

## BRITISH AMERICAN TOBACCO NEDERLAND B.V. - SAMENVATTING VAN REACTIE OP CONSULTATIE CONCEPTBESLUIT STANDAARDVERPAKKING VOOR SIGARETTEN EN SHAG

Hieronder vindt u een Nederlandse samenvatting van het onderstaande Engelse document met ons antwoord op de raadpleging over de invoering van standaardverpakkingen voor sigaretten en shag. Aangezien bij de consultatie het toevoegen van documenten beperkt wordt tot een document, zal BAT haar inbreng, inclusief een aantal expert rapporten ook separaat per email met het Ministerie van VWS delen. Indien gewenst vanuit het Ministerie zijn wij zeer bereid om het Engelse document met onze uitgebreide reactie, en eventueel ook de expert rapporten te vertalen naar het Nederlands.

- 1.1 We merken op dat de regering heeft verklaard in de toelichting bij het Besluit van 19 september 2017 tot wijziging van het Tabaks- en Rookwarenbesluit, dat het standaardverpakkingen zou introduceren *“Als blijkt dat het stellen van nadere verpakkingseisen niet langer doeltreffend is ter voorkoming van extra aandacht voor tabaksproducten” en dat “in het uiterste geval in de toekomst verplichte standaardverpakkingseenheden en - buitenverpakkingen worden overwogen”*.
- 1.2 Desalniettemin is er geen behoorlijke evaluatie, danwel een Regulatory Impact Assessment (“RIA”) uitgevoerd met betrekking tot de aanvullende verpakkingsvereisten die in juli 2018 van kracht zijn geworden. De overheid erkent dit ook in haar antwoorden op de feitelijke vragen die zijn gesteld over het Nationaal Preventieakkoord *“Met de in het Nationaal Preventieakkoord opgenomen stap van neutrale verpakkingen worden de bestaande verpakkingseisen inderdaad zonder grondige evaluatie verder aangescherpt.”*
- 1.3 Zoals in onze reactie op de raadpleging over standaardverpakkingen uitvoerig is uiteengezet, is BAT sterk gekant tegen de invoering van standaardverpakkingen. De procedure die de regering tot nu toe heeft gevolgd met betrekking tot standaardverpakkingen is fundamenteel ondoordacht en wij zijn van mening dat het voorstel onwettig is. Bovendien wordt middels de invoering van standaardverpakkingen de beoogde doelstellingen, namelijk de vermindering van de rookprevalentie, niet bereikt. In Australië, het enige land waar standaardverpakkingen voor een langere periode zijn ingevoerd, heeft dit niet de verwachte voordelen opgeleverd, en is dan ook een gefaald experiment. In feite hebben standaardverpakkingen in Australië onbedoelde gevolgen teweeggebracht die een negatieve invloed hebben op het publiek, het bedrijfsleven en de overheid. Er is geen reden om aan te nemen dat het resultaat in Nederland anders zou zijn.
- 1.4 **De regering volgt een gebrekkige en ontoereikende procedure.** Het niet uitvoeren en / of publiceren van een evaluatie en/of RIA, danwel een grondige raadpleging bij **alle** betrokken belanghebbenden over de intentie om met deze regelgeving te komen voordat inhoudelijke beslissingen zijn genomen, betekent dat dit besluit is genomen zonder deugdelijk

bewijsmateriaal of een analyse van de kosten, voordelen of andere effecten van de maatregel en zonder rekening te houden met alternatieve beleidsopties. De Nota van Toelichting bevat niet het bewijs en de analyse die nodig zijn om de beleidsontwikkeling te ondersteunen. De noodzaak van een goede, op feiten gebaseerde RIA is in dit geval nog dringender, gezien de verwijzing door de regering naar artikel 24 van de EU-Tabaksproductenrichtlijn ("TPD"), die alleen de invoering van een aanvullende maatregel toestaat *"mits dit gerechtvaardigd is op grond van de volksgezondheid, rekening houdend met het hoge beschermingsniveau van de volksgezondheid dat bij deze richtlijn tot stand wordt gebracht"* door de richtlijn wordt bereikt "en het evenredig is.

- 1.5 **Het standpunt van de regering dat inbreng van leden van de tabaksindustrie op basis van artikel 5.3 van het WHO-Kaderverdrag (FCTC) minder gewicht zullen krijgen is onjuist.** De Nederlandse interpretatie van artikel 5 lid 3 is onjuist gaat en gaat nadrukkelijk in tegen de vereisten van nationaal recht, waaronder beginselen van natuurlijke rechtvaardigheid en procedurele rechtvaardigheid. Bovendien, in plaats van het uitsluiten van informatie van de tabaksindustrie, vereist artikel 5 lid 3 dat het contact met de tabaksindustrie op transparante wijze plaatsvindt. Nergens vereist het WHO-Kaderverdrag uitsluiting van de tabaksindustrie van het besluitvormingsproces. In het onderhavige geval middels deze inbreng op deze consultatie worden de opmerkingen en bewijzen van BAT op een open en transparante manier gepresenteerd. Bijgevolg is er geen wettelijke basis om de opmerkingen en bewijzen van BAT uit te sluiten of minder zwaar te wegen.
- 1.6 **Standaardverpakkingen zouden de essentiële rol van handelsmerken op ontoelaatbare wijze wegnemen.** Standaardverpakkingen zouden het gebruik van handelsmerken elimineren en daarmee hun waarde vernietigen. Dientengevolge zouden tientallen jaren van investeringen in merken en hun gerelateerde handelsmerken, samen met hun inherente goodwill, verloren gaan. Markten zonder merken worden over het algemeen prijs gedreven markten. Indien alle producten er hetzelfde uitzien op de Nederlandse sigarettenmarkt kan dit leiden tot een verschuiving naar een zuiver prijs gedreven markt, welke juist kan leiden tot een toename van de consumptie en illegale handel.
- 1.7 **Standaardverpakkingen werken niet.** Uit het beschikbare bewijs uit Australië blijkt dat standaardverpakkingen niet hebben geleid tot een vermindering van het roken, en in plaats daarvan een aantal nadelige gevolgen kennen. Het bewijsmateriaal toont aan dat de introductie van standaardverpakkingen geen invloed heeft gehad op de mate van daling van het roken of op het aantal dagelijkse rokers. Uit de overheidsgegevens voor 2016, afkomstig van de Australian National Drug Household Survey, blijkt dat er voor het eerst sinds tientallen jaren geen statistisch significante daling was waar te nemen van de rookprevalentie in Australië na de introductie van standaardverpakkingen. In plaats daarvan zijn er een aantal onbedoelde gevolgen ontstaan die de volksgezondheidsdoelstellingen ondermijnen, waaronder een relatieve verlaging van de prijs van sigaretten, een toename van consumenten die op gaan naar goedkopere tabaksproducten en een forse stijging van de illegale tabaksverkoop. Analyse van gepubliceerde gegevens die beschikbaar zijn in het Verenigd Koninkrijk en Frankrijk, waar

standaardverpakkingen pas onlangs zijn ingevoerd, geeft evenzo aan dat standaardverpakkingen geen statistisch significante gevolgen hebben gehad voor het tabaksgebruik in het VK noch Frankrijk.

- 1.8 BAT voegt bij haar antwoord op deze consultatie onder andere de deskundigenrapporten van professor Kip Viscusi (bijlage 1) en de heer Neil Dryden (bijlage 2) toe. Zij zijn internationaal erkende deskundigen op dit gebied. Deze rapporten omvatten de meest uitgebreide en actuele analyse van het bewijs van de impact van standaardverpakkingen in Australië op de consumptie van sigaretten en de prevalentie van roken. Deze rapporten tonen verder aan dat de verpakkingsveranderingen die in 2012 in Australië zijn geïntroduceerd, niet effectief zijn geweest.<sup>1</sup>
- 1.9 In het bijzonder, zoals uiteengezet in de reactie van BAT, blijkt uit het beschikbare bewijsmateriaal vanuit Australië dat na de introductie van standaardverpakkingen:
- 1.9.1 Op de lange termijn er geen versnelling heeft opgetreden in de daling van het aantal rokers;
  - 1.9.2 Standaardverpakkingen de effectiviteit van gezondheidswaarschuwingen niet hebben vergroot;
  - 1.9.3 Standaardverpakkingen verband houden met een relatieve daling van de prijzen van sigaretten; een toename in consumptie van sigaretten; en een versnelling in de verschuiving van premium naar goedkopere merken in Australië; en
  - 1.9.4 het illegale gebruik van tabak sterk is toegenomen.
- 1.10 Deze gegevens over het daadwerkelijke effect van standaardverpakkingen op het rookgedrag is het beste bewijs om de adequaatheid van deze wijziging van het Rookwarenbesluit te onderzoeken en moeten worden verkozen boven conclusies op basis van studies naar intenties en percepties, waarbij die studies al bij voorbaat het beleid tot introductie van standaardverpakkingen promoten.
- 1.11 **Standaardverpakkingen zijn onwettig.** Standaardverpakkingen zijn in strijd zijn met het EU-beginsel van vrij verkeer van goederen, ontnemt BAT haar eigendomsrechten en het recht om haar handelsmerken te gebruiken, en is een inbreuk op het recht op vrijheid van meningsuiting, zoals beschermd krachtens het Handvest van de grondrechten en Europese Verdrag tot bescherming van de rechten van de mens en de fundamentele vrijheden.
- 1.12 **Standaardverpakkingen zijn disproportioneel.** Het voorstel is niet noodzakelijk. Er bestaat al een algemene bekendheid met de risico's van roken en de bestaande wetten die minderjarigen verbieden tabaksproducten te kopen en die het gebruik van mogelijke misleidende

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<sup>1</sup> Aangezien bij de consultatie het toevoegen van documenten beperkt wordt tot een document, zal BAT haar inbreng, inclusief de expert rapporten separaat per email met het Ministerie van VWS delen. Hoewel sommige van de onderliggende gegevens die door de experts in deze rapporten zijn geanalyseerd niet publiekelijk beschikbaar zijn, kan BAT op verzoek deze en de rest van de gegevens met de regering (of experts die zij benoemen) delen om de bijgevoegde gegevens op vertrouwelijke basis te beoordelen, en stelt de experts beschikbaar voor het beantwoorden van vragen die het ministerie van Volksgezondheid of regering mogelijk heeft. We nodigen het ministerie van Volksgezondheid uit om in dit verband contact met ons op te nemen, zodat we de nodige voorbereidingen kunnen treffen voor het verstrekken van de gegevens.

bewoordingen op de verpakking van tabaksproducten verbieden. Handelsmerken en verpakkingen zijn ook geen aanjagers van rookgedrag. Zoals hierboven aangegeven, toont het bewijs ook aan dat het voorstel niet effectief zou zijn in het verminderen van de prevalentie van roken onder jongeren of anderszins. Het voorstel zal waarschijnlijk ook ernstige nadelige gevolgen hebben die de doelstelling voor de volksgezondheid ondermijnen, waaronder:

- 1.12.1 Verdere toename van de illegale handel;
- 1.12.2 Stimulering van prijsconcurrentie die leidt tot verschuiving in verkoop naar relatief goedkopere producten, wat op zijn beurt kan leiden tot een toename van consumptie;
- 1.12.3 Verstorend effect op concurrentie en verhoging van de toetredingsdrempels op de tabaksmarkt; en
- 1.12.4 Beperkende werking om te innoveren.

**1.13 Standaardverpakkingen schenden de internationale verplichtingen van Nederland.** De introductie van standaardverpakkingen zal inbreuk maken op verschillende Wereldhandelsorganisatieovereenkomsten, zoals de Overeenkomst inzake handelsaspecten van intellectuele-eigendomsrechten, de Overeenkomst inzake Technische Handelsbelemmeringen en de Algemene Overeenkomst betreffende tarieven en handel 1994, die van fundamenteel belang zijn voor de eerlijke behandeling van binnenlandse handelsovereenkomsten. Verder hebben bepaalde bedrijven binnen de BAT-Groep aanzienlijke investeringen gedaan die worden beschermd door bilaterale investeringsverdragen. Het voorstel tot invoering van standaardverpakkingen zou deze verdragen schenden.

**1.14 Standaardverpakkingen zijn noch vereist noch geautoriseerd door het WHO-Kaderverdrag inzake tabaksontmoediging ("FCTC").** Naar internationaal recht is het FCTC slechts een "kaderovereenkomst" en bijgevolg verplicht zij de regering niet om specifieke maatregelen te nemen. In geen geval vermelden de bindende bepalingen van het FCTC standaardverpakkingen. En de (niet-bindende) WHO-richtsnoeren voor artikel 11 en 13 van het FCTC suggereren alleen dat Partijen standaardverpakkingen "zouden kunnen" (niet "zullen") "overwegen" ("niet aannemen"). Belangrijk is dat het FCTC Partijen niet dwingt maatregelen te nemen die in strijd zijn met nationale wetgevende criteria of procedures, wat wel het geval zou zijn met standaardverpakkingen.

**1.15 Het invoeren van standaardverpakkingen voor elektronische sigaretten is ook niet bewezen en zou niet gerechtvaardigd zijn.** Door voor te stellen dat standaardverpakkingen in de toekomst zullen worden uitgebreid naar e-sigaretten, faalt de overheid erin de gevolgen van een dergelijk voorstel voor de volksgezondheid te beoordelen. Het toepassen van standaardverpakkingen op e-sigaretten - een productcategorie met een aanzienlijk potentieel wat betreft minder schadelijkheid voor de volksgezondheid vergeleken met conventionele sigaretten (zoals bevestigd door vooraanstaande gezondheidsautoriteiten), en waarvan is aangetoond dat ze rokers helpen om te stoppen met roken -, is niet gerechtvaardigd en zal contraproductief zijn kijkend naar de doelstelling van de overheid. Als de overheid echt serieus streeft naar het verminderen van de prevalentie van roken, zou zij in plaats van de potentieel

minder schadelijke producten (PRRP's) te onderdrukken en potentieel nieuwe producten volledig te elimineren, efficiënte regelgevingsroutes moeten ontwikkelen om hoogwaardige PRRP's op de markt te brengen en rokers juist ondersteunen die willen overstappen. Het potentiële voordeel van PRRP's wordt onderstreept door bewijs uit landen met een flexibelere omgeving en regelgeving met betrekking tot deze innovatieve producten dat consumentenbewustzijn, toegang en gebruik vergemakkelijkt, en die aangeven dat PRRP's hebben bijgedragen tot een verminderde rookprevalentie. Sterker nog, een groeiend aantal vooraanstaande gezondheidsautoriteiten en overheden omarmen de PRRP's vanwege hun potentieel om bij te dragen aan het beperken van de schadelijke effecten van tabak.

- 1.16 **In het licht van het bovenstaande dringen wij er bij de regering met klem op aan om standaardverpakkingen niet in te voeren en het voorstel dan ook in te trekken.** Wij zouden graag de mogelijkheid krijgen om onze zorgen met betrekking tot standaardverpakkingen met de regering te bespreken en nodigen de overheid uit om contact met ons op te nemen met betrekking tot de gegevens die ten grondslag liggen aan de deskundigenrapporten van onder andere professor Viscusi en de heer Dryden.

**BRITISH AMERICAN TOBACCO NEDERLAND B.V. TO THE SECRETARY OF STATE  
FOR HEALTH, WELFARE AND SPORT**

**COMMENTS ON PROPOSAL TO AMEND THE TOBACCO AND RELATED  
PRODUCTS DECREE IN CONNECTION WITH THE INTRODUCTION OF PLAIN  
PACKAGING FOR CIGARETTES AND ROLL-YOU-OWN TOBACCO**

**24 MAY 2019**

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## 1. INTRODUCTION

- 1.1 This submission by British American Tobacco Nederland B.V. ("**BAT**") (the "**Response**") responds to the consultation on plain packaging for cigarettes and roll-your-own ("**RYO**") tobacco (the "**Proposal**"), issued by the Secretary of State for Health, Welfare and Sport, (the "**Consultation**").
- 1.2 BAT is a member of the British American Tobacco group of companies and is responsible for the importation, distribution and sale of tobacco in the Netherlands. BAT Nederland currently supplies eight brands, including brands such as Pall Mall and Lucky Strike.
- 1.3 As explained in detail in this Response, BAT is strongly opposed to the introduction of plain packaging. The procedure followed by the Dutch Government ("**Government**") to date in respect of plain packaging is fundamentally flawed and inadequate. We believe the Proposal is unlawful. Furthermore, the Proposal would not achieve its stated objectives. Plain packaging has failed to deliver any of the anticipated benefits in Australia, the only country in which it has been implemented for an extended period of time. Indeed, plain packaging has led, in Australia, to unintended consequences that adversely impact the public, business and the Australian Government. There is no reason to believe the result would be different in the Netherlands.
- 1.4 The submission is structured as follows:
  - 1.4.1 Section 2 addresses the process followed by the Government and explains why it is fundamentally flawed and inadequate. The standard of process, evidence and analysis falls well below that required for a policy decision of this type and magnitude.
  - 1.4.2 Section 3 explains that the proposal would eliminate the use of trademarks and, in doing so, destroy their value. As a result, decades of investment in brands and their related trademarks, along with their inherent goodwill, would be lost.
  - 1.4.3 Section 4 details the evidence available from Australia that demonstrates that plain packaging has not reduced smoking and is instead having a number of adverse unintended consequences. The evidence demonstrates that there has been no impact on the rate of decline of smoking or the number of daily smokers after the introduction of plain packaging. Indeed, the most recent 2016 government data from the Australian National Drug Strategy Household Survey suggests that for the first time in decades there was no statistically significant decline in smoking prevalence in Australia following the introduction of plain



packaging.<sup>2</sup> Instead, there have been a number of unintended consequences including a relative reduction in the price of cigarettes (which could result in increased consumption) and an increase in illicit tobacco sales. Analysis of initial data from the UK and France, where plain packaging has only been recently implemented, similarly indicates that plain packaging has had no statistically significant impacts on consumption in the UK or in France; and no statistically significant impact on prevalence in the UK.<sup>3</sup>

- 1.4.4 Section 5 explains that the adoption of plain packaging would be unlawful. The Proposal would violate the EU principle of free movement of goods, deprive BAT of, *inter alia*, its property rights and the right to use its trademarks, and infringe on the right to freedom of expression as protected under the Charter of Fundamental Rights and European Convention for the Protection of Human Rights and Fundamental Freedoms ("**ECHR**").
- 1.4.5 Section 6 explains that plain packaging is disproportionate and that the Proposal is not necessary. There is already universal awareness of the risks of smoking and existing laws in place prevent minors from purchasing cigarettes and RYO tobacco, and prohibit the use of any misleading and deceptive terms on tobacco product packaging. Evidence also demonstrates that the Proposal would not be effective in reducing smoking prevalence amongst youth or otherwise. The Proposal is also likely to have serious adverse consequences, including:
- exacerbating an illicit trade problem;
  - stimulating price competition leading to downtrading to cheaper products, which may in turn lead to an increase in consumption;
  - distorting competition and raising barriers to entry; and
  - stifling innovation.
- 1.4.6 Section 7 explains that plain packaging would violate international obligations under World Trade Organization ("**WTO**") Agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**TRIPS**")

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<sup>2</sup> <http://www.theaustralian.com.au/news/nation/more-smokers-lighting-up-despite-everincreasing-taxes/news-story/190014e7306548c49fc372dabb5a0555>.

<sup>3</sup> Europe Economics (2017), TPD2 and Standardised tobacco packaging – What impacts have they had so far? [http://www.europe-economics.com/publications/tpd2\\_and\\_standardised\\_tobacco\\_packaging\\_-\\_impact\\_on\\_prevalence\\_and\\_consumption\\_in\\_france\\_and\\_the\\_uk\\_1.pdf](http://www.europe-economics.com/publications/tpd2_and_standardised_tobacco_packaging_-_impact_on_prevalence_and_consumption_in_france_and_the_uk_1.pdf). With respect to smoking prevalence in France, the authors state: "*We have publicly available data with sufficient frequency to model prevalence impacts for the UK, but not for France.*"

**Agreement")**, the Agreement on Technical Barriers to Trade ("**TBT Agreement**") and the General Agreement on Tariffs and Trade 1994 ("**GATT**"), which are vital for the fair treatment of domestic exports. Further, certain companies within the BAT Group hold significant investments that are protected under Bilateral Investment Treaties ("**BITs**"). The Proposal would breach these treaties.

- 1.4.7 Section 8 explains that plain packaging is neither required nor authorised by the WHO Framework Convention on Tobacco Control ("**FCTC**"). As a matter of international law, the FCTC is a mere "framework" agreement, and consequently, it does not commit the Government to take any specific measures. In any event, none of the binding provisions of the FCTC itself even mention plain packaging and the (non-binding) WHO Guidelines to Article 11 and 13 of the FCTC suggest only that parties to the FCTC "should" (not "shall") "consider" (not "adopt") plain packaging.
- 1.4.8 Section 9 explains how the proposal to extend plain packaging to e-cigarettes / electronic nicotine delivery systems ("**ENDS**") is not evidence-based and would lead to negative consequences.

#### Appendices

1. Appendix 1 is the expert report of Professor W Kip Viscusi (University Distinguished Professor of Law, Economics and Management, Vanderbilt University, Nashville, Tennessee, USA), "An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data" dated January 2018.
2. Appendix 2 is the expert report of Mr Neil Dryden (Executive Vice President within Compass Lexecon's European Competition Policy Unit), "The effects of standardised packaging: an empirical analysis." dated October 2017.
3. Appendix 3 is the expert report of Dr Neil McKeganey, Director of the Centre for Drug Misuse, Glasgow, *Critical Analysis of Evidence that Standardised Tobacco Packaging Will Reduce Smoking Prevalence in the United Kingdom.*, dated 5 August 2014.
4. Appendix 4 is the expert report of Dr Gregory Mitchell, a psychologist and the Joseph Weintraub-Bank of America Distinguished Professor of Law at the University of Virginia, *Observations on the Chantler report: a psychological analysis of the potential impact of standardized cigarette Packaging on underage smoking.*, dated 30 July 2014.
5. Appendix 5 is the expert report of Professor Ronald Faber, Professor Emeritus of Mass Communications in the School of Journalism and Mass Communication at the University

of Minnesota, *The Role of Trademarks and the Brands They Represent.*, dated 1 August 2014.

6. Appendix 6 is the expert report of Mr Weston Anson, Chairman of Consor Intellectual Asset Management, *Preliminary Analysis of the UK Department of Health 2012 and 2014 Impact Assessments of Standardized Packaging for Tobacco Products.*, dated 4 August 2014.

## 2. THE GOVERNMENT HAS FOLLOWED A FLAWED AND INADEQUATE PROCESS

- 2.1 The procedure followed by the Government to date raises serious concerns.

- 2.2 The failure to undertake and/or publish a regulatory impact assessment or consultation before the substantive decisions were made means that the decisions were taken without proper evidence or analysis of the costs, benefits or other impacts of the measure and without consideration of alternative policy options. The Explanatory Memorandum does not include the necessary evidence and analysis to support policy development.

### 2.3 Failure to undertake a proper regulatory impact assessment

- 2.4 The Government has not published any proper regulatory impact assessment or studies in respect of the Proposal. No substantive explanation or evidence supporting why plain packaging is considered necessary has been provided, nor has the Government provided a proportionality analysis.
- 2.5 The Government stated in the Explanatory Memorandum to the Decree of 19 September 2017 (the "**Explanatory Memorandum**"), amending the Tobacco and Smoking Products Decree to prevent packages containing tobacco products from leading to extra attention for these product that:

***"If it appears that the further packaging requirements are no longer effective in avoiding additional attention for tobacco products, mandatory plain packaging will, as a last resort, be considered in the future. This is in line with the explanation of the adopted amendment to the amendments of the Dutch Tobacco and Related Products Act to implement Directive 2014/40/EU of Bruins Slot/Volp, which indicates that standard packaging will eventually be necessary. The proportionality of this measure and its impact on intellectual property rights will then be examined. If it is decided to introduce standard packaging, the basis for delegation set out in Article 3.4 of the Decree will be amended to allow further requirements for standard packaging to be set by the Regulation"*** (emphasis added) (Stb. 2017, no. 358, page 5).

- 2.6 Nevertheless, no proper regulatory impact assessment has been carried out. In fact, the answer to question 204 of the Parliament's questions on the National Prevention Agreement

(“NPA”) note “*With the step of neutral packaging included in the National Prevention Agreement, **the existing packaging requirements are indeed tightened further without a thorough evaluation***” (emphasis added).<sup>4</sup>

2.7 The Explanatory Memorandum does not include the necessary evidence and analysis to support policy development and is not an adequate basis to conclude that plain packaging is necessary, appropriate and proportionate, including:

2.7.1 The Explanatory Memorandum does not analyse the efficacy of current tobacco measures (including the current packaging requirements that have been introduced as of 1 July 2018 and measures to be introduced in the 'pipeline', including a display ban from 2020). This is notwithstanding that the Government has stated that plain packaging would only be introduced as a last resort and only if the current measures were shown to be inadequate. No assessment of the effectiveness of the current measures appears to have been undertaken, as acknowledged in the response to Parliament’s questions to the NPA.

2.7.2 The Explanatory Memorandum does not identify a problem with the existing warnings and other regulation which necessitates additional regulation such as the implementation of plain packaging.

2.7.3 The Explanatory Memorandum asserts that plain packaging is effective without any substantive analysis of the evidence and ignores direct evidence from Australia that points to the ineffectiveness of plain packaging in reducing smoking. As detailed below, the evidence available from Australia that is not addressed in the Explanatory Memorandum demonstrates that plain packaging has not worked and is instead having a number of adverse unintended consequences.

2.7.4 The Explanatory Memorandum does not provide any quantified or direct evidence on the impact of plain packaging. Indeed it is asserted that it is not possible to measure the absolute effect of solely introducing plain packaging. This does not satisfy the onus on the state to show that the measure is appropriate for securing the attainment of the objective and does not go beyond what was necessary to attain it. Furthermore, as discussed below expert analysis has shown that plain packaging has had a "zero effect" on smoking prevalence rates in Australia.

2.7.5 The Explanatory Memorandum does not even attempt to identify, let alone monetise or quantify the costs of the Proposal, including its impact on the value

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<sup>4</sup> Response to Question 204; Parliament questions on NPA.

of manufactures brands and related intellectual property. The lack of any analysis of the impacts renders the policy unjustified.

2.7.6 The Explanatory Memorandum does not consider any unintended consequences of plain packaging.

- 2.8 Accordingly, a regulatory impact assessment ("**RIA**") that conducted a thorough analysis of the Proposal, including whether it is necessary and whether there are less burdensome means of achieving the regulatory objective, should have been carried out to enable the Government to properly scrutinise the Proposal.
- 2.9 RIAs form an essential part of a transparent, accountable and empirically-based regulatory system. They provide a formal method for ensuring that government action is justified and based on a clear understanding of cause and effect, alternative policy options and the impacts of regulatory decisions on different stakeholder groups.
- 2.10 An RIA is also the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the Organization for Economic Co-operation and Development of which the Netherlands is a member. The importance of conducting an RIA was underscored by a 2019 OECD publication on Better Regulation Practices across the European Union, which states that "[w]here EU countries include additional regulatory measures in excess of those provided in EU laws, it is important that these measure[s] be subject to appropriate consultation and impact assessment as part of their design, to ensure that the anticipated gains from EU laws are realised."<sup>5</sup>
- 2.11 The EU Better Regulation initiative also explains the dangers of regulation not being correctly supported by a proper impact assessment: "*poorly conceived and ill-considered regulation can prove to be excessive and go beyond what is strictly necessary [...] regulation can be overly prescriptive, unjustifiably expensive or counterproductive. Layers of overlapping regulation can develop overtime, affecting businesses, the voluntary sector, public authorities and the general public.*"<sup>6</sup>
- 2.12 The need for a proper evidence-based RIA is even more pressing in this case given that the Government refers to Article 24 of the EU Tobacco products Directive ("**TPD**") to support its plain packaging initiative. Mandatory conditions must be satisfied before Article 24(2) can be invoked. In particular, Article 24(2) permits the introduction of an additional measure only

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<sup>5</sup> OECD (2019), Better Regulation Practices across the European Union. Available here: [https://read.oecd-ilibrary.org/governance/better-regulation-practices-across-the-european-union\\_9789264311732-en#page1](https://read.oecd-ilibrary.org/governance/better-regulation-practices-across-the-european-union_9789264311732-en#page1).

<sup>6</sup> *Better Regulation: Simply Explained*, European Commission, 2006 [http://ec.europa.eu/smart-regulation/better\\_regulation/documents/brochure/brochure\\_en.pdf](http://ec.europa.eu/smart-regulation/better_regulation/documents/brochure/brochure_en.pdf).

*“where it is justified on grounds of public health taking into account the high level of protection of human health achieved through the Directive” and it is proportionate.*

- 2.13 The Government's failure to undertake an evidence-based RIA violates these principles and means that the Proposal cannot be shown to be justified as proportionate, necessary or adequate or to comply with the obligations under Article 24(2) of the TPD and WTO Agreements such as the TRIPS Agreement and the TBT Agreement to “*ensure*” that requirements do not violate internationally protected intellectual property rights or constitute an “*unnecessary obstacle to trade*”.
- 2.14 **Lack of meaningful consultation**
- 2.15 The Government did not seek any views from stakeholders or allow them the opportunity to comment on the analysis and evidence used to justify the imposition of plain packaging before the regulations were published. Furthermore, the consultation now being run after the regulations have already been published indicates an intent to press ahead and calls into question the purpose of the Consultation. Far from the assertion made in the Explanatory Memorandum that internet consultation increases the transparency of the process, enables the public to participate, and contributes towards the quality of the legislation – the timing, content and unreasonable duration of the Consultation fails to provide any meaningful level of transparency or participation on the process.
- 2.16 It is a fundamental principle of consultation that it takes place at a time when proposals are still at a formative stage, and that the product of the Consultation is given conscientious consideration. This is highlighted by the European Commission Impact Assessment Guidelines, which also note that the consultation process should engage all affected stakeholders; ensure that stakeholders can comment on a clear problem definition, description of the possible options and their impacts; maintain contact with stakeholders throughout the process and provide feedback; and analyse stakeholders' contributions for the decision-making process and report fully in the impact assessment report on how the input was used.<sup>7</sup> The process being conducted by the Government doesn't meet any of these standards.
- 2.17 We also raise with some concern the Government's position that submissions made by members of the tobacco industry will be afforded less weight on the basis of Article 5.3 of the FCTC.
- 2.18 Article 5.3 is expressly limited by the requirements of national law, which include principles of natural justice and procedural fairness. As the Hague District Court ruled Article 5.3 is about “*protecting tobacco control policies from the interests of the tobacco industry*” (Dutch

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<sup>7</sup> European Commission Impact Assessment Guidelines at page 19, [http://ec.europa.eu/smart-regulation/impact/commission\\_guidelines/docs/iag\\_2009\\_en.pdf](http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/iag_2009_en.pdf).

*Stichting Rookpreventie Jeugd versus the State of the Netherlands*). Accordingly, Article 5.3 cannot be used as a basis to deny the tobacco manufactures right to fully participate in the Consultation.

- 2.19 Nor do the Guidelines on Article 5.3 provide any basis for the Government's position. The Guidelines only contain non-binding policy "recommendations" to address "*tobacco industry interference in public health policy*". These cannot in any way be characterised as being binding as a matter of international law and nor can they be used to provide an incorrect construction of Article 5.3 to say that somehow this provision now requires Governments to exclude tobacco industry evidence or afford it less weight as a matter of principle.
- 2.20 Rather than requiring the exclusion of tobacco industry evidence, Article 5.3 requires that dealings with the tobacco industry be conducted on a transparent basis. In the present case, BAT these submissions and evidence are being presented in an open and transparent manner.

### 3. **PLAIN PACKAGING WOULD IMPERMISSIBLY EVISCERATE THE ESSENTIAL ROLE OF TRADEMARKS**

- 3.1 Trademarks are used by manufacturers as an essential tool to distinguish their goods from similar products. The function of trademarks is to indicate the source or origin of the product and to identify the product by distinguishing it from its competitors. Trademarks also symbolize a product's quality and features and guarantee that the goods or services measure up to expectation. Trademarks are essential for effective competition in the market, as they enable firms to uniquely identify and differentiate their products other than on the basis of price alone. They are an important tool to permit market penetration and facilitate local and international trade. Trademarks can only perform these functions if they can be effectively used as they were registered.
- 3.2 The importance of trademarks to the global economy is recognized in the report of the World Intellectual Property Organization, *World Intellectual Property Report 2013: Brands – Reputation and Image in the Global Marketplace*.<sup>8</sup> According to this report, the "*public good*" of trademarks exists in their functional use as a communication tool. The report notes that "*the trademark system provides the legal framework underpinning [consumer] confidence*", and "*trademarks play an important role in preventing market failure*".<sup>9</sup> It concludes that "*society is bound to be worse off*" without the "*market-enabling role of trademarks*" as, without protected trademarks, consumers can no longer gain access to the product reputation mechanism to guide their brand selection and producers have a reduced incentive

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<sup>8</sup> WIPO Economics & Statistics Series, "World Intellectual Property Report: Brands – Reputation and Image in the Global Marketplace" (2013), available at [http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo\\_pub\\_944\\_2013.pdf](http://www.wipo.int/edocs/pubdocs/en/intproperty/944/wipo_pub_944_2013.pdf).

<sup>9</sup> *Id.*, p. 12.

to invest in product differentiation, thus undermining product quality and diversity.<sup>10</sup> This would gravely damage the interests of consumers in general.

- 3.3 The existing extensive ban on advertising and sponsorship of cigarettes in the Netherlands means that the limited space available on cigarette packs for trademarks is the only tool manufacturers have to identify and differentiate their products from other competitive offerings. Plain packaging would eliminate the use of trademarks and, in doing so, destroy their value. As a result, decades of investment in brands and their related trademarks, along with their inherent goodwill, would be lost.
- 3.4 Brands, including trademarks, play an important role in the cigarette market, and their erosion or elimination changes the nature of the market. In general, markets without brands become price-driven commodity markets.
- 3.5 Commodity markets produce lower prices that encourage more consumption. Commodity markets also make the market inhospitable to firms trying to enter the market and for existing brands, particularly small brands, to compete for a greater market share. Commoditization of the domestic cigarette market and a shift to pure price driven competition could also lead to an increase in illicit trade because without the added value of brands, legitimate products would be less clearly differentiated from illicit products in terms of appearance and perceived value.

#### 4. **EVIDENCE FROM AUSTRALIA SHOWS THAT PLAIN PACKAGING DOES NOT WORK**

- 4.1 The Government wrongly claims that plain packaging is an effective measure while also asserting that: "*it was not possible to measure the absolute effect of solely introducing neutral packaging in Australia.*" These assertions are incorrect. As set out in the following section, the empirical evidence from Australia clearly demonstrates that plain packaging does not work.
- 4.2 Australia implemented plain packaging in December 2012, and is the only country in the world with an extended period of real-world evidence of whether plain packaging is an effective policy measure. As discussed below, the evidence from Australia's experience with plain packaging shows that it is an ineffective policy measure that has not achieved any of the Australian Government's stated objectives.
- 4.3 As noted above, analysis of initial published data available from the UK and France, where plain packaging has only been recently implemented, similarly indicates that plain packaging has had no statistically significant impacts on tobacco use in the UK or in France.<sup>11</sup> The limited effect of standardised packaging in France has been underscored by the French

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<sup>10</sup> Id, p. 13.

<sup>11</sup> Europe Economics (2017), TPD2 and Standardised tobacco packaging – What impacts have they had so far? [http://www.europe-economics.com/publications/tpd2\\_and\\_standardised\\_tobacco\\_packaging\\_-\\_impact\\_on\\_prevalence\\_and\\_consumption\\_in\\_france\\_and\\_the\\_uk\\_1.pdf](http://www.europe-economics.com/publications/tpd2_and_standardised_tobacco_packaging_-_impact_on_prevalence_and_consumption_in_france_and_the_uk_1.pdf)



Minister of Health Agnès Buzyn, who stated: “[w]e know that plain packaging does not lead smokers to stop smoking” and concluded that “[U]nfortunately, in 2016, the official sales of cigarettes have increased in France: plain packaging did not contribute to the decrease of official tobacco sales.”<sup>12</sup>

- 4.4 Given that plain packaging has failed to achieve any of its objectives in Australia, it cannot be considered that it would be any more effective in the Netherlands.
- 4.5 In particular, as outlined below, the evidence available from Australia shows that after the introduction of plain packaging:
  - 4.5.1 There has been no acceleration in the long-term smoking rate decline;
  - 4.5.2 Plain packaging has not increased the effectiveness of health warnings;
  - 4.5.3 Plain packaging is associated with a relative reduction in the prices of cigarettes; an increase in the consumption of cigarettes; and an acceleration in the shift from premium to non-premium brands in Australia; and
  - 4.5.4 There has been a substantial increase in illicit tobacco .
- 4.6 This data of the actual effect of plain packaging on behaviour is the best evidence against which to test the adequacy of the Proposal and must be preferred to conclusions based on studies of intentions and perceptions which are relied upon to promote plain packaging policies.
- 4.7 The limitations of predictive survey data on attitudes and perceptions is acknowledged in the literature, including:
  - 4.7.1 By the UK Public Health Research Consortium in their systematic review of the literature in 2012 (the "**Stirling Review**"), where they stated:

*"It is also worth noting that findings regarding smoking-related attitudes, beliefs and behaviour from both the surveys and qualitative studies in the review are reliant upon self-report. Without any form of validation (such as validating reported changes in cigarette consumption) these have quite weak predictive validity. A common argument is that plain packaging research can never truly*

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<sup>12</sup> Statement issued on 29 November 2017 by the Minister of Health, Agnès Buzyn, in response to a Member of Parliament who interrogated her on the efficiency of plain packaging during the second vote on the Social Security finance bill. Available at: <http://www.assemblee-nationale.fr/15/cr/2017-2018/20180075.asp#P1117763>.

*replicate real market conditions and, as such, the suggested impacts on consumption, cessation and uptake are so far speculative.*"<sup>13</sup>

- 4.7.2 By Sir Cyril Chantler in his review undertaken for the UK Government where he stated that:

*"Several of the primary research studies in the Stirling Review aimed to test whether participants believed that standardised packaging would change their purchasing behaviour. Some of the studies (and further studies conducted since) have used an increasing range of methods that approximate behavioural outcomes including experimental auctions, eye-tracking, and naturalistic study designs. However, the authors were cautious about drawing overall conclusions about smoking behaviour, given the well-known weakness of stated intentions in predicting behaviour. This caution is justified, and to that extent the findings are essentially indirect and "speculative".*"<sup>14</sup>

- 4.8 The inadequacy of evidence on attitudes and precursors to behaviour as a basis to evaluate the effectiveness of tobacco control policies is also confirmed by the U.S. Court of Appeals decision in *R.J. Reynolds Tobacco Co. v. Food and Drug Admin.* Commenting on the U.S. Food and Drug Administration's reliance on this type of evidence to support the claim that graphic warnings would advance its interest in reducing the number of Americans who smoke, the Court stated as follows (emphasis added):

*"FDA makes much of the "international consensus" surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have directly caused a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think - or think more - about quitting smoking, Proposed Rule at 69,532, and FDA might be correct that intentions are a "necessary precursor" to behavior change, Final Rule at 36,642, it is mere speculation to suggest that respondents who report increased thoughts about quitting smoking will actually follow through on their intentions. And at no point did these studies attempt to evaluate whether the increased thoughts about smoking cessation led participants to actually quit. Another Australian study reported increased quit attempts by survey participants after that country enacted large graphic warnings, but found "no association with short-term quit success", Proposed Rule at 69,532. Some Canadian and Australian*

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<sup>13</sup> Moodie, C. et al. "Plain tobacco packaging: a systematic review" (2012) Stirling, Scotland, University of Stirling at p. 89. The authors also note that: "[t]he main limitation [of the review] was that because plain packaging has yet to be introduced in any country, it has not yet been possible to evaluate the impact of the policy in practice."

<sup>14</sup> Chantler C., "Standardised packaging of tobacco: Report of the independent review undertaken by Sir Cyril Chantler" (2014) at p. 29.

*studies indicated that large graphic warnings might induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent. See id. But again, the study did not purport to show that the implementation of large graphic warnings has actually led to a reduction in smoking rates.*"<sup>15</sup>

- 4.9 These observations apply equally to the survey data that attempts to show that plain packaging would work by reference to the impact of plain packaging on certain downstream psychosocial variables or intermediate outcomes. None of the evidence on intermediate outcomes is capable of determining whether plain packaging has reduced smoking.
- 4.10 As outlined below, reliable and probative data of the application of plain packaging in Australia now exists. This data is not supportive of plain packaging. To the contrary, such data indicates negative impacts on smoking behaviour after the introduction of plain packaging in Australia.

**There has been no increase in the rate of decline of smoking in the Australian population**

- 4.11 The Australian Government said that plain packaging was required to reduce smoking rates. In the six years following the introduction of plain packaging in Australia, there has been no increase in the rate of decline of smoking in the Australian population.
- 4.12 This lack of any observed impact on the long-term rates of smoking in Australia can be seen in a number of different data sources.

Australian National Drug Strategy Household Survey

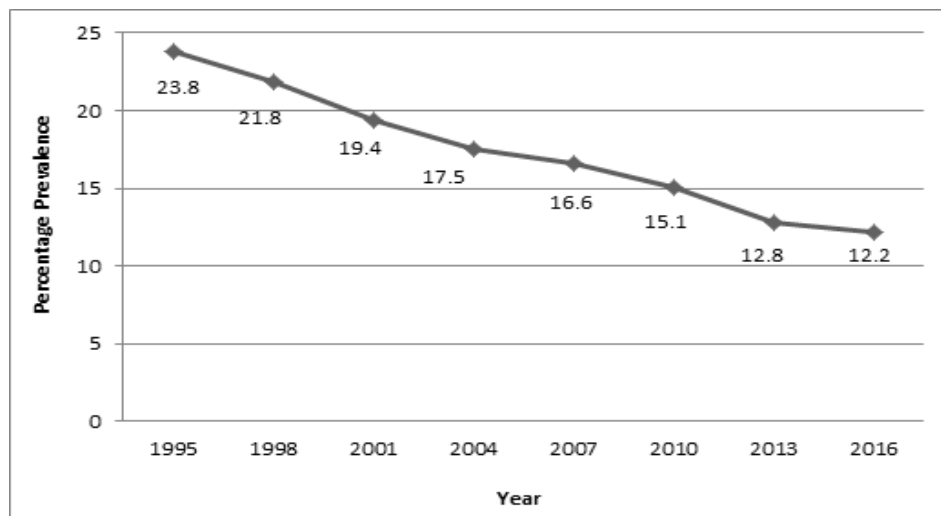
- 4.13 The Australian Federal government's National Drug Strategy Household Survey ("ANDSHS") data shows that while smoking prevalence rates had been declining steadily since 1995, for the first time in more than two decades, the daily smoking rate did not significantly decline over the most recent three-year period following the introduction of plain packaging (falling from 12.8% in 2013 to 12.2% in 2016, which was not statistically significant).<sup>16</sup> Accordingly, this data provides no evidence of an additional effect from plain packaging.

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<sup>15</sup> R.J. Reynolds Tobacco Co., et al. v. FDA, et al., U.S. District Court, District of Columbia, No. 11-01482 at p. 25.

<sup>16</sup> Australian Government, "National Drug Strategy Household Survey 2016 – Detailed Findings" (2013), p. 7. Available at: <https://www.aihw.gov.au/reports/australia-s-health/australia-s-health-2016/data>.

**Daily smokers aged 14 years or older 1995-2016 (per cent)**



Australian Government Bureau of Statistics

- 4.14 The most recent 2018 data from the Australian Government Bureau of Statistics shows that there was a rise in expenditure for the first time since 2004 in national household expenditure on tobacco products, increasing by 2.6%.<sup>17</sup> Again, this provides no evidence of any positive effect from plain packaging.

#### **Roy Morgan Single Source ("RMSS") Smoking Prevalence Data**

- 4.15 BAT has commissioned an expert report from Professor Kip Viscusi, Distinguished Professor of Law, Economics and Management, Vanderbilt University Law School, Nashville, United States, analysing the impact of plain packaging in Australia.<sup>18</sup> Professor Viscusi is an expert on hazard warnings and how they affect consumer behaviour. He has published more than 350 articles and 20 books dealing primarily with health and safety risks, and has been ranked among the top 25 economists in the world based on citations in economics journals. **A copy of Professor Viscusi's expert report is provided with this Response.**
- 4.16 Professor Viscusi conducted an empirical analysis of the RMSS data, a nationally representative, repeated cross-sectional survey of Australians aged 14 and over, which is the most comprehensive data on smoking prevalence available in Australia. Professor Viscusi's analysis included data up to December 2016, thus providing four years of data in the post-plain packaging period, which is a longer time period than in any published study.
- 4.17 Professor Viscusi's analysis leads to the conclusion that the tobacco packaging changes introduced in Australia in 2012, which included plain packaging and enlarged graphic health

<sup>17</sup> Available at:  
<http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/5206.0Dec%202017?OpenDocument>.

<sup>18</sup> Viscusi, W.K, (2018) An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data.

warnings on tobacco packaging, have had a zero effect on smoking prevalence rates in Australia. He concludes that:

*"the estimated statistical association of the 2012 Packaging Changes with smoking prevalence rates is zero. Instead, my analysis of the RMSS data found that the decline in smoking prevalence rates in Australia is a continuation of past nonlinear time trends, overall economic trends such as the general Australian consumer price index, and influences such as rising cigarette prices, and is not significantly related to the adoption of the 2012 Packaging Changes. The only sound conclusion based on this evidence is that the 2012 Packaging Changes are not associated with any change in smoking prevalence rates."*<sup>19</sup>

4.18 Professor Viscusi also considers the analyses of the RMSS dataset undertaken by Dr Tasneem Chipty which was commissioned by the Australian Department of Health and is the only econometric analysis of data that is relied on in the Australian Government's Post Implementation Review Report of the Australian Tobacco Plain Packaging Act 2011 ("**TPP Act**") published in February 2016.<sup>20</sup> Professor Viscusi identifies the following flaws in Dr Chipty's analysis:<sup>21</sup>

- Dr Chipty uses overlapping indicator variables. This creates confounding effects with other policy changes, with the result that any conclusions drawn from her analysis are highly speculative.
- Dr. Chipty uses a linear time trend when the time trend is nonlinear. Professor Viscusi finds that this leads to an "*unexplained 'policy impact' that is spurious, as it is not an effect of the policy but instead reflects an underlying nonlinear trend*".
- Dr Chipty's methodology for controlling for taxes is inadequate because she uses indicator variables only for the major tax increases that occurred in Australia. By doing so, she fails to recognise the continuous nature of excise tax levels (which are periodically adjusted for inflation) and generates a source of error in the treatment of taxes.
- Dr Chipty fails to include a cigarette price variable in her model. Price is the most important variable in models measuring economic demand for any consumer product (this is because consumers care about price, of which taxes are only a component).

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<sup>19</sup> Ibid at p 8.

<sup>20</sup> Dr. Chipty, "Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia" (24 January 2016), available on the Australian Government Department of Health website at: <http://www.health.gov.au/internet/main/publishing.nsf/content/study-pp-measure>.

<sup>21</sup> Viscusi, W.K, (2018) An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data, at ¶ 22-33.

- 4.19 Professor Viscusi concludes that: "[a]s a result of these shortcomings, the report of Dr Chipty provides no sound evidence in support of the efficacy of plain packs policies."<sup>22</sup>

#### **Smoking consumption data**

- 4.20 BAT has also commissioned an expert report from Mr Neil Dryden of Compass Lexicon in February 2017, analysing the impact of plain packaging on price, consumption and downtrading, using data up to and including December 2016 (i.e. four years after the implementation of plain packaging in Australia). Mr Dryden is Executive Vice President at Compass Lexecon, an economic consulting firm. He has over 20 years of professional experience as an economist, specialising in the economics of competition policy, regulation, public policy and market analysis and he was awarded the 2016 Economist of the Year by the Global Competition Review. **A copy of Mr Dryden's expert report is included with this Response.**<sup>23</sup>
- 4.21 Mr Dryden analyses the impact of plain packaging in Australia on cigarette consumption, cigarette prices, and down-trading by using New Zealand (where plain packaging had not been introduced) as a benchmark comparator.<sup>24</sup> This analysis, known as "*difference-in-differences*" ("**DID**"), is more robust than other statistical methodologies for analysing the effects of plain packaging on cigarette consumption, because it is able to isolate the effect of the relevant variable (i.e. plain packaging, from the effect of other confounding factors).<sup>25</sup> Mr Dryden's analysis includes data up to and including December 2016 (i.e. four years after the full implementation of plain packaging in Australia), which is a longer time period than in any published study.
- 4.22 Mr Dryden's empirical analysis shows that:
- 4.22.1 Plain packaging is associated with an increase in the per capita consumption of cigarettes in Australia relative to the consumption that would have prevailed had plain packaging not been implemented, i.e., relative to the counterfactual. In particular, plain packaging is associated with an increase in per capita cigarette consumption (relative to the counterfactual and up to December

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<sup>22</sup> Ibid, at ¶ 8.a.iv. 2.2. Expert analysis undertaken by Dr Lilico, the Principal and Chairman at Europe Economics, also calls into question the reliability of the conclusion reached in the Chipty Report. Dr Lilico's analysis finds two earlier statistically significant breaks in the smoking prevalence series, which, when introduced into models based on the data he has considered, have the effect of removing the impact reported by Dr Chipty. In his time series models, both with and without additional economic factors, there is no such impact. In other words, there is no basis for suggesting that there was a statistically significant decline in Australian smoking prevalence since the introduction of standardised packaging. See Dr A. Lilico, Europe Economics, (August 2016), "Analysis of the Chipty Report's conclusions regarding packaging changes and smoking prevalence in Australia", available at <https://www.jti.com/about-us/our-business/key-regulatory-submissions>.

<sup>23</sup> Neil Dryden, (2017) The effects of standardised packaging: an empirical analysis.

<sup>24</sup> Ibid at 4.14ff for Mr Dryden's rationale of why New Zealand is a good comparator for Australia.

<sup>25</sup> Ibid at 4.7ff.

2016) of 3.1%-3.5%, when control variables such as prices, excise taxes and income per capita are expressed in local currencies; and an increase of 2.2%-3.0% when these variables are expressed in purchasing power parity ("PPP").

4.22.2 Plain packaging is associated with a reduction in the average retail price paid by consumers for cigarettes in Australia relative to the counterfactual. In particular, plain packaging is associated with a decrease in the average price paid by consumers (relative to the counterfactual and up to December 2016) of 2.0-2.6%.

4.22.3 While consumers have been shifting from premium to non-premium brands ('down-trading') in Australia since at least 2009, the adoption of plain packaging is associated with a significant acceleration of this down-trading trend.

These results are reliable across a large set of robustness checks.

4.23 Mr Dryden also provides alternative empirical analyses on the effect of plain packaging on cigarette consumption using Australian only data, similar to approaches that have been adopted by other authors for estimating the effect of plain packaging in Australia.<sup>26</sup> Although, Mr Dryden considers that these alternative analyses are carried out in a less rigorous framework, the results are consistent with those of his DID analysis, and indicate that plain packaging is associated with an increase in cigarette consumption per capita relative to the counterfactual. Mr Dryden concludes that these analyses yield results that are *"consistent with those of my DID analysis, and indicate that standardised packaging is associated with an increase in cigarette consumption per capita relative to the counterfactual."*<sup>27</sup>

#### **The proportion of daily smokers has not changed**

4.24 In his expert report, Professor Kip Viscusi also reviewed the data from two key surveys on Australian smokers' beliefs and behaviours before and after the advent of the plain packaging policy which are relied on in a number of the studies that have been published following the implementation of plain packaging in Australia, i.e. the Cancer Institute New South Wales Tobacco Tracking Survey ("CITTS") and the National Tobacco Plain Packs Tracking Survey ("NTPPTS").<sup>28</sup>

4.25 Professor Viscusi's analysis of the CITTS data from February 2009 to June 2016 (thus providing 3 ½ years of data in the post-plain packaging period (which is a longer time period than in any published study) shows that after the implementation of plain packaging in Australia:

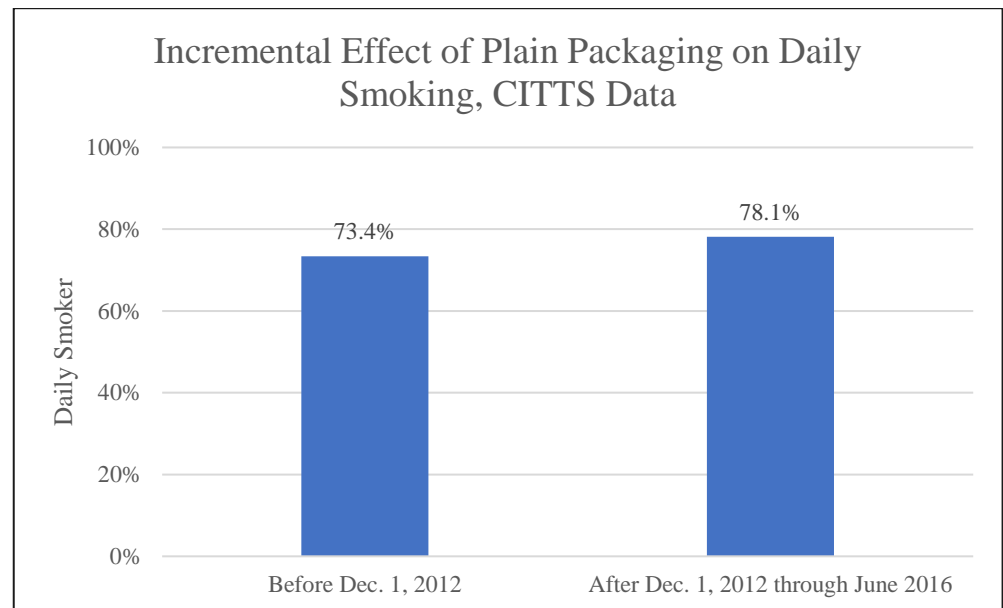
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<sup>26</sup> For example in the report by Dr Chipty discussed above.

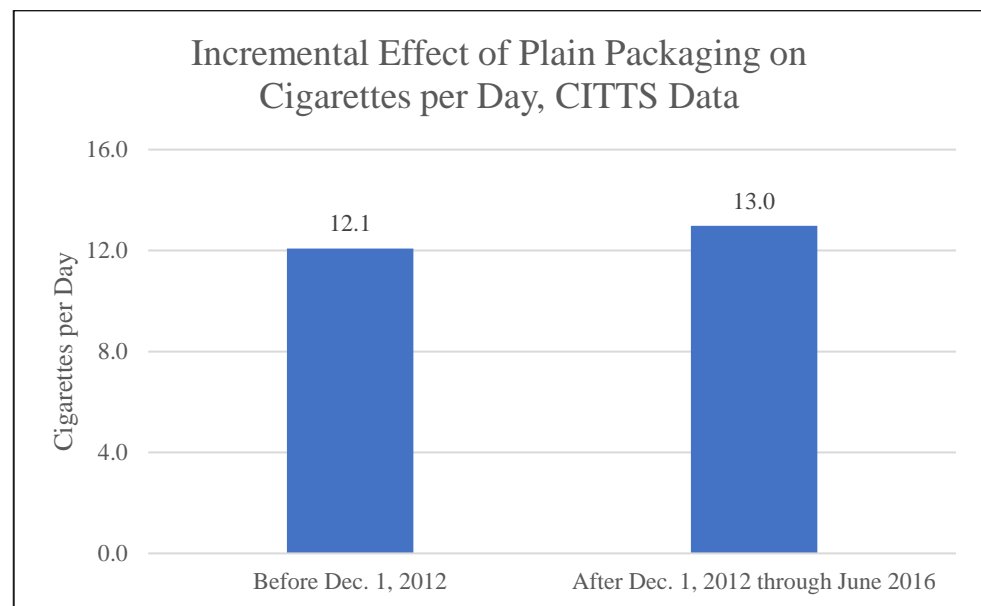
<sup>27</sup> Ibid at Section 5.

<sup>28</sup> The NTPPTS data is a national telephone adult smoker survey from April 2012 to March 2014.

- 4.25.1 There has been an increase in the intensity of smoking behaviour by those surveyed, with more smokers reporting that they are daily smoking;<sup>29</sup> and



- 4.25.2 The number of cigarettes smoked per day by those surveyed increased.<sup>30</sup>



- 4.26 Analysis of the NTPPTS data presented by Professor Viscusi also demonstrates that since the implementation of plain packaging in Australia, there has been no statistically significant change in the number of cigarettes smoked per day.<sup>31</sup>

<sup>29</sup> Viscusi, W.K, (2018) An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data.

<sup>30</sup> Ibid, p. 42-43.

<sup>31</sup> Ibid, p. 52.



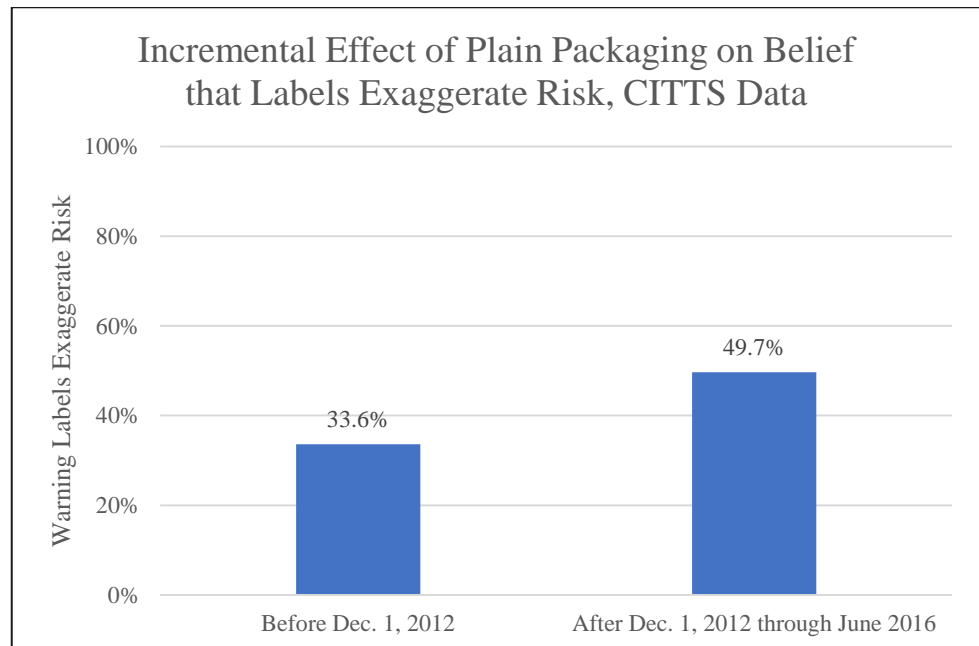
- 4.27 Professor Viscusi also reports that in a study of the NTPPTS data undertaken by Scollo et al. (2015),<sup>32</sup> the authors also did not find that plain packaging had had any impact on consumption.<sup>33</sup> The authors state that:

*"Among daily cigarette smokers, there was no change in consumption between pre-[plain packaging] and the transition phase or [plain packaging] year 1 period [...] Nor was any change detected when mean daily consumption was analysed among regular smokers [...] Mean daily consumption also did not change from the pre-[plain packaging] to subsequent two phases among current smokers [...] Furthermore consumption did not change from pre-[plain packaging] to the subsequent two phases among current smokers of brands of any market segment [...]"<sup>34</sup>*

**The implementation of plain packaging has not increased the efficacy of Graphic Health Warnings ("GHWs")**

- 4.28 Analyses of the CITTS and NTPPTS data presented by Professor Viscusi also demonstrates that the implementation of plain packaging in Australia has not increased the effectiveness of GHWs. Professor Viscusi's analysis of the CITTS data shows that after the implementation of plain packaging in Australia there is a statistically significant increase in whether smokers believe that:

- 4.28.1 health warnings exaggerate the health effects of smoking;



<sup>32</sup> Scollo, M., et al., "Changes in Use of Types of Tobacco Products by Pack Sizes and Price Segments, Prices Paid and Consumption Following the Introduction of Plain Packaging in Australia," (2015) *Tobacco Control* pp. ii66-ii75.

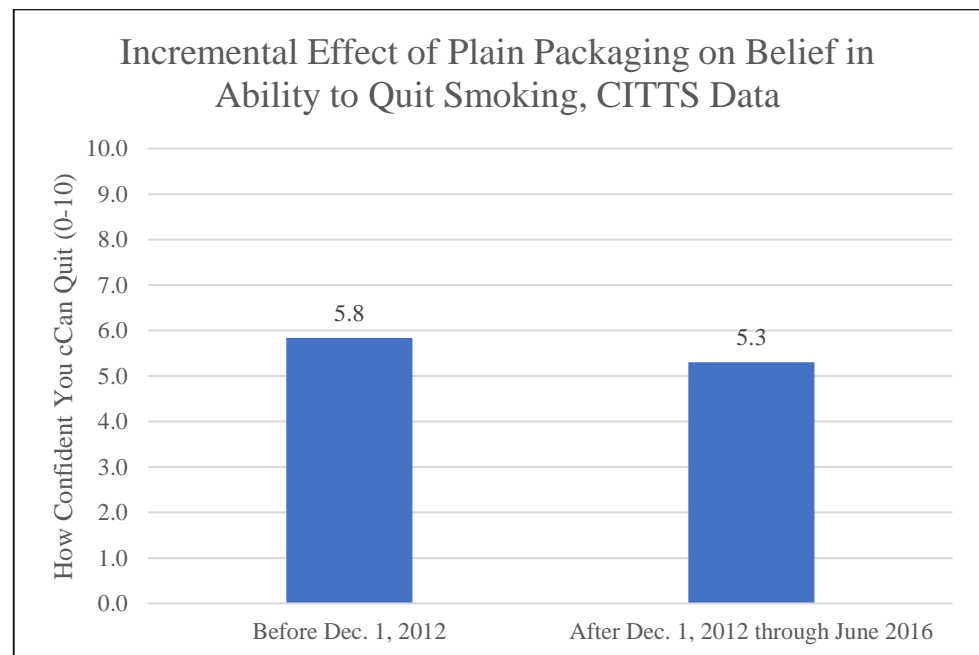
<sup>33</sup> Ibid, p. ii66.

<sup>34</sup> Ibid, at p. ii73.

- 4.28.2 the government pesters people too much about smoking risks;
  - 4.28.3 the health effects of smoking are exaggerated; and
  - 4.28.4 smoking is only harmful to heavy smokers.<sup>35</sup>
- 4.29 Professor Viscusi's analysis of the NTPPTS data also shows that after the implementation of plain packaging in Australia there has been no statistically significant impact on beliefs regarding:
- 4.29.1 the harmfulness of cigarettes; and
  - 4.29.2 the impact of smoking on respondents' own health.<sup>36</sup>

**The introduction of plain packaging has not encouraged smokers to stop smoking**

- 4.30 Professor Viscusi's analysis of the CITTS and NTPPTS data also indicates that plain packaging has not increased quit-related behaviours. Professor Viscusi's analysis of the CITTS data shows that after the implementation of plain packaging in Australia:
- 4.30.1 respondents rate it significantly more difficult to quit both in terms of how difficult it would be to quit and how difficult they thought it would be to quit;
  - 4.30.2 respondents are significantly less confident that they can quit; and



<sup>35</sup> Viscusi, W.K, (2018) An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data, p. 47.

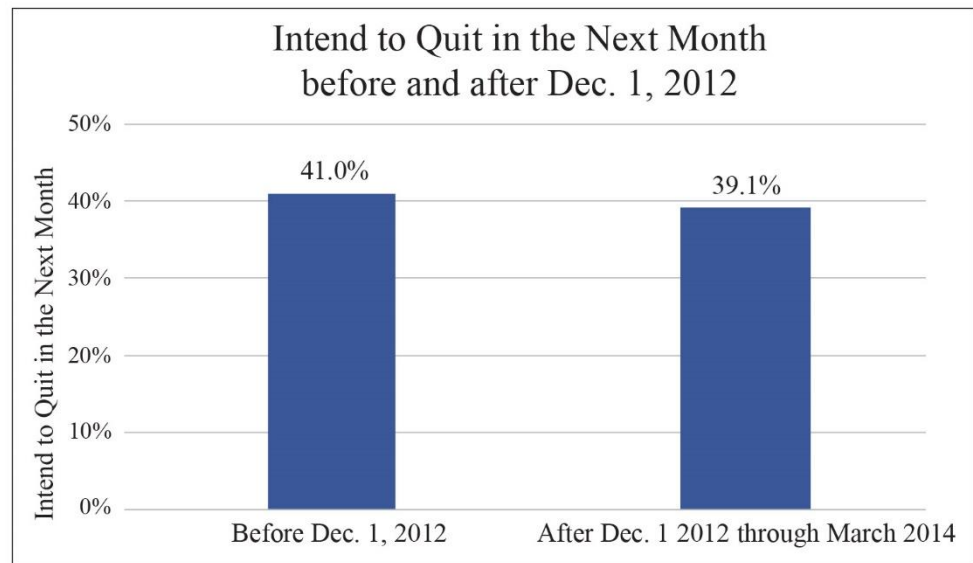
<sup>36</sup> Ibid, at p. 67.

4.30.3 there were no statistically significant effects of plain packaging on the perceived difficulty of the last quit attempt or confidence that they can stay as quitters.<sup>37</sup>

4.31 Professor Viscusi's analysis of the NTPPTS data also shows that after the implementation of plain packaging in Australia there is:

4.31.1 a decline in respondents' rating of the importance of quitting;

4.31.2 a decrease in respondents' intention to quit in the next month;<sup>38</sup>



4.31.3 no change in the fraction of respondents who have ever attempted to quit smoking;

4.31.4 no statistically significant difference in the number of days since respondents' last quit attempt; and

4.31.5 a statistically significant decrease in smokers stubbing out their cigarette after thinking about the harms of smoking.<sup>39</sup>

4.32 Professor Viscusi's analysis is corroborated by analysis of the NTPPTS data undertaken by Davidson and de Silva who found that the evidence drawn from the NTPPTS does not support the efficacy of the plain packaging policy.<sup>40</sup> Davidson and de Silva conclude that:

*"The Australian plain packaging policy has failed to meet its stated objectives. The [NTPPTS] research project commissioned to establish whether the policy had met*

<sup>37</sup> Ibid, p. 58.

<sup>38</sup> The observation period here is up to March 2014 which is the period of the NTPPTS survey.

<sup>39</sup> Ibid, p. 54-55.

<sup>40</sup> Davidson, S. & de Silva, A., "Stubbing Out the Evidence of Tobacco Plain Packaging Efficacy: An Analysis of the Australian National Tobacco Plain Packaging Survey" (2016).

*its stated objectives fails on a number of criteria including independence, transparency, replication and rigour."*<sup>41</sup>

- 4.33 Professor Viscusi also considers Cochrane review of the plain packing literature that was published in April 2017 (the "**Cochrane Review**")<sup>42</sup> which is the only report cited in the Explanatory Memorandum as evidence in support of plain packaging. However, Professor Viscusi notes that:

*"[f]or studies that focused on the effects of Plain Packaging on actual behavioral outcomes, including smoking prevalence and consumption, the Cochrane Review concluded that the confidence in the findings was "limited, due to the nature of the evidence available" and that the evidence was "mixed." The Cochrane Review also noted that: "[n]o studies assessed uptake, cessation, or relapse prevention"(p. 2). The results of many of the studies on other intermediate outcomes were also limited and mixed so that there is no consistent evidence of plain packaging being effective across a large number of variables. The Cochrane Review concludes that "[t]he available evidence suggests that standardised packaging may reduce smoking prevalence" (p. 2), which itself doesn't demonstrate the efficacy of plain packaging. In addition, based on my review of the actual data emanating from Australia and critical analysis of the published papers on this data, which the Cochrane Review did not undertake, the overwhelming evidence across all the datasets is not consistent with the 2012 Packaging Changes being effective in reducing smoking, while there is also evidence consistent with the policy being counterproductive on many of the intermediate or secondary measures that are relied upon to promote Plain Packaging."*<sup>43</sup>

- 4.34 Accordingly, the Cochrane Review does not provide any reliable evidence demonstrating that plain packaging is effective and therefore provides no reliable support for the introduction of plain packaging.

### **There have been a number of unintended consequences that undermine the public health objective**

Plain packaging is associated with a relative reduction in the prices of cigarettes; and an acceleration in the shift from premium to non-premium brands in Australia

- 4.35 Plain packaging prevents manufacturers from being able to differentiate their products and would make the packages all look the same. Without the ability to differentiate or offer the

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<sup>41</sup> Ibid at p. 12.

<sup>42</sup> McNeill, A., Gravelly, S., Hitchman, S.C., Bauld, L., Hammond, D., and Hartmann-Boyce, J., "Tobacco Packaging Design for Reducing Tobacco Use," Cochrane Database of Systematic Reviews 2017, Issue 4, Art. No.: CD011244.

<sup>43</sup> Viscusi, W.K, (2018) An assessment of the effect of Australian Plain Packaging regulation: analysis of Roy Morgan research data, CITTS data, and NTPPTS data, p 17.

quality and value attributes created by trademarks and the brands they represent, tobacco products would become increasingly standardised and manufacturers would only be able to compete on price. As such, price competition, which is already extremely vigorous in the tobacco market, would become even more intense leading to further price reductions.

- 4.36 The impact of reduced prices is likely to increase in consumption, especially among price-sensitive consumers, as tobacco products become more affordable. This would undermine the objective that plain packaging set out to achieve.
- 4.37 By implementing measures that distort competition, plain packaging would also betray domestic policy to facilitate fair competition, as inferred from the Dutch Competition Act.
- 4.38 As noted above, Mr Neil Dryden's empirical analysis of the plain packaging data found that:
  - 4.38.1 Plain packaging is associated with a reduction in the average retail price paid by consumers for cigarettes in Australia relative to the counterfactual. In particular, plain packaging is associated with a decrease in the average price paid by consumers (relative to the counterfactual and up to December 2016) of 2.0-2.6%.
  - 4.38.2 Plain packaging is associated with an increase in the per capita consumption of cigarettes in Australia relative to the consumption that would have prevailed had plain packaging not been implemented.
  - 4.38.3 Plain packaging is associated with acceleration in 'downtrading', i.e. the shift from premium to non-premium brands in Australia.<sup>44</sup>
- 4.39 By restricting the scope for branding of tobacco products, plain packaging distorts competition between premium and other brands. Indeed, Mr Dryden's analysis confirms that that high-quality brands lost market share following the introduction of plain packaging in Australia.<sup>45</sup>
- 4.40 This acceleration in downtrading to low priced cigarettes in Australia following the introduction of plain packaging is also confirmed by analysis undertaken by KPMG which shows that since 2012 the market share of low-priced cigarettes has increased by 27% to 2016.<sup>46</sup>

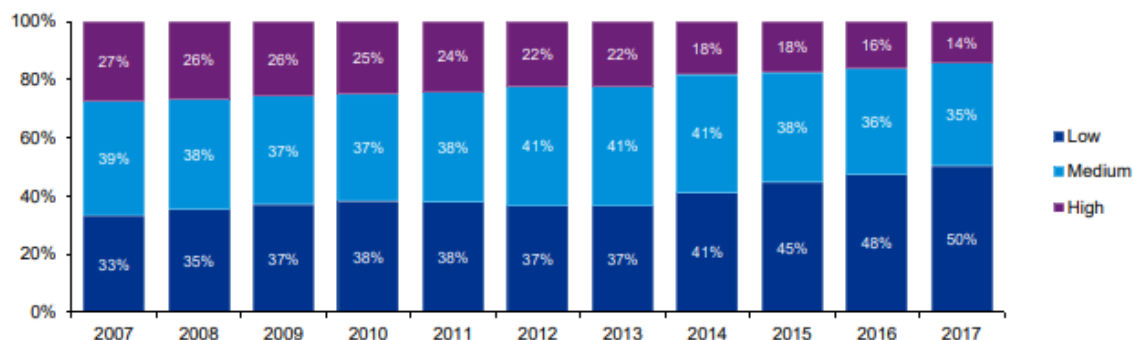
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<sup>44</sup> Neil Dryden, (2017) The effects of standardised packaging: an empirical analysis, at page 28

<sup>45</sup> Ibid, p. 25 at 4.51.

<sup>46</sup> KPMG, "Illicit Trade in Australia: 2016 Full Year Report", (20 March 2017), at p.11. Available at <https://home.kpmg.com/content/dam/kpmg/uk/pdf/2017/04/Australia-illicit-tobacco-Report-2016.pdf>.

Figure 2.2.2b: Market share of manufactured cigarettes by price category, 2007 – 2017<sup>(2)(3)</sup>



There has been a substantial increase in illegal tobacco since the introduction of plain packaging

4.41 A KPMG report shows that the volume and market share of illegal tobacco in Australia has increased significantly since the introduction of plain packaging. From 2012 to 2017, annual illegal volumes increased by 300,000 kilograms. This resulted in an increase of 30% in illegal tobacco's market share – from 11.5% in 2012 to 15.0% in 2017.<sup>47</sup>

4.42 A 2017 submission by a former Australian Border Force officer, Rohan Pike, to the ongoing Australian Parliamentary Joint Committee Inquiry into Illicit Tobacco has also estimated that the Australian illicit market has a value of around AU\$3.82 billion in customs duty forgone.<sup>48</sup>

## 5. PLAIN PACKAGING IS UNLAWFUL

5.1 Plain packaging is unlawful because:

5.1.1 It is contrary to the principle of justified expectations (*vertrouwensbeginsel*), on the basis that the Government is seeking to introduce plain packaging, despite previously stating that it would consider plain packaging only if current measures are no longer effective;

5.1.2 It violates the EU principle of free movement of goods, by restricting the free movement of tobacco products between the Netherlands and other Member States;

5.1.3 It violates the right to freedom of expression protected by Article 11 of the Charter of Fundamental Rights and Article 10 of the ECHR, by impairing the ability of manufacturers to communicate with adult consumers about the origin,

<sup>47</sup> KPMG, "Illicit Trade in Australia: 2017 Full Year Report", (20 April 2018) - Available at [https://assets.kpmg/content/dam/kpmg/uk/pdf/2018/05/australia\\_illicit\\_tobacco\\_report\\_2017.pdf](https://assets.kpmg/content/dam/kpmg/uk/pdf/2018/05/australia_illicit_tobacco_report_2017.pdf).

<sup>48</sup> [Submission by Rohan Pike into Parliamentary Joint Committee Inquiry into Illicit Tobacco.](#)

quality and other points of differentiation and innovation regarding their products; and

- 5.1.4 It amounts to a deprivation of BAT's valuable intellectual property rights in packaging, together with the goodwill arising in the brands without compensation, contrary to Article 17 of the Charter of Fundamental Rights and Article 1 of the First Protocol, and Articles 14 of the Constitution;

#### **Violation of Principle of Justified Expectations (*Vertrouwensbeginsel*)**

- 5.2 The Government has violated the principle of justified expectations by introducing plain packaging despite stating in September 2017 that it would only introduce such a measure if *"it turns out that setting further packaging requirements is no longer effective to prevent extra attention for tobacco products...It will then be examined whether this measure is proportional."*<sup>49</sup> However, the Government is proceeding without having conducted any evaluation of the efficacy of existing packaging requirements. This is underscored by the Government's responses to Parliament's questions on the NPA, in which the Government acknowledged that *"the existing packaging requirements are indeed tightened without a thorough evaluation."*<sup>50</sup>

#### **Violation of Free Movement of Goods**

- 5.3 Freedom of trade within the EU constitutes *"a fundamental principle of the common market."*<sup>51</sup> More specifically, the free movement of goods has repeatedly been recognised by the Court of Justice of the European Union ("CJEU") as *"one of the fundamental principles of the Treaty...entail[ing] the existence of a general principle of free transit of goods within the [EU]."*<sup>52</sup>
- 5.4 Article 34 of the Treaty on the Functioning of the European Union ("TFEU") provides that *"[q]uantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States."* It is settled EU law that *"[a]ll trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions."*<sup>53</sup>
- 5.5 It is self-evidently the case that the Proposal will restrict the movement of goods within the EU. The Proposal will partition the internal market by imposing purely national conditions and

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<sup>49</sup> Question 204; Parliament questions on NPA.

<sup>50</sup> Ibid.

<sup>51</sup> Judgment in *Rewe-Zentral AG v Direktor der Landwirtschaftskammer Rheinland*, 37183, EU:C:1984:89, [1984] ECR 1229, [18].

<sup>52</sup> See, inter alia, judgment in *SIOT*, 266/81, EU:C:1983:77, [1983] ECR 731, [16]; judgment in *Richardt and 'Les Accessoires Scientifiques'*, C-367189, EU:C:1991:376, [1991] ECR I-4621, [14]; judgment in *Commission v Austria*, C-320103, EU:C:2005:684, [2005] ECR I-9871, [63] and [65]; judgment in *Commission v Austria*, C-28109, EU:C:2011:854, [2011] I-13525, [113].

<sup>53</sup> Judgment in *Dassonville*, 8/74, EU:C:1974:82, [1974] ECR 835, [5].

requirements on the presentation and sale of tobacco products in the Netherlands. In doing so, it will simultaneously restrict the free movement of such products between the Netherlands and other Member States.

- 5.6 Whilst, as noted in the Explanatory Memorandum, it is open to the Government to defend the Proposal under Article 36, which states that "[t]he provisions of [Article] 34...shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of...the protection of health and life of humans", it is settled law that any measure inconsistent with Article 34 TFEU may only be justified on Article 36 TFEU grounds (including the protection of human health) if the measure complies with a strictly-applied test of proportionality.<sup>54</sup>

#### **Violation of Freedom of Expression**

- 5.7 As part of its engagement in the lawful trade and business of the manufacture and sale of cigarettes, BAT has the constitutional guarantee of freedom of expression stipulated in Article 11 of the Charter of Fundamental Rights and Article 10 ECHR. Plain packaging would impair BAT's ability to communicate with adult consumers about its products. The ability both of manufacturers to communicate and consumers to receive information is a fundamental right of free speech.

#### **Violation of Property Rights**

- 5.8 Plain packaging directly violates the right to property, which is guaranteed in Article 17 of the Charter of Fundamental Rights and Article 1 of the First Protocol. Plain packaging extinguishes BAT's and other rights holders' valuable property rights in their intellectual property, together with the goodwill arising in its brands. This deprivation of property is unjustified.
- 5.9 Plain packaging would prohibit manufacturers from using virtually all of their trademarks as registered (including logos and device marks). The value of these trademarks would be eliminated. While the use of some word marks would still be allowed, they would be required to be in a standardised form –preventing them from being able to adequately serve their essential functions of differentiating products and uniquely identifying their origin and quality. BAT would be unable to use and control its trademarks on its packaging, which goes to the essence of the property rights protected the Constitution. As a result, decades of investment

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See, e.g., Judgment in *Commission v Portugal*, C-265/06, ECLI:EU:C:2008:210, [37]-[39].



in trademarks and their related brands, along with the associated goodwill, would be destroyed.

**6. PLAIN PACKAGING IS DISPROPORTIONATE**

- 6.1 The Government has the burden of showing that plain packaging that the proposed measure can be justified and meet the requirements of proportionality . This is highlighted in this case where the Government relies on Article 24(2) of the TPD as a basis to implement the measure.
- 6.2 Contrary to the Government's position as set out in the Explanatory Memorandum, the requirement to justify the measure cannot be avoided by claiming that it is part of a set of measures aimed at reducing smoking. Such an assertion would empty the concept of proportionality of all substance and render the notion of proportionality moribund. The need to quantify the benefits specifically attributable to the measure is made more pressing by TPD. As stated above, Article 24(2) of TPD expressly demands that whatever "*further requirements*" may be introduced by Member States under that provision, they must take into account "*the high level of protection of human health achieved through this Directive*". That is logically an exercise which can only properly be performed on a case-by-case basis, whereby the incremental benefit to public health of each 'further requirement' is assessed against the benefit to public health achieved by TPD. The Government has not done this.
- 6.3 The Government also seeks to rely on CJEU rulings on Article 13 of TPD to claim that property rights are not absolute rights, and that restrictions may be imposed, provided they are justified by goals of general interest pursued by the EU. However, the Government fails to note that in the context of considering Article 13 the CJEU confirmed that any limitation on the exercise of the rights and freedoms set out in the Charter must be (a) provided for by law; (b) respect the essence of those rights and freedoms; and (c) comply with the principle of proportionality.<sup>55</sup>
- 6.4 It follows that a measure, such as the Proposal, that does not respect the essence of a relevant right or freedom will be unlawful, and cannot be saved by a proportionality analysis. Indeed, the absence of any meaningful possibility to use trademarks fails in itself to protect the essence of the tobacco manufactures intellectual property rights. As a result, the Proposal – which seeks not only to impose a standardised colour but also destroy branding and meaningful product differentiation – deprives tobacco manufactures of their various intellectual property rights and/or fails to respect the essence of those rights by providing no or insufficient opportunities for consumer-facing use of such property. The Proposal is consequently unlawful on that basis alone.

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<sup>55</sup> Case C-547/14 Philip Morris Brands SARL and others, para 149.

- 6.5 Furthermore, even if a proportionality analysis does fall to be applied, the CJEU made clear that the nature and extent of the interference with property rights is highly significant. Thus, the CJEU recognised the importance of competition between manufacturers and, in particular, of ensuring adequate space on the packs for product differentiation. For this reason, in the context of the challenges to the validity of the pack size and shape requirements and the health warning requirements contained in TPD, the CJEU placed weight on the fact that those provisions “*still allow adequate opportunities for product differentiation*”<sup>56</sup> This is clearly not the case with the Proposal.
- 6.6 Plain packaging is furthermore a disproportionate measure on each of the following grounds:
- 6.6.1 Plain packaging is not necessary because:
- (A) The risks of smoking have been universally known for decades: see *Romer v BAT* - Amsterdam District Court 17 December 2008, ECLI:NL:RBAMS:2008:BG7225 in which the Court stated: “*the risks in question must in any event have been known to the broad public...in the Netherlands by 1963.*” See also Hague Court of Appeal judgment (ECLI:NL:GHDHA:2018:3334) issued on the appeal submitted by Ms Anne Marie van Veen et al., in December 2018, which found, *inter alia*, “*it is the view of the court that the fact that smoking is harmful for health, involves serious health risks and may result in serious diseases and even death and is furthermore very addictive, can be considered public knowledge...*” The current GHWs on cigarette packets that occupy 65% of the front and back surfaces of tobacco packaging also continue to reinforce the existing awareness of smoking risks. The awareness of the risks of smoking exist with branded packaging. Accordingly, it is clear that branded packaging does not prevent consumers from seeing and assimilating the health warnings or mislead consumers about the harmful effects of smoking. The removal of trademarks from packaging is not required to, and would not in any event, increase the effectiveness of health warnings.
- (B) Trademarks and packaging are also not drivers of smoking behaviour and their removal is not required. It is clear from numerous government-funded studies that factors other than packaging are the real drivers of smoking behaviour. These studies have demonstrated that the real drivers of smoking initiation include factors such as parental influences, risk preferences, peer influences, socioeconomic factors, access and

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<sup>56</sup> Ibid at paras 199 and 209.

price.<sup>57</sup> Similarly, the drivers of cessation are well known and do not include packaging. The known drivers of cessation are concerns about current or future health effects of smoking; the desire to set a good example for children; the cost of smoking; and pressure from family and friends to quit.<sup>58</sup> None of these relate to cigarette packaging.

- (C) Furthermore, existing laws are sufficient to meet any demonstrable concerns regarding deceptive packaging so that plain packaging is not required. The existing protections against misleading communications on the packaging of tobacco products under domestic law (e.g. article 6:194 Dutch Civil Code and article 3.1 of the Dutch Tobacco and Related Products Regulation) are sufficient to address the types of allegedly misleading elements intended to be addressed by plain packaging, while also respecting the autonomy and rights of adults who choose to use tobacco products and allowing tobacco manufacturers, as a part of a legal industry, to communicate with consumers.

6.6.2 Plain packaging is not appropriate because:

- (A) As explained above, the objective evidence of actual smoking behaviour in Australia shows that, as expected, plain packaging has not reduced smoking behaviour and, has had a number of unintended and undesirable consequences, such as increasing illicit trade.

6.6.3 Plain packaging is disproportionate because:

- (A) The Government has not offered sufficient evidence to support the introduction of the Proposal. Indeed, the evidence currently available, upon proper assessment, does not justify the introduction of plain packaging.
- (B) It amounts to a deprivation of an industry's brands and trademarks and also represents an unprecedented assault on commercial expression, which cannot be justified.
- (C) The Government should not be introducing additional regulation when there is already regulation that can be enforced. For example, existing regulation already prohibits the use of any misleading and deceptive terms

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<sup>57</sup> See, e.g., Fuller, E., National Foundation for Educational Research, "Smoking, drinking and drug use among young people in England in 2012" London, (2013); US Government and Human Services. "Preventing tobacco use among young people: A report of the Surgeon General". (1994) (summarizing approximately 160 studies on the subject of the psychosocial risk factors associated with underage tobacco use). See also US Government and Human Services. "Preventing tobacco use among youth and young adults: A report of the Surgeon General" (2012), at Ch. 4 (reinforcing findings of 1994 Surgeon General's report with added emphasis on individual cognitive processes).

<sup>58</sup> See, e.g., Halpern, M. and Warner, K., "Motivations for Smoking Cessation: A Comparison of Successful Quitters and Failures," (1993) Journal of Substance Abuse, Vol. 5 (1993), pp. 247-256 at p. 247.

on tobacco, which could be used to address claims that particular trademarks or colours used on tobacco packaging mislead consumers.

- 6.7 There are a number of alternative regulations that are more effectively targeted to reducing smoking. These include, for example, implementing a consistent tax policy that discourages youth uptake of smoking while not incentivising consumers to purchase illicit products. The implementation of these measures has the capacity to significantly affect smoking rates without the implementation of illegal, disproportionate measures, in breach of international obligations.
- 6.8 Plain packaging would remove all trademarks and other branding from packs, except for standardised and inconspicuous word marks. As a result, premium tobacco products would lose their distinctiveness. Consumers would be deprived of essential information concerning product origin and quality that allows them to distinguish among products in the market and would increasingly focus on price alone. This would encourage consumers to downtrade to cheaper products and the illicit market. The only means by which tobacco companies could differentiate their products would be price.
- 6.9 In these circumstances, there can be no question that plain packaging would constitute an unjustified and disproportionate measure.
- 6.10 We note also that the Government's stated intention to also implement neutral requirements for the appearance of cigarettes and cigars themselves is not supported by any evidence. Cigarette standardisation would also exacerbate the illicit trade. The legal industry would lose the ability to differentiate its cigarettes from illegal counterparts with the mandated standardized product looking the same as the type of products produced by the illegal tobacco industry. In effect the Government would be creating a market in which tobacco packages and individual cigarettes must all look exactly the same – with their preferred standard being that of the organized crime groups behind the illegal tobacco trade. This would result in making it impossible for consumers and law enforcement agencies to differentiate between legal and illegal products.
- 6.11 We also submit with this Response the following expert reports for your consideration. These expert reports were submitted by British American Tobacco UK Limited in response to the UK government's 2014 consultation on plain packaging. In our view, the findings of these reports are still relevant today and should form part of the Government's assessment of the proportionality of the Proposal:
- 6.11.1 Expert report of Dr Neil McKeganey, Director of the Centre for Drug Misuse, Glasgow, *Critical Analysis of Evidence that Standardised Tobacco Packaging Will Reduce Smoking Prevalence in the United Kingdom.*, dated 5 August 2014. Dr McKeganey concluded that there is no evidence to suggest that tobacco packaging influences people's decision to start, continue or to resume

smoking. All of these decisions relate to complicated interactions between people's family backgrounds, psychological traits and physiological dependence on nicotine. The studies relied on by the UK Government had not attempted to track or estimate actual tobacco use following the introduction of plain packaging.

- 6.11.2 Expert report of Dr Gregory Mitchell, a psychologist and the Joseph Weintraub-Bank of America Distinguished Professor of Law at the University of Virginia, *Observations on the Chantler report: a psychological analysis of the potential impact of standardized cigarette Packaging on underage smoking.*, dated 30 July 2014. Dr Mitchell's report concluded that existing theories of adolescent decision-making and behaviour do not support the UK Government's contention that plain packaging will lead to net reductions in smoking because packaging does not drive adolescent smoking behaviour. The beneficial effects of plain packaging, if any, are likely to be so minor as to be cancelled out by price and substitution effects because standardising the packaging of tobacco will lead to competition on price, and therefore increased consumption.
- 6.11.3 Expert report of Professor Ronald Faber, Professor Emeritus of Mass Communications in the School of Journalism and Mass Communication at the University of Minnesota, *The Role of Trademarks and the Brands They Represent.*, dated 1 August 2014. Professor Faber concluded that trademarks and packaging are key factors in consumers' and manufacturers' ability to distinguish between different types of products. Eliminating the use of trade marks will limit adult smokers' ability to distinguish and identify preferred brands and adversely impact the ability of tobacco manufacturers to successfully sell their brands, but will not serve to reduce primary demand. This change in trademarked packaging will also adversely affect the goodwill and brand equity manufacturers have cultivated over years of investment.
- 6.11.4 Expert report of Mr Weston Anson, Chairman of Consor Intellectual Asset Management, *Preliminary Analysis of the UK Department of Health 2012 and 2014 Impact Assessments of Standardized Packaging for Tobacco Products.*, dated 4 August 2014. Mr Anson concluded that the UK Government had significantly undervalued the cost of lost brand equity in its estimate of the costs and benefits of plain packaging because it has not used a recognised valuation method. Brand intellectual property is the most valuable asset of every tobacco company. In Mr Anson's view, the valuation of lost brand equity is likely to run to several billions of pounds for the UK market alone if certain of the standard valuation methods are used.

## 7. PLAIN PACKAGING VIOLATES INTERNATIONAL OBLIGATIONS

### 7.1 Plain packaging violates international obligations under:

7.1.1 WTO Agreements; and

7.1.2 Bilateral Investment Treaties.

#### **World Trade Organization Agreements**

7.1 Plain packaging would violate several WTO Agreements, including the TRIPS Agreement (and the related Paris Convention), and the TBT Agreement. It is unquestionably in the national interest to comply, and ensure compliance by other WTO States, with these WTO Agreements. They are vital to the fair treatment of domestic exports.

7.2 Plain packaging would undermine intellectual property rights by altogether eviscerating the use of trademarks on the packaging of tobacco products and the enforcement of trademark rights. As a result of their impact on internationally protected trademark rights, plain packaging must be analysed under the provisions of the TRIPS Agreement. In particular, by removing or affecting BAT's right to use its trademarks, plain packaging would violate Article 20 of the TRIPS Agreement, as well as Articles 15 and 16 of the TRIPS Agreement.

7.3 Article 20 of the TRIPS Agreement provides that the use of trademarks in the course of trade shall not be "*unjustifiably encumbered by special requirements [...]*". Article 20 continues by clarifying that requirements that the trademark be used in a special form or that the trademark is used in a manner detrimental to the capability of the trademark to distinguish products are examples of unjustifiable encumbrances on the use of trademarks.

7.4 Plain packaging is the "*ultimate encumbrance*" as it prohibits the use of trademarks in retail trade. Given that there is no general health exception in the TRIPS Agreement and in light of the text, context and object and purpose of the TRIPS section on trademarks, a measure that impairs the very substance of the functional and relational trademark right and prevents it from performing its essential function of distinguishing products, is *ipso facto* an "*unjustifiable*" encumbrance. Even if the Proposal could be justified, the absence of any contribution to the reduction of smoking rates, let alone a material reduction, and the availability of less trademark-restrictive alternative measures that are equally or more effective, confirms that the encumbrances resulting from plain packaging are not "*necessary*" and thus certainly not "*justifiable*" under Article 20 of the TRIPS Agreement.

7.5 Plain packaging would also breach the obligation under Article 15.4 of the TRIPS Agreement, which provides that "[t]he nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark". Plain packaging would violate this obligation because it adversely affects only tobacco-related trademarks and prevents these from performing their essential functions, only because of the nature of the product.

- 7.6 Plain packaging would also violate Article 16 of the TRIPS Agreement because it would reduce the scope of protection of the rights conferred by Article 16 below its minimum guaranteed level. Plain packaging undermines the right of registered trademark owners effectively to prevent others from using similar signs that are likely to cause confusion. Article 16 of the TRIPS Agreement confers exclusive rights to owners of registered trademarks and provides a guaranteed minimum level of protection of the distinctiveness and reputation of the mark. The scope of protection guaranteed under Article 16 of the TRIPS Agreement is determined by the use made of the mark and the resulting strength of the mark. The more intensive the use made of the mark, the stronger the mark; and the stronger the mark, the greater its scope of protection. A measure that prevents the use of trademarks therefore significantly reduces the scope of protection of the trademark, in violation of Article 16.1.
- 7.7 The additional protection for well-known marks under Article 16.3 of the TRIPS Agreement is a confirmation and logical extension of this direct and intrinsic link between use of the trademark and the scope of the trademark owners' rights of protection against infringement. Article 16.3 of the TRIPS Agreement protects well-known marks from dilution and allows the owner of a well-known mark to prevent the use of similar marks even on dissimilar products when that use would risk damaging the trademark owner's interests and if it would suggest an association with the well-known mark. A plain packaging measure that prevents the use of all trademarks and requires the use of the brand name in a standardised form and font reduces the level of protection below that minimum level. A well-known mark that can no longer be used would soon lose its special status and its extended scope of protection. The Proposal would therefore violate the obligation to guarantee a minimum level of protection for well-known marks under Article 16.3 of the TRIPS Agreement.
- 7.8 This is not to say that trademarks that are misleading or deceptive or that are of such a nature to violate public morals cannot be dealt with domestically; those are all well-established reasons for invalidating the registration and protection of a trademark and can be the basis for preventing its use. However, that requires an analysis of the specific sign and its allegedly misleading nature. The Proposal does not provide for such an examination of individual trademarks against a general criterion of deception but simply bans all trademarks. That is not permissible under the TRIPS Agreement.
- 7.9 Furthermore, plain packaging would be inconsistent with Article 2.2 of the TBT Agreement as it would create an unnecessary obstacle to trade because it would:
- 7.9.1 significantly limit market entry for imported tobacco products;
  - 7.9.2 reduce product differentiation and lower the value of imported products; and
  - 7.9.3 strongly disincentivise imports into the country because of the required adaptation costs and the potential risk of penalties for non-compliance.

- 7.10 The Proposal would also make no contribution to the stated objective of lowering smoking. The available evidence demonstrates that plain packaging is an ineffective measure to change actual smoking behaviour, and there is no evidence that plain packaging would be apt to produce any effect on smoking behaviour in the future. As a result, the Proposal would fail to make any contribution to the objective of the Netherlands.
- 7.11 Moreover, there are reasonably available alternative measures available to the Netherlands which would produce an at least "equivalent contribution" to the objective of reducing smoking and which are less trade restrictive and/or entirely WTO consistent. These include, for example, implementing a consistent tax policy that discourages youth uptake of smoking while not incentivising consumers to purchase illicit products. It is recognised that tobacco tax increases are likely to have a significant effect on reducing tobacco consumption, prevalence and initiation among young people.<sup>59</sup> The WTO panel on *Australia – Tobacco Plain Packaging* (the "**Panel**"), to which the Proposal refers expressly, found that there are alternatives that have shown to provide a "meaningful contribution" to the reduction in smoking.<sup>60</sup>
- 7.12 Finally, the Proposal makes a reference to the decision of the Panel on *Australia – Tobacco Plain Packaging* of 18 June 2018, but failing to reflect that this first-instance decision is currently under appeal to the WTO Appellate Body. Indeed, appeals have been filed by Honduras and the Dominican Republic to reverse the Panel's erroneous finding that Australia's plain packaging measure is consistent with the TRIPS Agreement and the TBT Agreement.<sup>61</sup>
- 7.13 Thus, the legality of the plain packaging measure in Australia with the WTO agreements is still under review.
- 7.14 Furthermore, it is not correct to state that the Panel confirmed the effectiveness of plain packaging in Australia. In fact, examining the causal pathway of how plain packaging is supposed to operate from addressing elements of tobacco packaging to reducing smoking behaviour, the Panel consistently finds that the evidence is very weak or not existent. It thus finds that there is a lack of empirical evidence showing that plain packaging is operating as intended. For example:
- 7.14.1 On plain packaging's actual impact to decrease the ability of tobacco products to mislead adult consumers, the Panel finds that they and the enlarged GHWs

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<sup>59</sup> WHO Guidelines for implementation of Article 6 of the FCTC.

<sup>60</sup> Panel Report, *Australia – Tobacco Plain Packaging*, paras. 7.1447, 7.1453, 7.1523.

<sup>61</sup> WTO website, "Honduras files appeal against WTO panel ruling on tobacco plain packaging requirements" (19 July 2018), [https://www.wto.org/english/news\\_e/news18\\_e/ds435apl\\_19jul18\\_e.htm](https://www.wto.org/english/news_e/news18_e/ds435apl_19jul18_e.htm); and "The Dominican Republic files appeal against WTO panel ruling on tobacco plain packaging requirements" (23 August 2018), [https://www.wto.org/english/news\\_e/news18\\_e/ds441apl\\_23aug18\\_e.htm](https://www.wto.org/english/news_e/news18_e/ds441apl_23aug18_e.htm).



*“have had a more **mixed and limited** impact on the ability of the pack to mislead adult cigarette smokers about the harmful effects of smoking”*;<sup>62</sup>

- 7.14.2 On plain packaging’s actual impact to decrease the ability of tobacco products to mislead adolescents, the Panel concludes that *“the impact of the TPP measures ... on the ability of the pack to mislead adolescents about the harmful effect of smoking is more **mixed and limited**”*;<sup>63</sup> and
- 7.14.3 On plain packaging’s actual impact to **increase the noticeability of GHWs**, the Panel finds *“the impact of the TPP measures ... on adolescents’ health beliefs and cognitive processing of warning information on cigarettes packs is **much more limited**”*.<sup>64</sup>
- 7.14.4 On plain packaging’s actual impact on smokers’ quitting intentions and quitting-related cognition reactions, the Panel finds that *“[t]he impact of the TPP measures and enlarged GHWs on adult cigarette smokers’ quitting intentions and quitting-related cognition reactions is **very limited and mixed**”*;<sup>65</sup>
- 7.14.5 On plain packaging’s actual impact on smokers’ attempts at stubbing out and stopping smoking, the Panel finds that the evidence *“is **much more limited and mixed**”*;<sup>66</sup>
- 7.14.6 On plain packaging’s actual impact on smokers’ quit attempts, the Panel finds that *“the observed impact on quit attempts is **very limited and mixed**”*;<sup>67</sup>
- 7.14.7 On plain packaging’s actual impact on pack concealment among adolescent smokers, the Panel finds that although *“[n]o empirical evidence has been submitted on pack concealment among adolescent smokers”*, the evidence before the Panel suggests that *“the impact of the TPP measures and enlarged GHWs on adolescents’ refraining from smoking cigarettes and thoughts about quitting is **statistically not significant**”*;<sup>68</sup> and
- 7.14.8 On plain packaging’s actual impact on quitting intentions among cigar and cigarillo smokers, the Panel finds that the *“empirical evidence... is **limited**”*.<sup>69</sup>

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<sup>62</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.958(c). Emphasis added.

<sup>63</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.958(d). Emphasis added.

<sup>64</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.958(d). Emphasis added.

<sup>65</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.963(a). Emphasis added.

<sup>66</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.963(b). Emphasis added.

<sup>67</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.963(c). Emphasis added.

<sup>68</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.963(d). Emphasis added.

<sup>69</sup> Panel Report, *Australia – Tobacco Plain Packaging*, para. 7.963(e). Emphasis added.

7.15 In other words, the Panel finds that plain packaging is not working through its expected causal pathway as the measure is not having its intended effects. There is therefore no basis for concluding that the measure is apt to and actually contributes to the ultimate target of reducing the use of tobacco products.

7.16 **Bilateral Investment Treaties**

7.17 Plain packaging could also expose the Government to numerous claims from foreign investors under BITs.

7.18 Invariably, intellectual property is specifically included in the definition of investments protected by such treaties and introducing plain packaging would inevitably breach several of the usual protections afforded by BITs including those prohibiting expropriation of investments (including goodwill and intellectual property) without the payment of compensation, as well as those requiring fair and equitable treatment.

7.19 The "*fair and equitable*" standard requires the Government to act towards foreign investors consistently and to respect their legitimate expectations. Every legal business has a legitimate expectation of its continuity without unlawful or arbitrary impairment or obstruction, and that it would be able to use its registered trademarks and other intellectual property which it has used for decades in accordance with national legislation.

7.20 The Government must also act proportionately and not discriminate unjustifiably. Tobacco is a legal product and the tobacco industry is a legitimate industry. The implementation of plain packaging would frustrate BAT's legitimate expectation that it would be able to continue to use long-established trademarks. Moreover, as discussed above, the evidence from Australia's experience with plain packaging shows that plain packaging does not work.

7.21 Given the commercial value of BAT's trademarks and valuable goodwill, the Government would be exposed to a substantial damages award.

8. **PLAIN PACKAGING IS NEITHER REQUIRED NOR AUTHORISED BY THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL**

8.1 The FCTC neither requires nor authorises plain packaging.

8.2 First, as a matter of international law, the FCTC is a mere "*framework*" agreement which is an important reason why so many countries have been willing to sign up to the FCTC. As an expert commentator, writing for the World Health Organization, has noted "*even sceptical*

*States acquiesced in the adoption of [certain framework] conventions, since the conventions did not commit them to take any specific measures."*<sup>70</sup>

- 8.3 Second, none of the binding provisions of the FCTC itself even mention plain packaging. Furthermore, the WHO Guidelines to Article 11 and 13 of the FCTC which suggest that parties to the FCTC "*should*" (not "*shall*") "*consider*" (not "*adopt*") plain packaging are only "*intended to assist Parties in meeting their obligations*" under the FCTC and do not create legally binding obligations.
- 8.4 Importantly, the FCTC does not authorise Parties to implement measures that breach national law-making criteria or procedures, which would be the case with plain packaging. Article 11 of the FCTC expressly states that the implementation of measures shall be: "*in accordance with [a Party's] national laws*". Article 5(2) of the FCTC, which sets out the general obligations of parties, similarly acknowledges that the implementation of tobacco control measures must be in "*accordance with [Parties'] capabilities*". As explained above, plain packaging would be inconsistent with domestic law and, and would therefore be contrary to the FCTC.
- 8.5 Article 2.1 of the FCTC also confirms Parties' obligations to comply with international laws in respect of the implementation of any measures that exceed a party's obligations under the FCTC. It provides that: "*nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are **in accordance with international law***" (emphasis added). Thus, plain packaging, which goes far beyond the requirements in the FCTC to impose textual warnings covering 30%, must be "*in accordance with international law*." However, as explained above, plain packaging would violate international obligations under the TRIPS Agreement, the Paris Convention, and the TBT Agreement.
- 8.6 Furthermore, the FCTC directs Parties to implement only measures that are supported by evidence and that can be shown to be effective. This is confirmed by the requirement in in the FCTC, that Parties shall implement "*effective*" measures. The Guidelines for Implementation of Article 11 also state: "*Parties should consider the evidence and the experience of others when determining new packaging and labelling measures and aim to implement the most effective measures they can achieve*". If a measure is not effective – and, as explained above, plain packaging cannot be shown to contribute to any public health objective – they should not be implemented.
- 8.7 Finally, the evidential basis underpinning the standardised packaging recommendation in the Guidelines to Articles 11 and 13 cannot be relied on as justifying the measure. Indeed, the

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<sup>70</sup> Professor Daniel Bodansky, (1999) Framework Convention on Tobacco Control, Technical Briefing Series, "The Framework Convention/Protocol Approach", available at [https://www.researchgate.net/publication/289507490\\_Framework\\_ConventionProtocol\\_Approach](https://www.researchgate.net/publication/289507490_Framework_ConventionProtocol_Approach).

Guidelines to Articles 11 and 13 were drafted in 2008, prior to the implementation of standardised packaging in any jurisdiction. Accordingly, they were unable to consider any empirical evidence of the actual effect of the measure on behaviour, which is the only reliable way to test the effectiveness of the measure.

- 8.8 Accordingly, The FCTC does not require nor authorise plain packaging. Rather it requires that Governments examine the evidence to determine whether proposed regulatory measures are effective or whether alternative strategies should be preferred. Such an evidence base must be established by reliable science and empirical evidence that demonstrates the effectiveness of plain packaging in reducing prevalence rates.

## 9. APPLYING PLAIN PACKAGING TO ENDS WOULD BE UNJUSTIFIED

- 9.1 We note the Government's intention to also apply plain packaging to ENDS at a later date. While we will respond further when this proposal is published, we note at this point that such a proposal is against reason and unjustified. In proposing that plain packaging also be applied to ENDS, the Government is failing to assess the impact of the decision on public health overall or to value appropriately the rights of consumers to receive accurate information as to the relative health risks of products.

- 9.2 Applying plain packaging to ENDS – a product category with an estimated lower risk profile compared to cigarettes (as confirmed by public health authorities), and which have been shown to assist smokers to quit smoking is unjustified and discriminatory, and is liable to have an adverse impact on public health. Applying plain packaging to ENDS would convey the misleading message that the risks associated with ENDS are the same as those associated with cigarettes. This denies consumers accurate health information and is liable to deter consumers who smoke tobacco from switching to ENDS, or from using ENDS instead of combustible tobacco.

- 9.3 **The Government fails to recognise the role that potentially reduced risk products ("PRRPs"), including ENDS, can have in tobacco harm reduction**, which is an essential component of a rational and effective tobacco control policy. Regulating PRRPs in the same way as combustible products ignores the concept of tobacco harm reduction which is embedded in the FCTC<sup>71</sup> which the Netherlands is a party to, and is in accordance with

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<sup>71</sup> Specifically, in defining tobacco control, Article 1(d) of the FCTC recognises that "*tobacco control*" concerns not just "*a range of [tobacco] supply, demand*" measures, but also the adoption of "***harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke***" (emphasis added). The WHO has also recognised the role of tobacco harm reduction, stating: "[i]f the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement." WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems ("ENDS") and Electronic Non-Nicotine Delivery Systems ("ENNDS") to the seventh session of the Conference of the Parties*, available at [http://www.who.int/fctc/cop/cop7/FCTC\\_COP\\_7\\_11\\_EN.pdf](http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf) at paragraph 5.

fundamental rights, protected under Article 1 (human dignity), Article 7 (respect for private and family life) and Article 35 (health care) of the Charter of Fundamental Rights of the European Union. In proposing that plain packaging also apply to ENDS, the Government is not considering the impact of the decision on public health overall.

- 9.4 The findings of the 2007 report of the Royal College of Physicians (one of the oldest and most prestigious medical societies in the world) was unequivocal: "[i]n this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that **if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.**"<sup>72</sup>
- 9.5 There is increasing agreement among health experts that exclusive use of PRRPs confers reduced risks of harm as compared to smoking conventional cigarettes. In its 2016 report, "Nicotine without smoke: Tobacco harm reduction" the UK Royal College of Physicians states: "[a]lthough it is not possible to quantify the long-term health risks associated with e-cigarettes precisely, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure."<sup>73</sup> A recent systematic review of the scientific literature undertaken by the National Academies of Sciences, Engineering, and Medicine ("NASEM") for the US Food and Drug Administration,<sup>74</sup> also concluded, inter alia, that: "There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes".
- 9.6 The evidence also suggests that PRRPs have contributed to reduced smoking prevalence in countries with a more flexible regulatory landscape that facilitates consumer awareness of their availability and attributes. Data from the UK, Japan, Norway and Sweden, where there are substantial regulatory freedoms for PRRPs, indicate that these nations have experienced significant reductions in smoking prevalence compared to jurisdictions, such as Australia, which have adopted a comparably more restrictive approach to regulating such products. For example, recent data shows that most vapers in England (51%) have stopped smoking and of the 45% who still smoke, half say that they are vaping in order to stop smoking.<sup>75</sup> What is more, figures show that over 900,000 people have quit both smoking and

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<sup>72</sup> Royal College of Physicians. *Harm reduction in nicotine addiction: helping people who can't quit*. A report by the Tobacco Advisory Group of the Royal College of Physicians. London, United Kingdom; 2007 (emphasis added).

<sup>73</sup> Royal College of Physicians of London. *Nicotine without smoke tobacco harm reduction*. Royal College of Physicians of London; 2016 at p84.

<sup>74</sup> NASEM (2018), *Public Health Consequences of E-Cigarettes*.

<sup>75</sup> Public Health England (2018), *Public Health Matters (Blog) - Turning the tide on tobacco: Smoking in England hits a new low*. Available at: <https://publichealthmatters.blog.gov.uk/2018/07/03/turning-the-tide-on-tobacco-smoking-in-england-hits-a-new-low/>.

vaping in Great Britain.<sup>76</sup> In contrast, in Australia where there is a *de-facto* ban on tobacco-free vapour products there was no statistically significant decline in the three years from 2013-2016 (despite standardised packaging having been introduced for cigarettes in 2012, together with significant and repeated excise increases).<sup>77</sup>

- 9.7 Concerns regarding health risks to bystanders, 'renormalisation' and 'gateway' for PRRPs are not substantiated by the weight of the current evidence. For example, the UK Royal College of Physicians in its 2016 report<sup>78</sup>, states: *"There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking. To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely."*
- 9.8 A systematic review of the evidence conducted by the University of Victoria, Canada (2017) similarly concluded that: *"[t]here is no evidence of any gateway effect whereby youth who experiment with vapour devices are, as a result, more likely to take up tobacco use. The available evidence is that tobacco use by youth has been declining while use of vapour devices has been increasing" and the authors stated that "[p]olicy should not be driven by ungrounded fears of a "gateway effect" but, rather, be geared towards helping tobacco smokers quit and ensuring that only the safest devices are legally available, thereby reducing harm for both direct and second hand exposure."*<sup>79</sup>
- 9.9 Regulating PRRPs in the same way as combustibles risks foreclosing the product category and will undermine the potential public health benefits they offer. It will perpetuate the misconception that these products are the same as combustible tobacco products and will discourage consumers from switching to potentially reduced risk alternatives to traditional tobacco products. The negative impact of excessive regulation of ENDS has been noted by the UK Royal College of Physicians: *"[a] risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm [...] if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or*

<sup>76</sup> <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2017>.

<sup>77</sup> <https://www.aihw.gov.au/getmedia/15db8c15-7062-4cde-bfa4-3c2079f30af3/21028.pdf.aspx?inline=true>.

<sup>78</sup> Royal College of Physicians. Nicotine without smoke: Tobacco harm reduction (2016). p. 190. Available at: [file:///C:/Users/as18058/Downloads/Nicotine%20without%20smoke\\_0.pdf](file:///C:/Users/as18058/Downloads/Nicotine%20without%20smoke_0.pdf).

<sup>79</sup> Ibid.

***inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking.***" <sup>80</sup> (emphasis added)

- 9.10 If the Government is truly serious in its aim to reduce smoking prevalence, rather than stifling the PRRP category (including ENDS), and potentially eliminating new products altogether, it should ensure that consumers are informed about the growing scientific consensus – that ENDS likely pose substantially less risk than conventional tobacco products, and that tobacco heating products potentially do as well, and that cigarette smokers may be able to significantly reduce their risk of harm by switching completely to such products. As such, appropriate measures should be put in place to fully educate consumers about these facts, which could be achieved by allowing manufacturers to raise consumer awareness of these products, and by developing efficient regulatory pathways for bringing high quality PRRPs to market and supporting smokers who want to switch. The Government should do so immediately, rather than perpetuating misconceptions about PRRPs and undermining their potential by regulating them in the same way as combustible tobacco products.

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<sup>80</sup> Royal College of Physicians (2016), Nicotine without smoke – Tobacco Harm Reduction.