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### **Comments on draft proposal “reglugerð um útlit og viðvörunarmerkingar tóbaksvara, losun skaðlegra tóbaksefna, mæliaðferðir og skýrslugjöf”**

This submission by British American Tobacco Denmark A/S (BAT)<sup>1</sup> responds to the “reglugerð um útlit og viðvörunarmerkingar tóbaksvara, losun skaðlegra tóbaksefna, mæliaðferðir og skýrslugjöf” (“**Proposal**”) sent into public consultation on 31<sup>st</sup> of May 2024.

#### **1. Executive Summary**

In this response, BAT: (i) suggests that the Government clarifies that reporting should be made through EU-CEG; (ii) opposes the introduction of plain packaging, which is ineffective, expected to raise the levels of illicit trade, is disproportionate and unlawful; and (iii) urges the Government to accurately transpose the Tobacco Products Directive (“**TPD**”) definitions of 'smokeless tobacco product' and 'smoking tobacco product'.

#### **2. Introduction**

Whilst BAT supports the implementation the TPD, BAT is strongly opposed to plain packaging for smoking tobacco products, which goes beyond the provisions of the TPD.

BAT supports regulation for combustible tobacco products that is based on robust evidence and delivers intended health policy objectives, while preventing the growth of illegal tobacco sales. However, the Government has not carried out a regulatory impact assesment (“**RIA**”) to analyse the costs, benefits or other impacts of introducing plain packaging. In reality, the weight of scientific evidence shows that plain packaging is not effective and further incentivises the illicit market.

Eliminating the illicit trade in tobacco products is one of the WHO's top priorities. This is underscored by the adoption of the WHO Protocol to Eliminate Illicit Trade in Tobacco Products, which is the first and only protocol to the WHO FCTC, and a new international treaty in its own right.

The introduction of plain packaging will have significant consequences for our business in Iceland and will result in a huge negative impact on our trademark and marketing rights. As a key stakeholder, we also have an expert role to play in the development of effective regulation. We also have a legitimate interest, given that we are engaged in a legitimate business enterprise. Accordingly, the principles of procedural fairness mean that this

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<sup>1</sup> British American Tobacco Denmark A/S is a member of the British American Tobacco group of companies and is responsible for the importation, distribution and sale of tobacco in Iceland.

submission should be given serious consideration by the Government before it adopts plain packaging as part of the Proposal.

### **3. Comments on the implementation of TPD provisions on ingredients, reporting and emissions levels**

BAT acknowledges the Government's implementation of the TPD's mandatory provisions on ingredients, reporting and the provisions on the maximum level of harmful substances in cigarettes.

BAT believes that it is of high importance that the information on the ingredients contained in our products are available for assessment by the authorities and other stakeholders (subject to the protection of trade secrets).

We also believe that setting clear standards for the level of harmful emissions from cigarettes secures a level playing field for the legitimate industry.

Therefore, BAT supports the Government's implementation of the provisions mentioned in Chapter II and Chapter III of the Proposal.

However, it is unclear whether the information on ingredients and emissions should be reported through EU-CEG or another common electronic gateway. BAT suggests amending the Proposal to make clear that information on ingredients should be reported through EU-CEG.

### **4. Comments on the Implementation of Plain Packaging for Smoking Tobacco Products**

Article 20 of the Proposal introduces plain packaging for smoking tobacco products. This proposal goes beyond the requirements of, and actually violates, the TPD. BAT believes that this provision should be withdrawn from the final regulation for a number of reasons, set out in this section.

#### **The Government has not carried out an impact assessment**

The failure to undertake and/or publish an RIA means that plain packaging has been proposed without proper evidence or analysis of the costs, benefits or other impacts of the measure and without consideration of alternative policy options. An RIA is the cornerstone of internationally accepted principles of Better Regulation, such as those defined by the OECD, to which Iceland is a member. The need for a proper evidence-based RIA is even more pressing in this case given the Government is regulating products that fall within the remit of the TPD. Article 24(2) TPD (which has been incorporated into the EEA Agreement without any amendment) only permits the introduction of an additional measure "*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. The Government's failure to undertake an evidence-based RIA means that the introduction of plain packaging cannot be shown to be justified as proportionate, necessary or adequate or to comply with the obligations under Article 24(2) TPD. Furthermore, under Article 24(2) TPD, a formal notification is required in relation to the measure and its justification. There is no indication that this has been done.

### **Plain packaging would impermissibly eviscerate the essential role of trademarks**

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. Markets without brands generally become price driven commodity markets, which could also lead to an increase in consumption and illicit trade (as discussed further below).

### **Plain packaging has been proven to be ineffective**

Empirical evidence demonstrates that plain packaging has not reduced smoking prevalence or consumption.

The empirical evidence from Australia, where plain packaging was introduced in December 2012, shows that plain packaging is not an effective policy. This is confirmed in the following expert reports commissioned by BAT:

- A. [Expert report of LUISS Business School and Deloitte Financial Advisory, Italy on the impact of plain packaging on smoking in Australia, dated 8 November 2019.](#)

This report analyses the impact of introduction of plain packaging regulation in Australia in December 2012 on smoking prevalence and tobacco consumption over a 5-year period - using data up to December 2017. The authors conclude that plain packaging has not reduced smoking prevalence or tobacco consumption, and there is some evidence to suggest that plain packaging has had a counterproductive effect, resulting in an increase in cigarette consumption rather than a decrease. **A copy of this report is provided as Annex 1 to this response.**

- B. [Expert Report of Professor Viscusi on the effect of Australian plain packaging on smoking prevalence, dated 2 January 2018.](#)

The analysis looks at data from January 2011 to December 2016, thus providing four years of data in the post-plain packaging period. Professor Viscusi concludes that: "*[t]he only sound conclusion based on this evidence is that the 2012 Packaging Changes are not associated with any change in smoking prevalence rates*". Analyses of Australian Government survey data presented by Professor Viscusi also demonstrates that the implementation of plain packaging in Australia has not increased the effectiveness of graphic health warnings. **A copy of this report is provided as Annex 2 to this response.**

- C. [Expert Report of Mr Neil Dryden on the effect of Australian plain packaging on cigarette consumption, dated 10 October 2017.](#)

Mr Dryden, Executive Vice President at the economic consulting firm Compass Lexecon, has analysed the impact of plain packaging in Australia on cigarette consumption, cigarette prices and downtrading with comparative reference to New Zealand consumption data (where plain packaging had not been implemented during the period of analysis). Mr Dryden's report shows that – as compared to the no-plain packaging scenario – plain packaging is associated with an increase in per capita consumption, a decrease in the average retail prices paid for cigarettes and an increase in downtrading

to lower-priced products. He also presents an alternative empirical analysis of plain packaging's effect on cigarette consumption using Australian-only data, which likewise confirms that plain packaging is associated with an increase in per capita consumption.

**A copy of this report is provided as Annex 3 to this response.**

These findings are also confirmed by a peer reviewed published study by [Underwood et al., \(2020\)](#) which found that the plain packaging policy in Australia did not significantly affect smoking prevalence.

Analysis of empirical data from the UK and France also found that plain packaging had no statistically significant impacts on cigarette consumption. BAT has commissioned an [expert report, prepared by researchers from Casmef and LUISS Business School, LUISS Guido Carli University, Italy, and Deloitte Financial Advisory, Italy on the impact of plain packaging on tobacco consumption in the UK and France](#). The experts analyse cigarette consumption using retail sales data covering the period from January 2011 to December 2020 for the UK and from January 2011 to October 2020 for France. They conclude that their "*analyses show no statistically significant association between Plain Packaging implementation and cigarette consumption in the UK or France after more than three years of full implementation in each jurisdiction (i.e., the estimated effect is not distinguishable from zero) and, in case of the difference-in-differences regression for France, Plain Packaging is associated with a statistically significant increase in cigarette consumption.*" **A copy of this report is provided as Annex 4 to this response.**

In the context of legal proceedings brought by BAT in the Netherlands, an independent court appointed expert report by Professor Dr. Eddy KA Van Doorslaer has also been issued, which reviewed the empirical evidence on plain packaging presented in the expert reports prepared by Professor Viscusi and Mr. Dryden (both discussed above), as well as other key evidence on plain packaging. The Netherlands Government was also given the opportunity to comment on the report. This is the only court-appointed expert examination that has considered the efficacy of plain packaging to-date. Professor Van Doorslaer finds that "[t]he results presented in these two studies [(the expert reports by Professor Viscusi and Mr. Dryden)] use better methods as well as more extensive or different data and therefore [...] represent the best available evidence. Four years of data before and 4 years of data after the intervention seem to be the best basis for comparison to investigate the effect" of Australia's 2012 packaging changes. Professor Van Doorslaer finds that "[s]tandard packaging has not demonstrably led to an accelerated decrease in smoking prevalence in Australia (than in New Zealand), but it has led to increased tobacco consumption as a result of the average price decrease. Dryden shows that the latter is a consequence of the substitution of more expensive brands by cheaper brands." **A copy of this report is provided as Annex 5 to this response.**

### **Rise in counterfeit products and illicit trade**

The introduction of plain packaging will lead to unintended negative consequences for the legitimate industry, making it simple for the illicit industry to produce products that look very similar to legitimate products, whilst at the same time making it difficult for users to distinguish between real and counterfeit products. As mentioned above, plain packaging also leads to commoditization and a shift to pure price driven competition, which 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 perceived value.

Counterfeit products and illicit trade (which is run by organized criminal networks who, per the European Union [Serious and Organized Crime Threat Assessment](#) 2021, are also "*involved in the trade in drugs, organized property crime, excise fraud (including illicit tobacco), human trafficking, online and other frauds or migrant smuggling*") present serious widespread problems adversely affecting society:

1. Product safety standards: Consumers do not have any guarantee that the products are manufactured in accordance with any safety standards.
2. Underage access: Counterfeit products are sold on the black market giving an unlimited access to underage people.
3. Loss of tax revenue: There is no excise paid on counterfeit products which creates an uneven playing-field for the legitimate market and results in a loss of revenue from the tobacco excise for the Government. The [latest report by KPMG on illicit cigarette consumption in the EU, UK, Norway and Switzerland](#), found that illicit consumption (counterfeit and contraband) in the EU increased by 3.9% or 1.3bn cigarettes in 2021, continuing the growth seen in 2020. The report notes that if these cigarettes had been legally purchased in the countries in which they were identified, an additional c. EUR 10.4bn would have been raised in taxes in the EU.

### **Plain packaging is disproportionate**

As demonstrated above, the introduction of plain packaging is not necessary. There is already universal awareness of the risks of smoking and existing laws in place that prohibit minors from purchasing tobacco products, and that prohibit the use of any misleading and deceptive terms on tobacco product packaging. Trademarks and packaging are also not drivers of smoking behaviour. The evidence demonstrates that plain packaging would not be effective in reducing smoking prevalence amongst youth or otherwise and would lead to serious adverse consequences which undermine public health. When compared with the negative impact it will have on BAT and its competitors' trademarks, marketing rights and the ability to commercialize its products, the introduction of plain packaging clearly does not meet the requirement of proportionate regulation.

### **Plain packaging is unlawful**

As well as violating Article 24(2) TPD (discussed above), plain packaging would violate the principle of free movement of goods set out in Article 11 of the EEA Agreement. Any measure inconsistent with Article 11 may be justified "*on the grounds of...the protection of health and life of humans*" (per Article 13 EEA Agreement). As discussed above, it is clear that the Government has failed to conduct any such proportionality analysis, nor has it provided any evidence substantiating the efficacy of the measure. Plain packaging would also deprive BAT of, inter alia, its property rights and the right to use its trademarks, as protected under the European Convention for the Protection of Human Rights and Fundamental Freedoms.

**Conclusion on plain packaging: BAT recommends that Article 20 should be removed from the Proposal**



In light of the above, BAT believes that the proposed measure on plain packaging in Article 20 does not meet the requirements of a proportionate, necessary or accurate regulation and therefore it should be omitted from the Proposal after the consultation period.

#### **4. Definitions of Smokeless Tobacco and Smoking Tobacco**

We note that the Proposal, in implementing the Delegated Directive on heated tobacco products<sup>2</sup> ("HTPs"), has correctly defined an HTP as "*A tobacco product that is heated to produce an emission containing nicotine and other substances which are inhaled by the user and which, depending on its characteristics, is a smokeless tobacco product or a smoking tobacco product* (emphasis added)". It is clear from this definition that an HTP can be either a smokeless tobacco product or a smoking tobacco product, depending on its characteristics. This follows from the definitions of 'smokeless tobacco product' and 'smoking tobacco product' in the TPD, which are as follows: Article 2 (5) "*'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use* (emphasis added)"; and Article 2 (9) "*'tobacco products for smoking' means tobacco products other than a smokeless tobacco product*".

Accordingly, under TPD (as amended by the Delegated Directive), an HTP will be a smokeless tobacco product (and therefore will not be subject to the specific rules for smoking tobacco products) if it does not involve combustion<sup>3</sup>. However, the definitions in Article 2 of the Proposal incorrectly transpose the above TPD definitions. Rather, a 'smokeless tobacco product' is defined as a product "*not intended for smoking but for oral or nasal use*" and a 'smoking tobacco product' is defined as a product "*other than nasal and oral tobacco, e.g. ....heated tobacco*".

Clearly, the definitions of 'smokeless tobacco product' and 'smoking tobacco product' in the Proposal contradict the definition of heated tobacco product in the Proposal taken from the Delegated Directive. The incorrect transposition of these definitions will also lead to regulatory outcomes inconsistent with the TPD. We therefore urge the Government to amend Articles 2(19) and 2(26) of the Proposal so that the definitions of 'smokeless tobacco product' and 'smoking tobacco product' correctly transpose the respective definitions in Articles 2(5) and 2(9) TPD.

Best regards

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<sup>2</sup> Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions for heated tobacco products

<sup>3</sup> HTPs have been recognized as smokeless products by court judgments. For example, the Administrative Court of Braunschweig (Germany) concluded that HTPs are smokeless because they do not involve a combustion process (Administrative Court Braunschweig - 4th Chamber, case No. 4-A-427/20, British American Tobacco (Germany) GmbH v. Federal Republic of Germany, represented by the Federal Office of Consumer Protection and Food Safety, 23 September 2021).