaruit blijkt dat smaken een belangrijke rol spelen bij de succesvolle overgang van volwassen rokers van traditionele sigaretten naar vape producten - waarvan volksgezondheidsinstanties hebben geconcludeerd dat ze aanzienlijk minder schadelijk zijn voor de gezondheid. In deze reactie wordt getracht de meest recente wetenschappelijke gegevens over vape producten en smaken weer te geven om het ministerie te informeren over rechtmatig onderzoek en de rol van smaken bij de transitie van volwassen rokers uit de tabakscategorie.

Het huidige voorstel is niet gebaseerd op feitenmateriaal (‘real-world data’) en wordt ook niet ondersteund door de meest recente onderzoeksresultaten met betrekking tot de gevolgen van vape producten voor de gezondheid in vergelijking met brandbare sigaretten. Het voorstel gaat voorbij aan de cruciale rol die vape producten spelen bij het beperken van de tabaksschade en dreigt de verkeerde indruk te wekken bij volwassen rokers en het grote publiek dat vapen net zo schadelijk is als roken, ondanks overtuigend bewijs van het tegendeel. Tot slot wordt in de huidige motivering van het Ministerie om het voorstel in te voeren onvoldoende rekening gehouden met de wetenschappelijke gegevens over e-sigaretten en de gevolgen daarvan voor de gezondheid.

Volgens Imperial Brands Nederland zou een reeks van e-sigaret smaken moeten worden toegestaan om een optimale overgang van volwassen rokers naar vaping te ondersteunen. Het is niet gerechtvaardigd om tabakswetgeving toe te passen op e-sigaretten, aangezien deze geen tabaksproducten zijn en geen tabak bevatten. Het is eveneens niet gerechtvaardigd om de mogelijkheden te beperken voor volwassen rokers die een overgang overwegen – in het bijzonder als die overgang een aanzienlijk potentieel heeft tabaksschade te verminderen in de vorm van een daling van het aantal rokers.

Overheden en fabrikanten zijn verplicht ervoor te zorgen dat de verpakking, etikettering en marketing van e-sigaretten geschikt is en alleen bedoeld is om volwassen rokers aan te spreken. Dit, samen met een robuuste handhaving van jeugdpreventie, is voldoende om enerzijds de bezorgdheden inzake de aantrekkingskracht van smaken op jongeren weg te nemen, en anderzijds volwassen rokers toch de productinformatie te geven die zij nodig hebben.

# 2.Bedrijfsachtergrond

Imperial Brands Nederland is onderdeel van Imperial Brands, een wereldwijd opererend bedrijf. Onze producten zijn te koop in meer dan 160 landen. We hebben wereldwijd 38 fabrieken en tellen 32.500 medewerkers.

Imperial Brands produceert, distribueert en verkoopt een breed assortiment van tabak, sigaretten, shag, rookloze tabaksproducten, sigaren en papier, en vape producten. We ontwikkelen een portfolio van merken die verder gaan dan tabak, waaronder het e-vapour merk blu.

Onze entiteiten in Nederland, Van Nelle Tabak Nederland B.V. en Fontem Ventures bieden samen werkgelegenheid aan 519 werknemers in Nederland.

Wij verkopen onze producten (met of zonder tabak en/of nicotine) niet aan personen onder de 18 jaar of aan niet-rokers. Wij geloven dat onze producten alleen voor volwassenen zijn. We willen niet dat kinderen gaan dampen of gebruik maken van dampwaar.

Het voorkomen van het gebruik van dampproducten door kinderen is een maatschappelijk probleem dat moet worden opgelost. Wij spelen onze rol door de marketing van onze producten niet te richten op personen onder de 18 jaar en niet op niet-rokers of niet-dampers.

Wij steunen ook de handhaving van de wettelijke minimumleeftijd door de bevoegde autoriteiten voor de aankoop van dampwaar en sancties voor detailhandelaren die dampwaar aan kinderen verkopen.

Wij ondersteunen degelijke, wetenschappelijk onderbouwde, redelijke en uitvoerbare regelgeving voor elektronische sigaretten met of zonder nicotine.

# 3.Executive Summary

Naar onze mening mag het Ministerie geen smaakverbod voor elektronische sigaretten invoeren omwille van de volgende redenen, die we in de hiernavolgende hoofdstukken in detail onderbouwen:

**A. De feiten en het wetenschappelijk bewijs ondersteunen de 'opstap theorie' of het gebruik van e-sigaretten door jongeren niet.**

Er is geen ondersteunend bewijs dat e-sigaretten een opstap, of zogenaamde toegangspoort, zijn tot het roken van brandbare tabak. Wij zijn van mening dat de trends op het gebied van e-sigaretten nauwlettend in de gaten moeten worden gehouden en dat jeugdpreventie een topprioriteit moet blijven voor alle fabrikanten en overheden. Ondanks een aantal e-sigaret experimenten onder 'nooit rokers' in verschillende landen, is het regelmatig gebruik van e-sigaretten door mensen die nog nooit hebben gerookt uiterst zeldzaam. Experimenteren onder adolescenten wordt vaak verkeerd geïnterpreteerd in onderzoek en de daaropvolgende krantenkoppen zonder dat er gekeken wordt naar de eerdere rookgeschiedenis. Het is belangrijk om de nuances in gerapporteerd gedrag te begrijpen (eenmalig experimenteren en eenmalig gebruik in een periode van 30 dagen versus regelmatig wekelijks of dagelijks gebruik).

**B. Het voorgestelde smaakverbod is niet gebaseerd op bewijs. Smaken in e-sigaretten zijn een belangrijke factor in de transitie van volwassen rokers uit de tabakscategorie.**

Er is geen geloofwaardig of robuust bewijs dat een smaakverbod voor e-sigaretten, met of zonder nicotine, zou bijdragen aan de verbetering van de volksgezondheid. Het onbedoelde gevolg van een smaakverbod kan zijn dat het aantal volwassen rokers dat overgaat op e-sigaretten afneemt als gevolg van een verminderd aanbod aan beschikbare smaken om de overgang te vergemakkelijken. Aanzienlijk onderzoek toont aan dat smaken een cruciale rol spelen bij het aantrekken - en vasthouden - van volwassen rokers in de categorie e-sigaretten, wat direct bijdraagt aan de vermindering van de tabaksschade en de daling van het aantal rokers. Smaken zorgen ervoor dat volwassen rokers e-sigaretten smakelijk vinden en dus gemakkelijker kunnen overstappen.

**C. De feiten en het wetenschappelijk bewijs tonen aan dat e-sigaretten effectief zijn voor het stoppen met roken.**

Gerandomiseerde controle klinische studies, observationele studies en populatiegegevens tonen aan dat wanneer e-sigaretten proportioneel worden gereguleerd, ze een hoge mate van succes hebben in het bereiken van het stoppen met roken in vergelijking met andere alternatieven.

## D. Het huidige voorstel dreigt een willekeurige discriminatie in te houden die het vrije verkeer van goederen in de zin van artikel 34 VWEU zou beperken.

Het voordeel voor de volksgezondheid waarop het Ministerie zich beroept om deze beperking van het vrije verkeer van goederen in de zin van artikel 34 VWEU te rechtvaardigen, bestaat duidelijk niet.

Inzake beperkingen van de rechten van de Europese Unie, zoals het vrije verkeer van goederen, moet de mildste effectieve maatregel worden genomen. In deze context zou dit de invoering zijn van strengere wetten tegen de verkoop van elektronische sigaretten aan minderjarigen, met inbegrip van zogenaamde "proxy buying" (d.w.z. dat een volwassene die namens een minderjarige producten koopt, een boete krijgt). Deze maatregel zou moeten worden toegepast op nicotine- en nicotinevrije elektronische sigaretten en zou beter tegemoetkomen aan de gestelde doelen om er enerzijds voor te zorgen dat jongeren geen toegang hebben tot elektronische sigaretten én om volwassen rokers anderzijds toch de keuzemogelijkheden te bieden die zij nodig hebben om met succes de af te stappen van brandbare tabaksproducten.

In Nederland is er geen specifieke situatie die verschilt van andere lidstaten en die strengere maatregelen zou rechtvaardigen.

## E. De maatregel zal leiden tot onbedoelde gevolgen die een negatieve impact hebben op de volksgezondheid

Door het voorstel wekt de overheid ten onrechte de indruk dat elektronische sigaretten, die geen tabak bevatten, even schadelijk zijn als traditionele tabaksproducten. Dit kan er toe leiden dat verstokte rokers geen reden zien om (volledig) over te stappen naar e-sigaretten, of erger, zullen bestaande exclusieve dampers opnieuw overstappen naar tabaksproducten.

Bovendien houdt de voorgestelde maatregel geen rekening met het feit dat het beperken van vapers - waarvan de overgrote meerderheid volwassen rokers zijn die proberen te verminderen of stoppen met roken - tot één enkele e-vloeistofsmaak hun pogingen om te stoppen met roken zou kunnen ondermijnen.

Uit een schatting blijkt dat 260.000 vapers in Nederland terug zouden kunnen beginnen met het roken van brandbare sigaretten indien smaken in e-sigaretten verboden zouden worden.

## F. Het voorstel houdt geen rekening met recente wetenschappelijke studies omtrent e-sigaretten.

Het Ministerie houdt in zijn huidige voorstel geen rekening met de bredere basis van up-to-date wetenschappelijk bewijs rond e-sigaretten en hun gevolgen voor de gezondheid in vergelijking met het blijvend gebruik van brandbare sigaretten. Evenmin erkent het de aangetoonde en vitale rol van smaken in de transitie van volwassen rokers om minder of volledig te stoppen met roken.

Imperial Brands Nederland is daarom van mening dat het Ministerie het risico loopt een kortzichtig beleid te voeren dat naar alle waarschijnlijkheid weinig verschil zal maken inzake experimenteren

onder jongeren, maar dat zeker een negatieve impact zal hebben op het aantal bestaande rokers die kunnen overstappen op een minder schadelijk alternatief product.

Wij dringen er dan ook op aan dat het Ministerie zich vertrouwd maakt met de meest recente wetenschappelijke feiten, waaronder de internationaal erkende 2020 Cochrane Review over e-sigaretten. Hierin worden het effect en de veiligheid van het gebruik van e-sigaretten om rokers te helpen bij stoppen met roken op lange termijn, geëvalueerd, en 50 studies bij 12.430 volwassenen overwogen - studies die plaatsvonden in de VS (21 studies), het Verenigd Koninkrijk (9), Italië (7), Australië (2), Nieuw-Zeeland (2), Griekenland (2), en één studie in België, Canada, Polen, Zuid-Korea, Zuid-Afrika, Zwitserland en Turkije. Deze concludeerden dat nicotinehoudende e-sigaretten:

i) mensen helpen om te stoppen met roken (zelfs onder degenen die niet van plan zijn om te stoppen met roken) en beter werken dan NRT en nicotinevrije e-sigaretten;

ii) beter zijn voor het stoppen met roken dan geen ondersteuning, of gedragsondersteuning alleen;

iii) niet worden geassocieerd met ernstige ongewenste effecten of schade met maximaal twee jaar productgebruik.

Gelet op het feit dat Cochrane Reviews wereldwijd erkend worden als de gouden standaard van wetenschappelijk bewijs, zou het ministerie deze studie moeten overwegen naast andere meest recente wetenschappelijke onderzoeksconclusies.

Naar onze mening zou een reeks van e-sigarettensmaken moeten worden toegestaan om een optimale overgang van volwassen rokers naar vaping te ondersteunen. Het is niet gerechtvaardigd om tabakswetgeving toe te passen op e-sigaretten, aangezien deze geen tabaksproducten zijn en geen tabak bevatten.

Imperial Brands Nederland ondersteunt de doelstelling van het Ministerie om ervoor te zorgen dat e-sigaretten alleen worden gebruikt door het beoogde publiek (volwassen rokers), maar wij zijn van mening dat dit het beste kan worden bereikt door de bestaande EU-wetgeving, productrapportage-eisen en verantwoorde e-sigarettenverpakkingen en -etikettering. Zonder dat er een willekeurig verbod op gearomatiseerde vape producten hoeft te worden ingevoerd - waarvan is bewezen dat ze een belangrijke bijdrage leveren aan de overgang van volwassen rokers - waardoor een snellere vermindering van het aantal rokers in Nederland wordt bemoeilijkt.

# 4. Gedetailleerde onderbouwing van ons standpunt

## 1. E-cigarette use among young people

**REAL-WORLD DATA AND THE SCIENTIFIC EVIDENCE BASE DO NOT SUPPORT THE 'GATEWAY THEORY' OR THE UPTAKE OF E-CIGARETTES BY YOUNG PEOPLE**

Despite some e-cigarette experimentation amongst never-smokers in different countries, regular use of e-cigarettes by people who have never smoked is extremely rare. Experimentation amongst adolescents is often misconstrued in research and subsequent media headlines with no understanding of previous smoking history documented. It is important to understand the nuances in reported behaviour (I.e. one-off experimentation and one-off use in a 30-day period versus regular weekly or daily use).

We believe e-cigarette usage trends must continue to be closely monitored and youth access prevention should remain a top priority for all manufacturers and governments, however there is no supportive evidence that e-cigarettes are a gateway product to smoking combustible tobacco in any Member State. A number of studies from the Netherlands demonstrate the lack of youth uptake in the country:

- The number of young people in the Netherlands who have ever tried e-cigarettes has declined in the past five years by a quarter [2].
- The number of young people in the Netherlands who use e-cigarettes is very low. Only 0.2 percent of 14- to 16-year-olds vaped regularly in 2019 [3]. It is important to note, 23.5% of 15 – 16 year olds in the Netherlands have smoked, as reported by RIVM in the 2019 youth substance use data, a fact which should be taken into consideration when reviewing e-cigarette experimentation in the same age group.
- Overall, a total of 99.8 percent of all Dutch e-cigarette users were smokers before they started vaping [4].

The lack of evidence of youth uptake, disproving the gateway theory, has also been replicated in the UK. When the EUTPD was transposed into national legislation and frequent monitoring was conducted, it was shown in 2019 that, amongst 11-18 year olds *who also smoked*, regular use (at least once a week) of e-cigarettes remained very low at 1.7% [5]. Amongst *never* smokers, regular use of e-cigarettes was 0.2% with youth smoking rates at an all-time low.

A UK YouGov survey [6] commissioned by Action on Smoking and Health (ASH), a UK-based organisation striving to end tobacco harm, has, in line with previous findings, indicated that "vaping is a gateway away from smoking."

- For the first time, current e-cigarette use has declined year-on-year, from 7.1% to 6.3% of the adult population in Great Britain, amounting to 3.2 million people.
- Over half (58.9%) of current vapers are ex-smokers and the proportion has grown year-on-year, while the proportion of vapers who also smoke (known as dual users) has fallen to 38.3% in 2020.
- The proportion of adult smokers who had never tried e-cigarettes fell rapidly from 2010 until 2014, and continued falling, but gradually, from 2015 onwards. In 2020 it was 32.4%.
- Only 0.3% of never-smokers are current vapers (amounting to 2.9% of vapers), down from 0.8% in 2019, reported the survey in January 2021.

The findings also indicated that only 2% of current vapers were never-smokers, and an overall 60% of the adult vapers identified their health as their "number one reason for taking up e-cigarettes." Michael Landl, director of the World Vapers' Alliance, pointed out that once again these results indicate that "vaping is a gateway away from smoking." In line with this, an Australian review released in 2020 titled, "Does the gateway theory justify a ban on nicotine vaping in Australia?," also debunked the 'Gateway Theory', which is unfortunately one of the major arguments that local authorities use to justify the ban on nicotine vaping products. Review authors Colin Mendelsohn and Wayne Hall, pointed out that a more plausible explanation as to why young people who vape are more likely to smoke, are personality factors. This means that those teens who vape are risk-takers and are therefore also more likely to smoke, drink alcohol, use cannabis and other substances. This argument has already been emphasised by other experts in multiple studies.

**THE SCIENTIFIC AND REAL-WORLD EVIDENCE DOES NOT SUPPORT THE CONCLUSION THAT E-CIGARETTES ARE A GATEWAY TO CIGARETTE SMOKING**

As referenced and discussed below, there is limited credible scientific or real-world evidence that e-cigarettes are a gateway product to cigarette smoking for never-smoker youth or adults in countries where e-cigarettes are regulated and widely available to adult smokers.

Scientific and real-world evidence shows smoking rates across the EU are at an all-time low, and demonstrates e-cigarettes are a ***gateway from*** cigarette smoking, as detailed below.

1. **In the UK,** the largest ever analysis of data from 60,000 11-16-year-olds found no evidence that e-cigarette use is leading young people into smoking. The study, a collaboration between the UK Centre for Tobacco and Alcohol Studies, Public Health England, Action on Smoking and Health (ASH), and the DECIPHer Centre at the University of Cardiff, analysed five large-scale surveys conducted in the period 2015-2017 involving over 60,000 11–16-year-olds. Among young people who have *never* smoked, regular use of e-cigarettes was negligible – between 0.1% and 0.5% across the five surveys assessed [7].

2. **In Greece,** a study that assessed prevalence and correlates of e-cigarette use in 2017 (representative sample of 4058 adults living in Attica prefecture; 35% of the Greek adult population) found e-cigarette use is largely confined to current or former smokers, while current use and nicotine use by never smokers is "extremely rare" (around 0.2%), and most participants overestimate the harmfulness of e-cigarettes relative to smoking [8].

A second Greek study of 309 participants found that 82.5% were daily e-cigarette users; the vast majority (>98%) were smokers before e-cigarette initiation, and only 1% were never smokers, and 1% had quit smoking before e-cigarette initiation with the authors concluding "*Vape shops customers in Greece are mainly current and former smokers with the majority of them having quit smoking. E-cigarette use by never smokers is rare and none of them subsequently initiate smoking*" [9].

A third Greek study, which performed an analysis of a representative population sample, found that current and daily e-cigarette use are strongly associated with recent smoking cessation, suggesting a positive public health impact in a country with the highest prevalence of smoking in the EU; and e-cigarettes do not appear to promote relapse in long term former smokers [10].

3. **France:** A Public Health France study finds that over seven years (2010-2017), 700,000 smokers have used e-cigarettes to quit smoking. Less than 1% of e-cigarette users were never smokers. Anne Pasquereau, Scientific Researcher Public Health France, said: "The electronic cigarette does not seem to be becoming a new product used by adults without any link with tobacco". In three years, the share of daily smokers halved among e-cigarette users, while the number of former smokers doubled. Among dual users, cigarette consumption significantly by 80% (from a packet a day to 9 on average).[11]

4. **France:** An analysis of data from a French national representative survey collected in 2017 (n=39,115) on the role of ever using e-cigarettes on daily cigarette smoking status at 17 among ever smokers (n=21,401) found that among ever-smokers, adolescents who declared having ever used e-cigarettes were less likely than those who did not to transition to daily smoking at 17. The authors also found similar results for those who experimented with e-cigarettes before initiating smoking. The authors concluded that they found no evidence of an increased risk of transitioning to daily smoking at 17 among ever-smokers who also experimented with e-cigarettes.[12]

**LACK OF EVIDENCE FOR GATEWAY EFFECT IN THE US**

There is no credible evidence that e-cigarettes are a gateway product to combustible cigarette smoking for never smoking adults or youth in the US. However, the regulatory environment for e-cigarettes in the US differs to the EU, which is more strictly regulated. For example, there are no nicotine caps mandated in the US market and US vape products were (and US marketing was) inadequately regulated at their introduction. Both the nicotine levels and marketing of vape products in Europe are highly regulated via EUTPD meaning it is difficult to draw comparisons between the two jurisdictions. There are specific grounds to believe that youth access is not a significant issue for the blu e-cigarette brand in the US because we are a responsible manufacturer. This is strongly supported by new evidence from the 2020 Youth Tobacco Study,[13] which shows negligible numbers of non-smoking youth have tried blu.

- **US:** A recent research paper published in Tobacco Control found the observed 'gateway' effect of e-cigarettes use among teens is "likely to be small," with only a tiny proportion of experimental vapers going on to smoke regular cigarettes. An analysis of first experimentation with different types of tobacco products among nearly 40,000 US teens, using responses to the National Youth

Tobacco Survey for 2014-17 found that less than 1% of teens who tried EVPs became established smokers, a proportion that was significantly smaller than any other product category. The researchers also found that the association of subsequent use of EVPs was stronger for adolescents initiating with cigarettes than the association of subsequent cigarette smoking for EVPs initiators and commented in an accompanying press release that "…over the time period considered, EVPs were unlikely to have acted as an important gateway towards cigarette smoking, and may, in fact, have acted as a gateway away from smoking for vulnerable adolescents....The postulated gateway effect is likely to be small."[14].

- **US:** An analysis of the 2018 National Youth Tobacco Survey data (NYTS) (N=20,189; all students [middle and high school; 6-12th grades; 9-19 years old]) found that 81.4% of students had not used any tobacco or vapour product in the past 30-days (p30d), and 86.2% had not vaped in the p30d. An analysis of the US NYTS dataset showed that among tobacco naïve adolescents, 0.4% regularly used e-cigarettes on 20+ days [15]. Among all students, of the 13.8% vaped in the p30d, just over half vaped on ≤5 days (7.0%), and roughly a quarter each vaped on 6-19 days (3.2%) and on 20+ days (3.6%). Almost three quarters of p30d vapers (9.9%) reported past or concurrent tobacco use and the remainder (3.9%) were tobacco naïve. 2.8% of students were tobacco naïve and vaped on ≤5 days; 0.7% were tobacco-naïve and vaped on 6-19 days, and 0.4% were tobacco-naïve and vaped on 20+ days. The authors concluded that the results underscore the importance of including the full context of use patterns. The majority of vapers (60.0% - 88.9% by use frequency) were concurrent p30d or ever tobacco users. About 4% of students were tobacco naïve and vaped in the p30d, but few (0.4%) vaped regularly on 20 or more days."[15].

- **US:** An analysis of e-cigarette use and dependence in the NYTS in relation to lifetime history of use of tobacco products using a nationally representative survey of high school students in 2017 and 2018 (10,186 students in 2017 and 10,991 in 2018) found past-30-day e-cigarette use increased by 78% from 11.7% in 2017 to 20.8% in 2018. In both years, past-30-day use was strongly associated with lifetime tobacco use history: it was seen in 8.4% of never tobacco users in 2018, in 29.0% of those who had tried a non-combustible, but never a combustible, product by comparison with never tobacco users, and in 71.0% of those who had smoked more than 100 cigarettes in their lifetime. Frequent use (20+ days) occurred in 0.1% of never tobacco users in 2017 and 1.0% in 2018. The authors state that their analysis of NYTS data from 2018 and earlier years shows a strong association between lifetime history of use of tobacco products and use of e-cigarettes: in 2018, high school students who had smoked more than 100 cigarettes in their lifetime were some 27 times more likely to have used e-cigarettes in the past 30 days than students who had never tried any tobacco product. Use of e-cigarettes on 20 or more days in the past month was seen in only 1.0% of those who had never tried any tobacco product in 2018. Symptoms of dependence were rare among students who use e-cigarettes without having used any other tobacco products. The authors also note that their paper "is not intended as a challenge to the current direction of FDA policy on the regulation of e-cigarettes. That would be presumptuous on our part. Rather, we have sought to examine the evidence brought forward to support new regulatory initiatives. We find a gaping chasm between the vision of an epidemic of e-cigarette use threatening to engulf a new generation in nicotine addiction and the reality of the evidence contained in the NYTS" [16].

To conclude, firstly, the statistics to-date do not support the view that significant numbers of non-smokers are vaping regularly. Secondly, the available data shows the opposite is occurring and e-cigarettes are acting as a gateway from smoking or serve as a 'roadblock' to smoking for those that may be inclined to smoke. The available data shows vaping is accelerating declines in smoking rates, as outlined below:

1. The World Health Organization acknowledged in 2014: "*At least for the United Kingdom, renormalization as measured by prevalence of smoking is not occurring currently*".[17]

2. An analysis of e-cigarette uptake amongst UK youth from various separate studies revealed that, although there is some experimentation amongst never-smokers, there is no evidence of this group of young people regularly using e-cigarettes.[18]

3. The UK Royal College of Physicians also concluded: "*E-cigarettes are not a gateway to smoking – in the UK, use of e-cigarettes is limited almost entirely to those who are already using, or have used, tobacco*." [19]

4. The UK's largest ever analysis of data showed there is no evidence that e-cigarettes are leading young people into smoking. The study, a collaboration between the UK Centre for Tobacco and Alcohol Studies, Public Health England, Action on Smoking and Health, and the DECIPHer Centre at the University of Cardiff analyzed five large-scale surveys conducted in the period 2015-2017 involving over 60,000 11-16 year-olds and found among young people who have never smoked, regular use of e-cigarettes was negligible – between 0.1% and 0.5% across the five surveys. [20;21]

5. The UK British Medical Association noted in their key messages for policymakers: "*Though awareness of and experimentation with e-cigarettes is increasing in the UK, few children are becoming regular users of e-cigarettes. Nearly all of those that are currently or have previously smoked*" and "*Current data on e-cigarette use and smoking does not support concerns that e-cigarettes will promote tobacco use among children and young people. Youth cigarette smoking has declined over the period of time that e-cigarettes have become increasingly available*".[22]

6. The 2018 Public Health England evidence review update concluded "… *the evidence suggests that EC [EVPs] have contributed tens of thousands of additional quitters in England*" estimating e-cigarettes contributed to an *additional* 57,000 quitters (lower bound estimate 22,000) in England in 2016.[23]

## Vaping is not demonstrated to be a gateway to smoking

### Evidence does not support the conclusion that vaping is a gateway to cigarette smoking for never-smoker youth...

- Youth smoking rates in the UK are in decline, falling as much as 9% from 2008-18 in some age groups.[1,2] Regular vape use in young people remains low.[3] The Royal College of Physicians subsequently concludes "e-cigarettes are not a gateway to smoking – in the UK, use of e-cigarettes is limited almost entirely to those who are already using or have used tobacco."[4]

- Likewise, researchers analysing US national youth smoking data conclude vapes are "unlikely to have acted as an important gateway towards cigarette smoking, and may, in fact, have acted as a gateway away from smoking for vulnerable adolescents".
- In Canada – where vaping was recently legalised due to increasing evidence of its Tobacco Harm Reduction potential – the number of current smokers age 12-17 fell by 9% compared from 2018-19.[6,7,8]


1. ASH Use of e-cigarettes (vapes) amongst adults in Great Britain 2020 https://ash.org.uk/wp-content/uploads/2020/10/Use-of-e-cigarettes-vapes-among-adults-in-Great-Britain-2020.pdf
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### Well regulated vape markets demonstrate declining smoking rates...

- Vaping is reducing the UK's smoking rate. 13.9% of adults smoke, down from 19.3% in 2011[1,2],now one of the lowest smoking rates in Europe. Public Health England says vapes have "contributed to tens of thousands of additional quitters".[3]

- The US is the world's largest vape market. Its smoking rate fell to 13.7% in 2018, a significant reduction from 20.9% in 2005. The proportion of ever smokers who have quit has also increased.[4]
- In Canada, where vaping is also popular, the number of current daily smokers age 18-34 fell by 9% from 2018-9.[5,6,7]


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## The proposed flavours ban is not evidence-based (making e-cigarettes less attractive)

### A BAN ON ATTRACTIVE FLAVOURINGS

Around 65 percent of adult vapers in Europe use fruit or sweet liquids [24] and this variety in choice is one of the key factors in changing adult smoker behaviour and preventing vapers from going back to smoking.

There is no credible or robust evidence that a flavour ban for e-cigarettes, with or without nicotine, would contribute to improving public health. The unintended consequence of a flavour ban may be a decrease in the number of adult smokers who transition to e-cigarettes as a consequence of a reduced range of available flavours to aid those who seek to transition.

### E-LIQUID FLAVOURS ARE AN IMPORTANT FACTOR IN ADULT SMOKERS' TRANSITIONING AWAY FROM TOBACCO CIGARETTES

Substantial research shows flavours play a critical role in attracting - and retaining – adult smokers into the e-cigarette category, directly contributing to tobacco harm reduction and declining smoking rates. Flavours ensure adult smokers find e-cigarettes palatable and therefore easier to transition to. Regular use of multiple e-liquid flavours has been shown to be associated with significantly higher odds of having quit smoking [25] and flavoured e-cigarette use is associated with higher rates of smoking cessation [26]. Daily e-cigarette use of flavoured products is also associated with higher odds of being a former smoker [27].

Data from the US shows that non-tobacco flavours are no more associated with youth smoking initiation than tobacco flavours, but are associated with increased adult smoking cessation amongst adults, with those who began e-cigarette use with non-tobacco flavours more likely to quit smoking than those who use tobacco flavours [28] . Consistent with this, US adult smokers tend to initiate e-cigarette use with tobacco-flavours, but then transition to exclusive or predominant use of non-tobacco flavoured products, particularly fruit, sweet and dessert flavours [29]. Moreover, US adult smokers who transition to non-tobacco flavoured e-cigarettes (or multiple non-tobacco/menthol flavours) are 2.5-3 times more likely to have quit or reduced smoking in the past year compared to non-e-cigarette users. [30]

In the UK, in March 2020, when Public Health England released its annual review of scientific evidence on vaping, it stated that any ban on flavoured e-liquids could push current vapers towards illicit products, calling for more research into e-cigarette flavour preferences amongst youth rather than proposing to further regulate e-liquids themselves to the detriment of adult smokers.

There is a growing body of research which shows flavours play a critical role in attracting - and retaining - adult smokers into the vaping category, directly contributing to tobacco harm reduction and declining smoking rates, with full details below:

1. Flavours play an important role in adult e-cigarette product use, ensuring smokers find products palatable and therefore easier to switch to. Regular use of multiple e-liquid flavours is associated with significantly higher odds of having quit smoking: a study of 4,618 e-cigarette users found 63%

vary their flavours on a daily basis, noting that flavours "appear to contribute to both perceived pleasure and the effort to reduce cigarette consumption or quit smoking" and play a major role in reducing relapse into tobacco smoking. [31]

2. Flavours are associated with higher rates of smoking cessation. [32]

3. **US:** An analysis of the U.S. Population Assessment of Tobacco and Health (PATH) study (Waves 1-4) showed vaping non-tobacco flavours was no more associated with youth smoking initiation than vaping tobacco-flavours but was associated with increased adult smoking cessation. Adults who began vaping non tobacco-flavoured e-cigarettes were more likely to quit smoking than those who vaped tobacco flavours. [33]

4. **US:** Evidence from cross-sectional surveys of nationally representative samples of U.S. adults and non-probabilistic surveys of dedicated e-cigarette users suggests that smokers tend to initiate e-cigarette use with tobacco-flavoured e-cigarettes, but transition to exclusive or predominant use of non-tobacco flavoured products – particularly fruit, sweet and dessert flavours – with increased frequency and duration of e-cigarette use. [34]

5. **US:** Data from the U.S. PATH study shows the majority of daily e-cigarette users were currently using non-tobacco flavours and were significantly more likely than moderate and infrequent e-cigarette users to have initiated e-cigarette use with a non-tobacco flavour. [35] At the same time, daily e-cigarette use was associated with higher odds of being a former smoker.

6. **US:** A study found that most former smoking e-cigarette users initiated vaping with non-tobacco flavours, while initiation with tobacco flavours was more common for dual users. These data indicate that smokers who initiate e-cigarette use with a non-tobacco-flavoured product are more likely to become daily users, and in turn, more likely to quit smoking. [36]

7. **US:** A separate analysis of the U.S. PATH data found that young adult (age 18-34) cigarette smokers at Wave 1 (2013/14) who were using one non-tobacco/menthol flavour or multiple non-tobacco/menthol flavours in an e-cigarette product at Wave 2 (2014/15) were 2.5 and 3 times more likely to have quit or reduced smoking in the past year, respectively, compared to non-e-cigarette users. [37]

8. **US:** An online survey that assessed first e-cigarette flavour and current flavours used by a non-probabilistic sample of 20,836 adult frequent e-cigarette users in the US found the majority of frequent users, who had completely switched from smoking cigarettes to using e-cigarettes (nearly 16,000), were increasingly likely to initiate vaping with non-tobacco flavours, and to have transitioned from tobacco to non-tobacco flavours over time. In the study the most popular currently used e-cigarette flavours in the US were fruit/fruit beverage, where up to 82.9% of sampled users reporting regular purchase and use of vape liquids in this category, with dessert/pastry flavours next at 68.5%. Tobacco and menthol flavours ranked as the 5th and 6th most popular currently used flavours, respectively. [38]

9. **US:** A longitudinal study that examined changes in flavour use patterns in long-term e-cigarette users (383 adult participants) in two online e-cigarette surveys in 2012-2014 (baseline survey) and in 2017-2019 (follow-up survey) found preference for tobacco and menthol or mint flavours decreased over time (40% baseline, 22% follow-up); preference for fruit remained stable (23%

baseline and follow-up), but chocolate/candy or other sweets preference significantly increased (16% baseline, 29% follow-up) and other flavours increased slightly. Migration to sweet flavours was more noticeable in younger adults (18-45 years) and exclusive e-cigarette users more commonly preferred sweet flavours than poly-users [i.e. e-cigarette and other tobacco product use] (31% vs 19%). Nearly 50% of the participants reported that they would "find a way" to buy their preferred flavour or add flavouring agents themselves if non-tobacco flavours were banned. The authors concluded flavour migration towards sweet flavours occurred in long-term e-cigarette users, a trend most pronounced in younger and exclusive e-cigarette-users. [39]

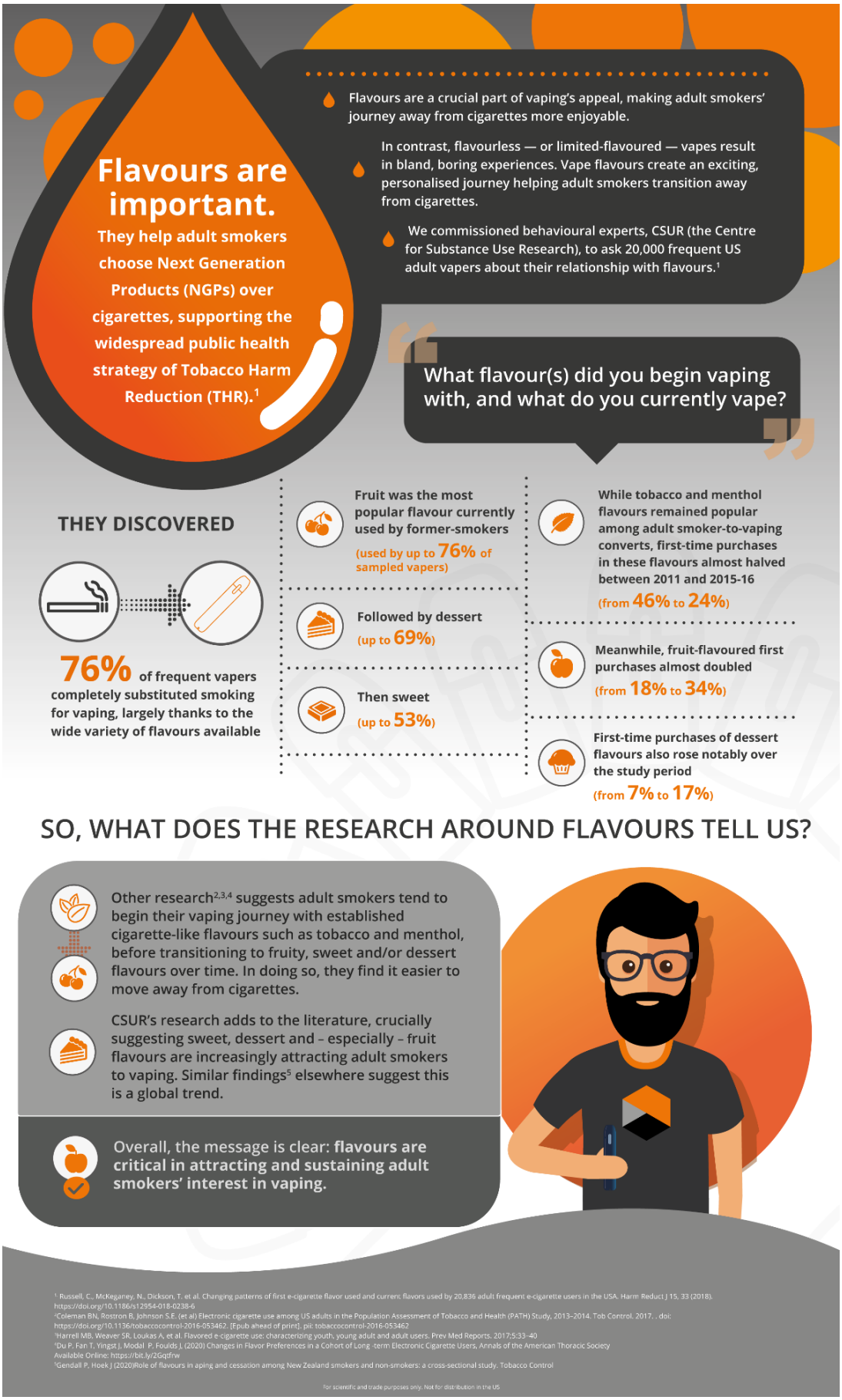
**UNINTENDED CONSEQUENCES OF EXTENDING A FLAVOUR BAN TO LESS HARMFUL ALTERNATIVES**

The proposal does not consider the negative consequences of the damaging public health message that is communicated to consumers by equalising the use of e-cigarettes with combustible tobacco products. Through the extension of the existing flavours ban on combustible cigarettes to e-cigarettes (which are by a growing scientific community, including by the RIVM [40] , considered as less harmful than smoking cigarettes), the Government creates an erroneous impression that e-cigarettes, which do not contain tobacco, are as equally harmful as combustible tobacco products.

Furthermore, the proposed measure does not consider the fact that restricting vapers – the vast majority of whom are adult smokers trying to reduce or replace smoking – to a single e-liquid flavour (proposed to be tobacco) could well undermine their attempts to quit smoking thus preventing any public health benefits through a reduction in smoking rates, or the realisation of tobacco harm reduction.

Indeed, one estimate approximates that 260,000 vapers in The Netherlands could revert back to smoking in the event flavours are banned [41]. Researchers at Yale in the US found that vaping non-tobacco flavours was no more associated with youth smoking initiation than vaping tobacco flavours but was associated with increased adult smoking cessation. They also found that adults who began vaping non-tobacco flavoured e-cigarettes were more likely to quit smoking that those who vaped tobacco flavour [42].

## The importance of flavours to adult smokers and vapers



**LIMITATIVE LIST OF DESIGNATED ADDITIVES**

While Imperial Brands is a strong advocate for robust product and manufacturing standards and adheres to all product notification and reporting requirements globally, we do not believe in either positive or negative limitative lists for product ingredients or additives. The goal of such lists – to support public health and protect consumers – is best achieved through existing regulation and manufacturer reporting requirements.

E-cigarettes, together with other NGPs, represent a rapidly evolving sector – one that is underpinned by technology and innovation. To enable increased numbers of smokers to transition to less harmful products, then private sector investment in these products must continue without overt and overly burdensome regulatory hindrance.

A limited list of designated additives threatens to stifle future investment and innovation in e-cigarettes, significantly reducing manufacturers' capacity to develop new formulations – all of which are aimed at increasing adult smoker satisfaction thereby increasing their chances of transitioning away from smoking.

The current proposal to implement a list of permitted additives would not only be anti-competitive for manufacturers, but it could also ultimately severely limit future product pipelines and choices that may be deemed more effective in assisting adults to reduce or cease smoking.

We believe by raising ingredients standards, the EU can guarantee a level playing field amongst e-cigarette manufacturers in addition to boosting consumer trust and safety. Imperial Brands encourages regulators and standards bodies to ensure all e-cigarettes in different jurisdictions meet similar high standards with regards to e-liquid ingredients. It is our view that all EU manufacturers selling e-liquids should be held accountable to the same standards, which should apply equally to nicotine and non-nicotine containing e-liquids.

Regulatory measures should limit the ability for users to alter the generated aerosol and flavour ingredients. This was unfortunately demonstrated recently in the US, where Federal and State scientists found illicit tetrahydrocannabinol (THC)-containing e-cigarettes (not regular nicotine-containing products) with vitamin E acetate (used as a thickening agent) were responsible for more than 350 cases of lung illnesses. In response, the US Centers for Disease Control and Prevention recommended: "*not [to] modify e-cigarette products or add any substances to these products that are not intended by the manufacturer*." We fully endorsed this message and believe regulatory measures should be applied to limit the ability for users to alter the generated aerosol or add ingredients not intended by the manufacturer. [43]

We believe pod-based (closed-system) e-cigarette devices offer the best opportunity to ensure ingredients fall within pre-defined and regulated standards and we support regulatory measures which limit the ability of users to alter the ingredients used within them. Closed-system, pod-based devices can help ensure both the flavour ingredients and the generated aerosol fall within pre-defined and regulated EU standards. Closed-systems offer an enhanced product quality profile over other e-cigarette devices and the most consistent vaping proposition for adult smokers. To boost consumer trust in product quality and safety, regulatory measures that improve product quality, safety and manufacturing standards should be considered to limit opportunities for e-cigarettes to be adulterated and abused.

## 2. Global evidence demonstrating e-cigarettes as a smoking cessation aid

**REAL-WORLD DATA AND THE SCIENTIFIC EVIDENCE SHOWS E-CIGARETTES ARE EFFECTIVE FOR SMOKING CESSATION**

Randomised control clinical trials, observational studies and population data shows that when e-cigarettes are regulated proportionately, they have high rates of success in achieving smoking cessation compared to other alternatives.

We would refer to the Cochrane Review 2020 [44] as highlighted in Section 4 below for comprehensive details of the most recent scientific evidence in support of e-cigarettes. Additionally, recent evidence from a range of countries is outlined below.

In **France**, regular e-cigarette use is associated with a significantly higher decrease in the number of cigarettes smoked per day compared with daily smokers who do not vape, as well as a higher adjusted relative risk of smoking cessation [45].

In the **UK**, adult smokers who use e-cigarettes to quit smoking are 60% more likely to succeed than those using traditional, over-the-counter NRT products or willpower alone [46], with e-cigarettes having helped an estimated 50,000 extra smokers per annum stop smoking each year who would otherwise have continued [47].

In **New Zealand**, e-cigarettes are the most used aid to help quit or cut down tobacco smoking [48].

In the **US**, the increase in e-cigarette use by adult smokers has been shown to be associated with a statistically significant increase in smoking cessation rates at population level [49] daily e-cigarette users 3 times more likely to quit smoking than smokers who never used e-cigarettes [50]. An analysis of the US Population Assessment of Tobacco and Health nationally representative survey has also showed that, for smoking cessation among current adult smokers at Wave 1, 17.3% had quit smoking at Wave 3 and smoking cessation was more likely amongst frequent vapers who used flavoured e-cigarettes compared to less frequent users or adult smokers who never used e-cigarettes [51].

To-date, scientific research has demonstrated that e-cigarettes are an integral and satisfactory route out of continued smoking for many millions of adults across the EU. The multidisciplinary Tobacco Addiction and Cessation of Smoking Support for the Health Sector (Directive 40) states that the most effective way to stop smoking is to use cessation coaching in combination with the use of nicotine substitutes – and, as we know from scientific evidence, many millions of adult smokers currently rely on flavoured e-cigarette products to assist them.

To conclude, we believe that the Ministry has acknowledged the role that e-cigarettes can play in assisting smoking cessation. According to the Directive, "*the use of the e-cigarette is not a first choice, but should not be discouraged*." and therefore to overly restrict the use of flavours, would undermine this role which represents a crucial factor for adult smokers looking to transition.

## 3. Tobacco Products Directive and free movement of goods

The category of e-cigarettes has been expressly regulated with the specific provision of art. 20 Directive 2014/40 ("EUTPD"). This article makes several cross-references to other provisions of EUTPD, already providing deep regulation of the category. Additives are already regulated by art. 7 of EUTPD, which provides a detailed list of prohibited additives.

The assumption that flavour restrictions will bring health benefits is based on an abstract theory lacking any evidence and scientific rigour. It would only service to deprive adult smokers of opportunities to transition, making them much more susceptible to either continued smoking or relapse from vaping. As outlined in Section 4, substantial research shows flavours play a critical role in attracting - and retaining – adult smokers into the e-cigarettes category, directly contributing to tobacco harm reduction and declining smoking rates. Flavours ensure adult smokers find e-cigarettes palatable, reminding them less of smoking and therefore making vape products easier to transition to.

The Government of the Netherlands has tried to justify its restriction of the free movement of goods within the meaning of article 34 TFEU which clearly does not exist. When it comes to restrictions of European Union rights such as free movement of goods, the mildest effective measure should be taken. In the flavour context, this would be introducing stricter laws against sales of e-cigarettes to minors, including so called "proxy buying" (i.e. an adult buying adult products on behalf of a minor would be fined). This measure should be applied to nicotine and non-nicotine containing e-cigarettes and would better address the stated goal of ensuring that young individuals cannot access e-cigarettes, while still allowing adult smokers the choices they need to successfully switch from combustible tobacco products. In the Netherlands, there is no specific situation that differs from other member states which would justify stricter measures.

The health risks associated with smoking are well known. Public health experts worldwide have concluded that the highest risks from smoking are from burning tobacco and inhaling the smoke and that nicotine is not the primary cause of smoking-related diseases. To date, the scientific consensus is that nicotine has not been established to cause, by itself, cardiovascular disease, or cancer [52; 53; 54; 55; 56; 57; 58; 59]. Nicotine is not a known carcinogen and its use in traditional medicinal nicotine products (e.g. nicotine gums and patches) has been well-established through years of pharmaceutical clinical trials.

Although consumption of nicotine may contain some health risk, it is widely accepted that e-cigarettes present an attractive tobacco harm reduction alternative for adult smokers because the nicotine in these products is consumed without burning tobacco.

Like many substances, at high doses nicotine can be poisonous. However, it is not poisonous at the levels typically consumed through e-cigarettes when the products are used as intended by adult smokers. E-cigarettes need to be stored securely and retailed responsibly, with appropriate packaging and labelling to ensure that vulnerable people including minors cannot gain access to them and they should not be adapted or tampered with.

We are not aware of any studies indicating that the flavourings included in the list are dangerous for the public health or that relevant use poses any health risks. If the rationale is only to reduce nicotine

delivery vehicles, it should at least be acknowledged that there would be no public health contra-indication to use such flavourings in non-nicotine containing liquids.

In the absence of any scientific studies concluding that proposed restricted flavourings are dangerous, there is no apparent risk to public health. The current proposal is therefore at risk of becoming an arbitrary discrimination of ingredients that would restrict the free movement of goods within the meaning of article 34 TFEU.

## 4. The proposal does not reference recent scientific studies in support of e-cigarettes regarding their public health impact.

The consultation, which serves as a justification to the legislative proposal, does not reference recent scientific studies which demonstrate the positive impact the use of e-cigarettes can have for public health, via the reduction of adult smoking rates.

**E-CIGARETTES ARE MORE EFFECTIVE THAN NRT FOR ADULT SMOKERS TO REDUCE AND REPLACE CIGARETTE SMOKING**

The 2020 Cochrane Review [60], which evaluated the effect and safety of using e-cigarettes to help smokers achieve long-term smoking abstinence, and considered 50 studies in 12,430 adults - studies that took place in the USA (21 studies), the UK (9), Italy (7), Australia (2), New Zealand (2), Greece (2), and one study each in Belgium, Canada, Poland, South Korea, South Africa, Switzerland and Turkey - concluded nicotine-containing e-cigarettes:

> [i] do help people to stop smoking (even amongst those who do not intend to quit smoking) and work better than NRT and nicotine-free e-cigarettes;
>
> [ii] are better for smoking cessation than no support, or behavioural support alone;
>
> [iii] and are not associated with serious unwanted effects or harm with up to two years product use. Given Cochrane Reviews are internationally recognised as the gold standard of scientific evidence, the 2020 Cochrane Review should be considered by the Ministry.

Outside of randomised control clinical settings extensively presented in the Cochrane Review, real-world data has shown that over 6.1 million adult smokers quit smoking using e-cigarettes in the EU, while another 9.2 million had significantly reduced their cigarette consumption [61]. A recent EU study also showed current daily e-cigarette use was rare among former smokers and was positively associated with recent smoking cessation [62]. Consistent with this, an analysis of Eurobarometer survey data also showed that while the use of medically licensed pharmacotherapy has become less popular, use of e-cigarettes for smoking cessation has increased substantially from 3.7% in 2012 to 9.7% in 2017 [63].

In considering the effectiveness of e-cigarettes in smoking cessation, the Ministry should also ascertain how different Member States' regulatory environments may influence this. A recent study found the use of e-cigarettes in the real-world is only effective for sustaining smoking absence in a less restrictive e-cigarette environment and the benefits of e-cigarettes for population-level tobacco harm reduction are highly dependent on the regulatory environment [64]. Thus, it is not surprising the UK now has one of the lowest smoking rates in Europe given their pragmatic approach to the regulation of e-cigarettes via EUTPD, coupled with regulatory and public health endorsement of the category as a tool for smoking cessation. To reiterate this point, we would like to highlight the following statement, made by Professor John Newton, Director for Health Improvement at Public Health England alongside the publication of Public Health England's 2018 E-cigarette evidence review: "*our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know*."

The independent scientific evidence to date as outlined in this submission demonstrate the effectiveness of e-cigarettes in assisting smoking cessation.

## 5. Conclusion

It is Imperial Brands' view that the Ministry should not proceed with the proposal in view of the substantial body of existing scientific evidence which demonstrates the important role flavours play in successfully transitioning adult smokers away from combustible cigarettes and onto vape products, which have been concluded by public health bodies to be significantly less harmful to health. Our submission to the Ministry endeavours to lay out the most up-to-date scientific evidence behind vape products and flavourings in order to inform the Ministry of legitimate research and the role of flavours in adult smokers' unique journeys out of the tobacco category.

We support sound, evidence-based, reasonable, and practicable regulation of e-cigarettes with or without nicotine.

- **REAL-WORLD DATA AND THE SCIENTIFIC EVIDENCE BASE DO NOT SUPPORT THE 'GATEWAY THEORY' OR THE UPTAKE OF E-CIGARETTES BY YOUNG PEOPLE**

There is no supportive evidence that e-cigarettes are a gateway product to smoking combustible tobacco in any Member State. We believe e-cigarette trends must continue to be closely monitored and youth access prevention should remain a top priority for all manufacturers and governments. Despite some e-cigarette experimentation amongst never-smokers in different countries, regular use of e-cigarettes by people who have never smoked is extremely rare. Experimentation amongst adolescents is often misconstrued in research and subsequent media headlines with no understanding of previous smoking history documented. It is important to understand the nuances in reported behaviour (one-off experimentation and one-off use in a 30-day period versus regular weekly or daily use).

- **THE PROPOSED FLAVOURS BAN IS NOT EVIDENCE-BASED – E-LIQUID FLAVOURS ARE AN IMPORTANT FACTOR IN ADULT SMOKERS' TRANSITION AWAY FROM COMBUSTIBLE CIGARETTES**

There is no credible or robust evidence that a flavour ban for e-cigarettes, with or without nicotine, would contribute to improving public health. The unintended consequence of a flavour ban may be a decrease in the number of adult smokers who transition to e-cigarettes as a consequence of a reduced range of flavours available to facilitate transition. Substantial research shows flavours play a critical role in attracting - and retaining – adult smokers into the e-cigarettes category, directly contributing to tobacco harm reduction and declining smoking rates. Flavours ensure adult smokers find e-cigarettes palatable and therefore easier to transition to.

- **REAL-WORLD DATA AND THE SCIENTIFIC EVIDENCE SHOWS E-CIGARETTES ARE EFFECTIVE FOR SMOKING CESSATION**

Randomised control clinical trials, observational studies and population data shows that when e-cigarettes are regulated proportionately, they have high rates of success in achieving smoking cessation compared to other alternatives.

- **FLAVOUR BANS INTRODUCED IN THE INTERNATIONAL CONTEXT**

There is no credible or robust evidence that a flavour ban for e-cigarettes, with or without nicotine, would contribute to improving public health. The unintended consequence of a flavour ban may be a decrease in the number of adult smokers who transition to e-cigarettes, as a consequence of a reduced range of available flavours to aid those who seek to transition.

- **TOBACCO PRODUCTS DIRECTIVE AND FREE MOVEMENT OF GOODS**

The public health benefit argument pursued by the Government of the Netherlands to justify a restriction on the free movement of goods within the meaning of article 34 TFEU, clearly does not exist. When it comes to restrictions of European Union rights such as free movement of goods, the mildest effective measure should always be taken. In the flavour context, this would be introducing stricter laws against sales of e-cigarettes to minors, including so called "proxy buying" (i.e. an adult buying adult products on behalf of a minor would be fined). This measure should be applied to nicotine and non-nicotine containing e-cigarettes and would better address the stated goals of ensuring young individuals do not have access to e-cigarettes, while simultaneously ensuring adult smokers have the necessary product choices to enable successful transition from combustible tobacco products.

Importantly, there is no specific situation in The Netherlands that differs from other EU member states which would justify such stricter measures.

- **THE PROPOSAL DOES NOT REFERENCE RECENT SCIENTIFIC STUDIES IN SUPPORT OF E-CIGARETTES REGARDING THEIR PUBLIC HEALTH IMPACT.**

The Ministry for Health, in its current proposal, does not consider the broader base of up-to-date scientific evidence around e-cigarettes and their health implications when compared to ongoing use of combustible cigarettes. Nor does it acknowledge the demonstrated and vital role of flavours in adult smokers' journeys to reduced or complete cessation of smoking. Imperial Brands' therefore believes the Ministry for Health is at risk of implementing a short-sighted policy that, in all likelihood, will make little difference to youth experimentation but will most certainly limit the number of existing smokers who may transition to a less harmful alternative product.

We would therefore urge the Ministry, as an immediate priority, to familiarise itself with the latest science, including the internationally recognised 2020 Cochrane Review on e-cigarettes [52], which evaluated the effect and safety of using e-cigarettes to help smokers achieve long-term smoking abstinence, and considered 50 studies in 12,430 adults - studies that took place in the USA (21 studies), the UK (9), Italy (7), Australia (2), New Zealand (2), Greece (2), and one study each in Belgium, Canada, Poland, South Korea, South Africa, Switzerland and Turkey - concluded nicotine-containing e-cigarettes:

> [i] do help people to stop smoking (even amongst those who do not intend to quit smoking) and work better than NRT and nicotine-free e-cigarettes;
>
> [ii] are better for smoking cessation than no support, or behavioural support alone;
>
> [iii] and are not associated with serious unwanted effects or harm with up to two years product use.

Given Cochrane Reviews are globally recognised as the gold standard of scientific evidence, the Ministry should consider this study alongside other most recent scientific research conclusions.

**In our view a range of e-cigarette flavours should be permitted to support optimal transition of adult smokers to vaping. It is unjustified to apply tobacco legislation to e-cigarettes since they are not tobacco products and do not contain tobacco. Imperial Brand's supports the Ministry's objective of ensuring e-cigarettes are only used by their intended audience (adult smokers) but we believe this can best be achieved through existing EU legislation, product reporting requirements, and responsible e-cigarette packaging and labelling mandates, without the need for implementation of an arbitrary ban on flavoured products which are proven to significantly assist adult smoker transition, hindering more rapid smoking rate reductions in The Netherlands.**

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