

**PHILIP MORRIS LIMITED**

**Response to the Consultation on “Standardised Packaging”**

7 August 2014

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## I. Introduction

“Standardised packaging” is a euphemism for government-mandated destruction of property. It is unlawful, disproportionate, and at odds with the most basic requirements of the rule of law. Philip Morris International (“PMI”) respectfully encourages the Department of Health (the “DH”) to honor the UK principles of sound policy and reject “standardised packaging” in favor of legally sound alternatives. If necessary, however, PMI is prepared to protect its rights in the courts and to seek fair compensation for the value of its property.

There is no dispute that tobacco is harmful and that the UK government has a clear interest in subjecting it to strict regulation. In fact, the UK has done so extensively for decades. But the mandatory de-branding of tobacco products is no ordinary regulation. The DH is not banning tobacco (thereby preserving the substantial tax revenues that the UK government derives each year from its continued sale); nor is it restricting its usage as such. Instead, “standardised packaging” targets intellectual property, which the proposed measure treats as sinister agents of “Big Tobacco” that must be destroyed. While proponents of this excessive measure may believe that all is fair in their bid to extinguish the tobacco companies’ intellectual property, the law requires the UK government to satisfy a higher standard:

*First*, the DH cannot dismiss the tobacco companies’ trademarks as something short of property that can be obliterated by fiat. Intellectual property is *property* – and is subject to the same legal protections as any other form of property. For that reason, the DH’s proposal must be held to the same legal standards as if it were taking the tobacco companies’ factories or other assets. Thus, even if the DH could establish that the measure were in the public interest, the UK must, as with any deprivation of property, compensate owners for the value of their property. This obligation binds the UK government regardless of whether the value of deprived property is small or substantial. In this case, however, the value is enormous. Since the DH’s proposal does not countenance any compensation for the deprivation, the measure would be unlawful. The subtle drafting of the regulations would not avoid this result. While the draft regulations (the “Draft Regulations”) proposed by the DH in its consultation paper<sup>1</sup> purport to maintain some semblance of trademark usage by allowing tobacco companies to register their trademarks and use them in the wholesale trade, this remaining “usage” does not serve the trademarks’ essential functions.

*Second*, the DH’s proposal does not address whether the proposed measure complies with the EU’s Community Trademark Regulation (the “CTMR”), which gives trademark owners the right to use their Community trademarks by “*identical means*” throughout the entirety of the EU, regardless of frontiers. In fact, the DH’s proposal would simultaneously prohibit tobacco companies from using Community trademarks in the UK and force them to use their brand names in a way that is diametrically opposed to how they are used throughout the rest of the EU. In this and other ways, the proposal would violate the CTMR and contradict the free movement principles the CTMR serves.

*Third*, the DH does not answer another key question: What is the scope of the UK’s legal authority under EU law to enact the proposed measure? As the DH is aware, the tobacco

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<sup>1</sup> DH, Consultation on the introduction of regulations for standardised packaging of tobacco products, 26 June 2014.

companies are currently seeking review by the Court of Justice of the European Union (the “CJEU”) of the validity of the revised Tobacco Products Directive (the “TPD2”)<sup>2</sup>, which purports to harmonize labelling and packaging requirements across the EU while allowing Member States to adopt even stricter requirements without regard for the free movement of goods. As the DH is aware, however, the CJEU previously struck down another tobacco-related directive on the grounds that the EU cannot harmonize Member State laws on the basis of its internal market powers while simultaneously allowing Member States to prohibit the trade in products from other Member States that otherwise comply with the directive’s harmonized rules. As the CJEU held, to do so would rob the directive of any genuine internal market purpose. Given this precedent, it would be unwise for the DH to proceed with the proposal before the CJEU’s determination of this issue.

*Last*, the DH has not undertaken a sufficient analysis of whether the proposed measure would constitute a proportionate or disproportionate interference with the tobacco companies’ fundamental rights and freedoms. At a minimum, the DH must carefully and objectively consider the measure’s potential impact on fundamental rights and freedoms and consider whether the measure is narrowly tailored to achieve its purported objectives while impacting the affected rights and freedoms as little as possible.

The DH has not satisfied these requirements. For example, the DH estimates that the proposed “standardised packaging” measure *might* reduce overall smoking prevalence by 0.69 percentage points by 2025. The basis for this projection in the DH’s Impact Assessment (the “IA 2014”), however, is deeply flawed. As the DH acknowledges, its assumptions are based entirely on a single exercise that sought to elicit the subjective guesswork of a panel of anonymous tobacco control advocates, most of whom declared biases and financial interests with respect to the measure. Moreover, the means by which the DH proposes to achieve the hypothetical – and at 0.69 percentage points, quite modest – reduction are drastic. The measure would: (i) deprive tobacco companies of the value of their trademarks and other protected property rights; (ii) force tobacco companies to communicate their brands in a manner that is intended to rob them of their distinctiveness and other core functions; (iii) prohibit tobacco companies from communicating basic information about their products to consumers; (iv) force tobacco companies to disparage their own products by paradoxically signaling that each and all of the brands are of the lowest possible quality and no different in quality from any other product on the market; (v) force tobacco companies to disparage their own brands by requiring them to be conveyed in the most unattractive manner possible; and (vi) distort competition and intra-EU trade by making it impossible for tobacco companies to compete on the basis of their brands.

Given this dramatic impact on the tobacco companies’ fundamental rights and freedoms, the DH should have – in keeping with the UK’s robust standards for policy making – taken into account the “*best information available*” as to whether the measure will contribute in a demonstrably meaningful way to its purported objectives. However, the DH chose to disregard the real-world data emerging from Australia – the only country in the world to have implemented “standardised packaging” – as relevant to whether “standardised

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<sup>2</sup> Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

packaging” has had any significant impact on smoking prevalence or consumption and whether there have been unintended consequences, especially with respect to illicit trade. By disregarding the Australia data and proceeding instead on the basis of the guesswork at the heart of the IA 2014, the DH has made it impossible to determine whether its proposed measure will accomplish the stated public health objectives in a meaningful way or whether less restrictive means would do so, perhaps even more effectively.

## **II. The DH’s Proposal Violates the Cardinal Rule of Property: No Deprivation Absent Compensation**

### **A. Basic Principles of Law**

The law on deprivation of private property is straightforward: trademarks are legally protected property, and if the UK government wants to deprive an owner of that property, it must, as with any other form of property taken for a public purpose, compensate the owner for its value. These points are explicit in Article 17 of the Charter of Fundamental Rights of the European Union (the “Charter”), which provides:

*“1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. **No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss.** The use of property may be regulated by law in so far as is necessary for the general interest.*

*2. Intellectual property shall be protected.”* (Emphasis added)

The European Court of Human Rights (the “ECtHR”) has also repeatedly emphasized the rules governing property in its jurisprudence under Article 1 of Protocol No 1 (“A1P1”) to the European Convention on Human Rights (the “ECHR”):

*“... under the legal systems of the Contracting States, **the taking of property in the public interest without payment of compensation is treated as justifiable only in exceptional circumstances** ... As far as Article 1 (P1-1) is concerned, the protection of the right of property it affords would be largely illusory and ineffective in the absence of any equivalent principle. **Clearly, compensation terms are material to the assessment whether the contested legislation respects a fair balance between the various interests at stake and, notably, whether it does not impose a disproportionate burden on the applicants** ....”<sup>3</sup>*

The need for just compensation is also a bedrock principle of several centuries of the UK law that remains valid today. Indeed, as Blackstone emphasized in his 1765 Commentaries on property:

*“The third absolute right, inherent in every Englishman, is that of property...”*

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<sup>3</sup> ECtHR, *James and Others v UK*, [1986] EHRR 123, paragraph 54 (emphasis added). The only “deprivation” case to date in which the ECtHR has found that no compensation was necessary is ECtHR, *Jahn and Others v Germany*, [2006] 42 EHRR 49. The case concerned the unique situation of German reunification whereby the owner of the property had not been entitled to ownership in the first place.

He continued:

*“In vain may it be urged, that the good of the individual ought to yield to that of the community. In this, and similar cases the legislature alone can, and indeed frequently does, interpose, and compel the individual to acquiesce.”*

Blackstone clarified, however:

*“But how does it interpose and compel? Not by absolutely stripping the subject of his property in an arbitrary manner; but by giving him a full indemnification and equivalent for the injury thereby sustained . . . All that the legislature does is to oblige the owner to alienate his possessions for a reasonable price; and even this is an exertion of power, which the legislature indulges with caution, and which nothing but the legislature can perform.”<sup>4</sup>*

In sum, the following inarguable principles govern the DH’s consideration of “standardised packaging”:

*First*, trademarks are legally protected property. As such, the DH’s proposal would be held to the same standards as if it were depriving the tobacco companies of their factories or other assets (whether tangible or intangible).

*Second*, if the DH wants to deprive the tobacco companies of their trademarks – even for a valid public purpose – it must compensate them for the value of that property. In other words, the lawfulness of the deprivation would not merely depend on its purported efficacy, which is a necessary but not sufficient requirement for the lawfulness of a deprivation.

*Third*, absent compensation, a deprivation of property is unlawful.

## **B. The DH’s Proposal Would Deprive the Tobacco Companies of Their Intellectual Property**

The DH seems to assert that “standardised packaging” is not a deprivation of property. The DH should not base that assessment, however, on the mere fact that the tobacco companies would continue to retain formal “ownership” of their trademarks. A proper inquiry looks behind the appearances and investigates the reality of the situation complained of to assess “*whether the consequences of the situation are so serious as to amount to a de facto deprivation of property.*”<sup>5</sup> Rhetoric cannot alter reality: the DH’s proposal would destroy the very substance of the tobacco companies’ trademarks, thereby depriving them of their property.

### **1. The Role and Function of Trademarks**

Trademarks are a type of intellectual property that act as a “sign” to distinguish goods and services of one enterprise from those of others. As the UK Trade Marks Act 1994 states: “A trade mark may, in particular, consist of words (including personal names), designs, letters, numerals or the shape of goods or their packaging.” According to the CJEU, these “signs” perform certain essential functions, *i.e.*, they serve to “*guarantee the identity of the*

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<sup>4</sup> William Blackstone, Commentaries, paragraphs 1:134-35, 140-41 (emphasis added).

<sup>5</sup> ECtHR *Fredin v. Sweden*, [1991] 13 EHRR 784, paragraph 43; *see also* ECtHR *Sporrong and Lönnroth v Sweden*, [1982] ECHR 5, paragraph 63.

*origin of the marked goods or service to the consumer or end user by enabling him, without any possibility of confusion, to distinguish the goods or service from others which have another origin.*”<sup>6</sup> Trademarks also act as a “guarantee” as to the quality of the goods, a means of communicating with consumers, an “*instrument of commercial strategy ... to develop customer loyalty*”, and a source of investment that trademark owners can convey, license, or otherwise exploit.<sup>7</sup>

Those functions have enormous value. They allow the owner to develop a unique identity for its product, *i.e.*, a “brand”, which enables the owner to generate goodwill and establish a position for itself in a crowded marketplace. In its 2014 report on the “Top 100 Most Valuable Brands”, for example, BrandZ valued *Marlboro* as the ninth most valuable brand in the world, with an estimated market value of **67 billion USD**, after *Coca-Cola* (sixth), *McDonald’s* (fifth), *Apple* (second) and *Google* (first).<sup>8</sup>

Moreover, some of the most valuable trademarks in the world are purely graphical, *i.e.*, they do not contain any words or brand names. For example, consumers can instantly identify the following trademark as identifying products developed by Apple, Inc.:



The same is often true for well-known tobacco brands. Indeed, even without any reference to the brand name, consumers will identify the following trademarked design as representing PMI’s iconic *Marlboro* brand:



To illustrate the point further, we refer to a “brand board” that graphically depicts all of the major tobacco brands in the UK market by company. Each of the packs depicted in the board looks different (*i.e.*, different colors, designs, images, styles, *etc.*), which means that consumers can identify their chosen brands without any likelihood of confusion.

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<sup>6</sup> See CJEU Case C-39/97 Canon [1998] ECR I-05507, paragraph 28; CJEU Case C-517/99 *Merz & Krell* [2001] ECR I-06959, paragraph 22.

<sup>7</sup> See, *e.g.*, CJEU Case C-323/09 *Interflora v Marks and Spencer* [2011] ECR I-8625, paragraph 39.

<sup>8</sup> BrandZ, Top 100 Most Valuable Global Brands 2014, available at <http://www.millwardbrown.com>.

ITL		JTI		PMI	BAT	
Regal Superkings	B&H Gold Camel	Silk Cut	Marlboro Virginia S.	Dunhill Lucky Strike Rothmans Vogue		
L&B Smoking kills	B&H Silver					
JPS Richmond	Sovereign Mayfair	Marlboro Bright Leaf Marlboro Gold Touch	Vogue Perle Royals			
Windsor Blue JPS Silver	Players Carlton	Sterling Winston Berkeley Sovereign Blue	Chesterfield	Rothmans Value Pall Mall		

Now compare a brand board for the Australian market, which shows cigarette packs without any branding (aside from the small, non-distinctive typeface as mandated by the Australian legislation). Will consumers be able to easily identify their chosen brands without any risk of confusion? If we reference the IA 2014, there is no indication that the DH even considered this question.

BAT															
PMI															
IMPERIAL TOB. LTD.															

## 2. The DH's Proposal Would Deprive PMI's Trademarks of Their "Very Substance"

In *British American Tobacco (Investments) Limited and Imperial Tobacco Limited*, the CJEU specifically noted that the tobacco companies must be provided "*sufficient space ... to affix other material, in particular concerning their trade marks*" on their packs. Otherwise, they would suffer a "*disproportionate and intolerable interference*" with the "*very substance*" of their property.<sup>9</sup> As the CJEU has repeatedly emphasized, the "*very substance*" of a trademark is, among other things, the valuable function it performs in enabling consumers to easily identify a product's source and to distinguish it from competing products without any risk of confusion.<sup>10</sup> As illustrated above, however, the DH's proposal aims to destroy this function by making all competing tobacco products as similar as possible to each other (and in a manner that aims to denigrate the characteristics of all brands). Thus, even though PMI would still "own" its trademarks, the essence of the proposal is to strip the trademarks of the very purpose that EU and UK registration has long protected.<sup>11</sup>

PMI has submitted evidence on this point previously.<sup>12</sup> Two years ago, we shared with the DH the opinion of Lord Hoffmann, a former Law Lord, who is currently Chair of the Intellectual Property Institute's Research Council and Visiting Professor of Intellectual Property Law at Oxford University. Lord Hoffmann concluded that:

*"A prohibition on the use of a mark is ... a complete deprivation of the property in that mark ...."*<sup>13</sup>

He also explained that there is:

*"...no reason why depriving someone of his proprietary interest in a trade mark for a tobacco product (however much it may be in the public interest to do so) should be different in principle from any other deprivation in which compensation is required."*<sup>14</sup>

Similarly, the Australian High Court specifically noted this point when ruling on the legality of Australia's de-branding legislation. Although the Court held that Australia's law did not amount to an "acquisition" of the tobacco companies' intellectual property

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<sup>9</sup> CJEU Case C-491/01, *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraphs 132, 149.

<sup>10</sup> See, e.g., CJEU, Case C-206/01, *Arsenal/Reed* [2002] ECR I-10299, paragraph 48; CJEU, Case 102/77, *Hoffmann-La Roche* [1978] ECR 01139, paragraph 7.

<sup>11</sup> Indeed, the proposed measure would constitute a sweeping ban on the use of all tobacco trademarks without any individualized assessment as to whether consumers are capable of identifying their chosen brands without those trademarks or whether banning them would directly advance the measure's purported objectives. This blanket approach to extinguishing individual property rights violates otherwise applicable general principles that trademarks "*must be assessed in concreto*." See, e.g., CJEU, Case C-421/13 *Apple v DPMA* [2014], paragraphs 22-23 (emphasis added).

<sup>12</sup> See **Annex 1**, Overview of key materials provided to the UK DH for consideration: Requirement to pay compensation for the deprivation of brands.

<sup>13</sup> Opinion of Lord Hoffmann, 24 May 2012, paragraph 19 (emphasis added).

<sup>14</sup> *Ibid.*, paragraph 20.

(which, unlike in the EU, is the relevant standard for determining whether the Australian government is required to pay compensation), it specifically found that there was a deprivation of property.

Indeed, French CJ concluded:

*“rights to exclude others from using property have no substance if all use of the property is prohibited.”*<sup>15</sup>

And in his opinion, Gummow J stated:

*“The rights mentioned in respect of registered trade marks are in substance, if not in form, denuded of their value and thus of their utility by the imposition of the regime under the Packaging Act.”*

As he further explained:

*“the result is that while the trade marks remain on the face of the register, their value and utility for assignment and licensing is substantially impaired.”*<sup>16</sup>

As a majority of the Australian High Court found, the law constituted a *“taking in the sense that the plaintiffs’ enjoyment of their intellectual property rights and related rights is restricted....”*<sup>17</sup>

The UK government should be particularly mindful of the Australia High Court opinions, especially because they align with the standard for assessing a deprivation of property that the courts would apply when evaluating the legality of the proposed measure.<sup>18</sup>

### **3. The DH’s Proposal Cannot Withstand Scrutiny as a Deprivation Simply by Preserving the Illusory “Rights” to Register Trademarks and Use Them with Retailers and in the Wholesale Trade**

The DH’s proposal seeks to obscure its primary intent, *i.e.*, to do away with the tobacco companies’ intellectual property without having to pay for it. To that end, it purports to preserve some semblance of trademark ownership and usage in order to create the illusion that the measure is not a deprivation of property. Again, however, the reality remains: The vestigial “ownership” and “usage” that the proposal purports to maintain miss the point of trademarks.

*First*, the DH’s proposal preserves the right of trademark owners to register their tobacco-related trademarks and to keep them on the registry after five years of non-use. However, this “right” does not justify deprivation without compensation because the proposed ban would gut the trademarks of their essential function. The proposal also upends one of the basic foundations of trademark law, which is that trademarks are only valid if they are being used. This “use it or lose it” rule prohibits enterprises from registering trademarks

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<sup>15</sup> High Court of Australia, *JTI and others v Commonwealth* [2012] HCA 43, 5 October 2012, paragraph 37.

<sup>16</sup> *Ibid.*, paragraphs 138-139.

<sup>17</sup> *Ibid.*, paragraph 44.

<sup>18</sup> See also Opinion of the Committee of Legal Affairs of the European Parliament on the revised Tobacco Products Directive, 25 June 2013, 2012/0366(COD), p. 4, footnote 4, available at <http://www.europarl.europa.eu>.

for purely defensive or “negative” purposes, *i.e.*, to register the trademarks just to prevent others from using them. If enterprises want trademark protection, they have to show that they genuinely intend to use those trademarks. And if they fail to use those trademarks, the trademarks are subject to cancellation. The DH’s proposal distorts this basic principle by turning the registry into a repository of “negative rights” that can only be enforced against third parties who are, in any event, prohibited from using them by virtue of “standardised packaging.” Indeed, the only real purpose that this repository serves is to mask the reality that all meaningful use of the trademarks will in fact be prohibited.<sup>19</sup>

*Second*, the DH’s proposal allows trademark owners to use their trademarks with retailers and in the wholesale trade (“*for example, for stock management in a warehouse*”)<sup>20</sup>, thus suggesting that some remaining use of their trademarks remains possible. Here too, however, this remaining “use” ignores the *raison d’être* of trademarks. As the CJEU has emphasized, trademark rights must be assessed from the perspective of the end consumer, not the intermediary chain of distribution.<sup>21</sup> If trademark owners cannot use their trademarks to perform their essential functions, *e.g.*, to allow consumers to easily identify a product’s source and to distinguish the product from competing products without any risk of confusion, the trademarks do not acquire, build, and preserve value,<sup>22</sup> an outcome that denies trademark owners their legally protected rights – including those that the UK

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<sup>19</sup> The DH’s attempt to deem “standardised packaging” to be a “proper reason” for non-use within section 46(1) of the Trade Marks Act 1994 in Draft Regulation 16, is also incompatible with EU law. As the CJEU has repeatedly emphasized, the notion of “genuine use” and “proper reasons” relating to Community trademarks is an autonomous concept of EU law that cannot be qualified by Member State legislation. *See, e.g.*, CJEU Case C-40/01 *Ansul BV* [2003] ECR I-02439, paragraph 31; CJEU Case C-246/05 *Hauptl* [2007] ECR I-4694, paragraph 45. In CJEU Case C-234/06 P, *Il Ponte Finanziaria SpA v OHIM* [2007] ECR I-07333, paragraph 102, the CJEU held: “*The concept of ‘proper reasons’ mentioned in that article [of the CTMR] refers essentially to circumstances unconnected with the proprietor of a trade mark which prevent him from using the mark, rather than to national legislation which makes an exception to the rule that a trade mark that has not been used for a period of five years must be revoked, even where such lack of use is intentional on the part of the proprietor of the trade mark.*” *See also* AG Sharpston’s opinion in that case at paragraph 88 which makes clear that the question of proof of use is governed solely by the relevant provisions of the CTMR and “... *not by any provision of national law adding a rider to the rule that a national trade mark is liable to revocation if it has not been put to genuine use over a period of five years.*”

<sup>20</sup> Consultation on the introduction of regulations for standardised packaging of tobacco products, 26 June 2014, paragraph 5.8.

<sup>21</sup> *See e.g.*, CJEU Case C-517/99 *Merz & Krell* [2001] ECR I-06956, paragraphs 21-22; CJEU Case C-299/99 *Philips v Remington* [2002] ECR I-5490, paragraph 30 (recognizing that distinctiveness for the purposes of Article 3(1)(b) of the Trade Marks Directive must be judged from the consumer’s perspective because the essential function of a trademark is to “*guarantee the identity of the origin of the marked product to the consumer or end-user*”); CJEU Case C-409/12 *Kornspitz*, [6 March 2014] (finding that consumer perceptions were determinative in deciding whether a trademark had become generic even if retailers were aware of the trademark’s source).

<sup>22</sup> *See, e.g.*, CJEU Case C-40/01 *Ansul BV* [2003] ECR I-02439, paragraph 37 (defining “genuine use” under the Trade Marks Directive as “*use of the mark on the market for the goods or services protected by that mark and not just internal use by the undertaking concerned. The protection the mark confers ... cannot continue to operate if the mark loses its commercial raison d’être, which is to create or preserve an outlet for the goods or services that bear the sign of which it is composed, as distinct from the goods or services of other undertakings*”).

government has long protected through registration and a strong system of intellectual property law.

*Last*, UK law already severely restricts tobacco companies from using their trademarks on non-tobacco related products. This fact raises another important question: what meaningful use of tobacco trademarks would remain if the DH's proposal were enacted? Absent compensation, the hypothetical "*stock management in a warehouse*" to which the proposal refers would be insufficient to save "standardised packaging" from being struck down as an unlawful deprivation of intellectual property.

#### **4. The DH's Proposal Would Not Survive Scrutiny Because It Fails to Provide Compensation for PMI's Property**

In sum, PMI respectfully submits that the DH's proposal would be unlawful because it fails to provide any compensation for the value of the tobacco companies' property. In this regard, the IA 2014 is *per se* deficient because it does not even consider the *possibility* of just compensation. This omission should be particularly troubling from the perspective of the UK Treasury, as the appropriate compensation would be substantial. Indeed, as PMI and others pointed out in their responses to the DH's 2012 Consultation on "standardised packaging" of tobacco products (the "2012 Consultation"), the total compensation could amount to billions of Pounds.<sup>23</sup>

The IA 2014 does not, however, address this aspect of the proposal. Instead, it simply references the lost profits that *UK shareholders* – as distinct from non-UK shareholders who are apparently of no concern – might suffer as a result of down trading to lower-priced products and reduced prevalence (estimated at £44 million). But the IA 2014 fails to consider the most relevant question, *i.e.*, what is the value of the intellectual property that will be lost? Short of that, the DH is simply asking the UK government to roll the dice without being told how much it is wagering or the odds of whether it will have to make good on its bet.

### **III. The DH's Proposal Is Invalid Because It Would Violate the CTMR**

The DH's proposal is also invalid because it would violate the CTMR, which gives trademark owners the right to use their Community trademarks by "*identical means*" throughout the entirety of the EU, regardless of frontiers.

As the CTMR's second recital makes clear, the CTMR is intended to create:

*"... legal conditions ... which enable undertakings to adapt their activities to the scale of the Community, whether in manufacturing and distributing goods or in providing services. For those purposes, trade marks enabling the products and services of undertakings to be distinguished by **identical means** throughout the*

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<sup>23</sup> In 2014, global research and equities firm Exane BNP Paribas estimated "*this value at £9 billion to £11 billion in Britain*" (see, e.g., Tobacco giants may sue over "standardised packaging", "[I]ndustry had a robust case" and could claim compensation in billions, The Irish Times, 21 July 2014, available at <http://www.irishtimes.com>). See also, e.g., Adam Spielman, Submission on the Future of Tobacco Control, 2008, p. 11, available at <http://www.scribd.com>: "*If a court does order compensation, then it could potentially be very large indeed. We outline two valuation approaches that both lead to 'fair' values for the brand designs of about £3-5 billion for the UK industry as a whole.*"

*entire Community, regardless of frontiers, should feature amongst the legal instruments which undertakings have at their disposal.”* (Emphasis added)

This intent is echoed in CTMR’s fourth recital, which states:

*“... trade marks should be created which are governed by a uniform Community law directly applicable in all Member States.”*

In order to achieve those objectives, Article 1(2) of the CTMR states that a Community trademark is to be a single instrument governed only by Community law:

*“A Community trade mark shall have a **unitary character**. It shall have equal effect throughout the Community: it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, **nor shall its use be prohibited**, save in respect of the whole Community. This principle shall apply unless otherwise provided in this Regulation.”* (Emphasis added)

Moreover, as the CJEU has specifically recognized:

*“As regards the objectives pursued by Regulation No 207/2009, if recitals 2, 4 and 6 thereto are read together, it is apparent that the regulation seeks to remove the barrier of territoriality of the rights conferred on proprietors of trade marks by the laws of the Member States by enabling undertakings to adapt their activities to the scale of the Community and carry them out without restriction. **The Community trade mark thus enables its proprietor to distinguish his goods and services by identical means throughout the entire Community, regardless of frontiers.**”<sup>24</sup>*

The DH’s proposal would violate this framework by simultaneously prohibiting tobacco companies from using Community trademarks in the UK and forcing them to use their brand names in a way that is diametrically opposed to how they are used throughout the rest of the EU. The proposal is therefore invalid as breaching the CTMR.

#### **IV. The DH Should Not Proceed Until the CJEU Determines Whether the UK Can Enact the Proposed Measure on the Basis of Article 24(2) of TPD2**

As the DH is aware, PMI and other parties recently commenced judicial review proceedings to challenge the validity of the TPD2.

Among its claims, PMI challenges the validity of Article 24(2) of the TPD2, which purports to allow Member States to introduce measures relating to the “standardisation” of packaging that are stricter than those contained in the TPD2. PMI submits that were it not for Article 24(2), the UK government would have no power to introduce the DH’s proposal. If the CJEU annuls Article 24(2) or annuls the TPD2 in its entirety, the UK government would not be able to introduce the DH’s proposed measure.

The DH has recognized that PMI’s claim to challenge the validity of the TPD2 is arguable and has therefore agreed that it would be appropriate for the Administrative Court to grant permission for the challenge to proceed and also make a reference to the CJEU for a

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<sup>24</sup> CJEU Case C-149/11, *Leno Merken BV v HagelKruis Beheer BV* [2012], paragraph 40 (emphasis added).

preliminary ruling. On 30 July 2014, Supperstone J granted permission for PMI's challenge to proceed.

Indeed, the UK government appears to accept the importance of resolving this point because it has asked PMI to seek expedition of its claim so that the Administrative Court makes the reference to the CJEU as soon as possible. PMI agreed to request expedition of the claim and, on 25 July 2014, Davis J ordered that the claim should be listed in court as soon as possible after 1 October 2014.

Given that the CJEU may well make a ruling that means Member States have no power to enact "standardised packaging", it would be premature for the DH to implement its proposal while TPD2 is *sub judice*.

#### **V. The DH Has Failed to Undertake Any Meaningful Analysis of Whether the Proposed Measure Would Meet the Standards for a Proportionate Interference with Fundamental Rights and Freedoms**

The DH has failed to undertake the necessary and proper analysis of whether the proposed measure would constitute a proportionate interference with the tobacco companies' fundamental rights. These interferences are undeniably sharp in intent and severe in effect. For example, the measure would: (i) essentially prohibit tobacco companies from *any* commercial speech about their products and brands; (ii) compel the tobacco companies to disparage their own products and brands; and (iii) deprive them of their property.

The measure would also constitute a clear barrier to trade within the meaning of Article 34 of the Treaty of the Functioning of the European Union (the "TFEU"), which prohibits "*quantitative restrictions on imports and all measures having equivalent effect*" between Member States. According to Article 34 TFEU, if a product is lawfully produced and marketed in one Member State, it should be admitted for marketing and sale in any other Member State without restriction.<sup>25</sup> The measure, however, would explicitly ban branded products lawfully produced and marketed in other Member States from being sold in the UK and instead require firms to make special non-branded packs solely for the UK market.<sup>26</sup> It would also prevent firms from other Member States from using their brand equity to retain consumers and gain market share. Similarly, the measure is likely to discriminate against new market entrants and smaller players in the market who rely on their brands to gain market share against larger and more established players.

If Member States choose to deviate from the free movement of goods by erecting barriers to intra-Union trade, they must "*demonstrate that their rules ... are necessary in order to achieve the declared objective*"<sup>27</sup> and provide "*appropriate evidence or ... analysis of the*

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<sup>25</sup> CJEU Case 120/78, *Cassis de Dijon* [1979] ECR 649.

<sup>26</sup> As **Annex 2** illustrates, PMI produces its products for sale in the United Kingdom in factories across four Member States. If the DH's proposal were to be implemented, however, branded packs produced in factories in Portugal, Poland, Lithuania, or the Czech Republic could no longer be sold in the UK.

<sup>27</sup> CJEU Case C-434/04, *Ahokainen and Leppik* [2006] ECR I-09171, paragraph 31 (emphasis added).

*appropriateness and proportionality of the restrictive measure ... and precise evidence enabling its arguments to be substantiated.*<sup>28</sup>

The DH would also be required to show that the measure constitutes proportionate interference with the tobacco companies' fundamental rights.<sup>29</sup> In the context of fundamental rights, the CJEU has held that "*derogations and limitations ... must apply only in so far as is strictly necessary.*"<sup>30</sup> To that end, the DH would be required to show compelling evidence that the measure is capable of achieving its public health objectives and that there are no less restrictive means of achieving those objectives. It must also show that the restriction strikes a fair balance between the UK government's interest in introducing the measure and its impact on the fundamental rights and freedoms affected.

As discussed below, the DH fails to satisfy these requirements. Given the seriousness of the rights and freedoms at stake and the severity of their infringement, the DH must show that the proposed measure would result in significant benefits that would demonstrably justify the infringement of protected rights and legitimate expectations. But the DH's evidence base is so limited and deeply flawed that it is not even possible to determine whether the proposed measure is proportionate.

#### **A. The DH Disregards Its Own Practices for Developing Sound Policy**

According to the UK's Legislative and Regulatory Reform Act 2006, Section 21, "*regulatory activities should be carried out in a way which is transparent, accountable, proportionate, consistent and targeted.*"<sup>31</sup> To that end, the UK government's IA Guidance counsels: "*Good policy making should not start with the solution.*"<sup>32</sup> Rather, a "*good RIA will: include the best information available at the time.*"<sup>33</sup> IAs are designed "*to help policy makers to fully think through the reasons for government intervention, to weigh up various*

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<sup>28</sup> European Commission, "Free movement of goods: Guide to the application of Treaty provisions governing the free movement of goods," p. 30; CJEU Case C-254/05, *Commission v Belgium* [2007] ECR I-04269, paragraph 36 (emphasis added).

<sup>29</sup> By acting on the basis of its purported powers under Article 24(2) of TPD2, the UK would be subject to the constraints imposed by the Charter, which apply by virtue of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, OJ (EU) C 306 of 13 December 2007, pp. 1 et seq. According to Article 52(1) of the Charter: "*Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.*"

<sup>30</sup> See, e.g., CJEU Joined Cases C-293/12 and C-594/12, *Digital Rights Ireland*, 8 April 2014, paragraph 52; Joined Cases C-92/09 and C-93/09, *CJEU Schecke and Eifert v State of Hesse* [2010] ECR I-11063, paragraph 86; CJEU, Case C-236/09, *CJEU Vugt & Basselier* [2011] ECR I-00773 (emphasis added).

<sup>31</sup> See **Annex 3** for an overview of applicable Better Regulation principles.

<sup>32</sup> See HM Government, *Impact Assessment Guidance, When to do an Impact Assessment*, August 2011, paragraph 5.

<sup>33</sup> Cabinet Office, *Regulatory Impact Unit, Better Policy Making: A Guide to Regulatory Impact Assessment*, 2003, paragraph 1 (emphasis added).

*options for achieving an objective and to understand the consequences of a proposed intervention.*”<sup>34</sup>

As detailed below, the DH disregarded these principles: it failed to follow the appropriate process to reach sound conclusions; it limited itself to a narrow piece of evidence that was – by virtue of its design – deeply flawed and non-transparent; and it failed to consider available data from Australia on the impact (if any) of “standardised packaging” in that jurisdiction. As a result, the DH has failed to create a sufficient record to objectively determine – let alone show – whether the proposed measure constitutes a proportionate interference with the tobacco companies’ fundamental rights and freedoms.

## **B. The Circuitous Process Leading Up to the Issuance of the DH’s Proposal**

The UK government has considered the possibility of requiring the mandatory de-branding of tobacco products on several occasions over the past several years, indeed as early as 2008. Each time, however, the UK government decided to shelve these proposals and noted that there was insufficient evidence to conclude that the measure would result in any positive public health benefits.<sup>35</sup> Indeed, in its 2012 Impact Assessment (the “IA 2012”), the DH highlighted that a *“key difficulty in evaluating this policy ... is the lack of quantifiable evidence on the likely impact of plain packaging, given that no country has yet introduced this measure.”*<sup>36</sup>

### **1. The Curious Tale of Pechey and the Anonymous Group of Conflicted “Experts”**

The DH announced in the IA 2012 that it would try to fill the critical gap in the evidentiary record by commissioning Pechey et al. to conduct an *“elicitation of subjective judgments”* from panels of tobacco control experts to obtain their *“best guess estimates”* as to the measure’s likely effects.<sup>37</sup> According to the IA 2012, Pechey personally selected a number of individuals, all of whom are described as tobacco control experts, to serve on these panels.<sup>38</sup> By design, these experts have remained anonymous throughout the entire process.<sup>39</sup> The DH did disclose, however, that each of the panel members would be partial and/or have an economic or personal stake in the outcome of the process. According to the DH, *“impartiality and lack of an economic or personal stake in potential findings are*

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<sup>34</sup> HM Government, Impact Assessment Guidance, When to do an Impact Assessment, August 2011, paragraph 4.

<sup>35</sup> See **Annex 4** for an overview of the UK government’s statements on the lack of convincing evidence.

<sup>36</sup> IA 2012, paragraph 122 (emphasis added).

<sup>37</sup> IA 2012, Annex 2; in January 2013, Pechey published the results of this elicitation process in Rachal Pechey, David Spiegelhalter and Theresa M Marteau, Impact of plain packing of tobacco products on smoking in adults and children: an elicitation of international experts’ estimates, BMC Public Health 2013, available at <http://www.biomedcentral.com> (hereinafter “Pechey et al.”).

<sup>38</sup> IA 2012, paragraphs 125, 126.

<sup>39</sup> IA 2012, paragraph 128 (“[p]articipants will be asked not to provide any details that could allow them to be identified, and the time and date of data collection will not be recorded”). See **Annex 5** showing that a private recruiting company was specifically hired to shield against Freedom of Information requests.

*considered impractical in this area.*<sup>40</sup> Of the 33 participants (all of whom completed anonymous and vaguely worded declarations of interest), 23 declared competing interests. Of these 23, some worked as consultants for pharmaceutical companies; others were senior officers in anti-tobacco organizations that lobbied for “standardised packaging”; and others served as expert witnesses in litigation concerning “standardised packaging.”<sup>41</sup> With respect to the participants from the UK, all 14 declared competing interests.

According to the IA 2012, the anonymous panelists were provided with information on “standardised packaging” and then asked to provide their “*best guess estimates*”<sup>42</sup> after “*giving some thought to likely impact*” of “standardised packaging.”<sup>43</sup> By its own admission, the Pechey exercise used unrealistic hypotheses to elicit these subjective guesses: “*A more substantial concern regards the need to impose restrictions on estimates in form of using a hypothetical scenario, i.e. all other factors remaining constant, which does not reflect reality, as noted by many participants.*”<sup>44</sup> Specifically, the participants were asked to disregard the impact that price and the illicit trade might have on smoking prevalence rates.

In connection with the IA 2012, Professor Hora, who in the 1990s had developed an elicit judgment method upon which the Pechey exercise was purportedly based, submitted a pointed critique of the exercise’s design. For example, he commented that he “*strongly disagree[d] with decision to have anonymity*” and questioned: “*Why are impartiality and lack of economic or personal stake considered impractical? Who considers them impractical and why?*”<sup>45</sup> He also criticized the methodology for failing to control for overconfidence, which Professor Hora noted was “*the most severe and prevalent bias.*”<sup>46</sup>

Neither the DH nor Pechey took Professor Hora’s comments into account; nor did they consider the comments made by various other stakeholders in the 2012 Consultation.<sup>47</sup> Indeed, unbeknownst to the public, the Pechey exercise was in fact conducted *prior* to the closing of the 2012 Consultation.<sup>48</sup>

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<sup>40</sup> IA 2012, paragraph 125; *see also* the IA 2014, paragraph 230.

<sup>41</sup> **Annex 6** provides an overview of the composition of the panels and the competing interests the various participants had declared.

<sup>42</sup> IA 2012, paragraph 129; Pechey et al., p. 5.

<sup>43</sup> IA 2012, paragraph 127.

<sup>44</sup> Pechey et al., p. 6 (emphasis added).

<sup>45</sup> Stephen Hora, Comments to DH on expert judgments, 14 June 2012.

<sup>46</sup> *Ibid.*

<sup>47</sup> *See Annex 7*, Comments on DH “Subjective judgment elicitation” methodology.

<sup>48</sup> Pechey et al. was published in January 2013. The first manuscript of the exercise, however, was already made public on 20 August 2012 (*see Annex 8*). The manuscript describes that “[p]rior to interview participants were sent a copy of a new (currently unpublished) systematic review on the impact of plain packaging of tobacco products” (p. 4, footnote 6 with reference to Crawford Moodie, Martine Stead, Linda Bauld, Ann McNeill, Kathryn Angus, Kate Hinds, Irene Kwan, James Thomas, Gerard Hastings and Alison O’Mara-Eves, Plain Tobacco Packaging: A Systematic Review, University of Stirling, 2011). The Stirling Review was published on 17 April 2012. The 2012 Consultation ran from 16 April 2012 to 10 August 2012, *i.e.*, the exercise, including the selection of experts and the interviews, appears to have already taken place

When the Pechey exercise was ultimately made public in January 2013, it reported that the panelists had estimated that “standardised packaging” would – over a two-year period – reduce adult smoking prevalence by one percentage point and the rate of children trying smoking by three percentage points.

According to the record, Pechey sought the opinions of people who have similar views about tobacco control and have various conflicts of interest. As such, it is not surprising that the group’s “best guess” hypothesized that “standardised packaging” would reduce prevalence.

## 2. The DH Waits for Evidence from Australia

In July 2013, the UK government announced that it would “*wait until the emerging impact of the decision in Australia can be measured*” before deciding whether to proceed with “standardised packaging.”<sup>49</sup> That announcement therefore appeared to suggest that the DH was preparing to look beyond the best guess estimates of Pechey and focus instead on actual data from Australia as to whether “standardised packaging” was having a significantly demonstrable effect on tobacco usage.

Indeed, Jane Ellison, the Under Secretary of State for Health, stated as recently as 14 October 2013:

*“The Government have decided to wait before making a final decision on standardised packaging. This allows time to benefit from the experience in Australia, where they introduced standardised packaging in December 2012.”*<sup>50</sup>

This view appeared to echo an earlier suggestion from the authors of the Stirling Review on the need for a proper data-driven assessment:

*“Plain packaging is not yet in place in any country and therefore it has not yet been possible to conduct research that could fully evaluate the potential impact of this policy.”*<sup>51</sup>

In a similar vein, Pechey recommended that:

*“Future research could compare these results **with the actual impact of plain packaging**, to inform understanding of the validity of experts’ estimates by looking at the accuracy of these predictions.”*<sup>52</sup>

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prior to the 2012 Consultation. In any event, given that the first manuscript with results was already made public only 10 days after the DH’s consultation closed, it is clear that the DH knew from the outset that it would not be able to take into account any comments on its subjective judgment elicitation method.

<sup>49</sup> See **Annex 4** for an overview of the UK government’s statements about waiting to evaluate developments in Australia.

<sup>50</sup> House of Commons Hansard Written Answers for 14 October 2013 (pt 0007), available at <http://www.publications.parliament.uk>.

<sup>51</sup> Crawford Moodie, Martine Stead, Linda Bauld, Ann McNeill, Kathryn Angus, Kate Hinds, Irene Kwan, James Thomas, Gerard Hastings and Alison O’Mara-Eves, *Plain Tobacco Packaging: A Systematic Review*, University of Stirling, 2012, p. 88.

<sup>52</sup> Pechey et al., p. 5 (emphasis added).

### **3. The Data Emerging from Australia**

#### **a) Youth smoking prevalence trend analysis**

In March 2014, Professors Kaul and Wolf from the University of Zurich and the University of Saarland made public a study, funded by PMI, which analyzed whether there was evidence for a significant effect of “standardised packaging” on smoking prevalence among minors (Australians aged 14 to 17 years) during the 13 months from introduction of “standardised packaging” in December 2012 through December 2013.<sup>53</sup> In conducting their analysis, the professors relied on data covering the time period from January 2001 to December 2013, based on a total sample size of 41,438 survey responses. The data were collected by Roy Morgan Research, an independent Australian research firm that regularly collects data on a range of consumer products. Public health experts and the Australian government regularly rely on Roy Morgan Research data. The professors’ analysis did not find evidence of an actual “standardised packaging” effect.

PMI submitted this study as part of a review into “standardised packaging” of tobacco products conducted by Cyril Chantler (the “Chantler Review”), and the two experts met personally with the Chantler Review team to discuss their work.<sup>54</sup> Neither the Chantler Review nor the IA 2014 so much as mentions the study.

#### **b) Overall smoking prevalence trend analysis**

A second study by Kaul and Wolf, made public in June 2014, analyzed whether “standardised packaging” had had any significant effect on smoking prevalence among Australians aged 14 and above.<sup>55</sup> The total sample size over the entire period was around 700,000; the average annual sample size around 54,200 surveys.

In both studies, using standard techniques for statistical analysis and applying the standard statistical significance level of 5%, the experts found no evidence that “standardised packaging” had had an effect on smoking prevalence among Australians aged 14 to 17 years old (in the case of the March study) or Australians aged 14 and above (in the case of the June study). Kaul and Wolf confirmed that if there had been an effect in reality (including of the magnitude predicted by Pechey and the DH), it would have been reflected in the data. According to the study, however, no effect was found.

#### **c) South Australia government data**

Recent data from South Australia indicate that, in that State, smoking prevalence has increased since the introduction of “standardised packaging” (reversing the previously declining trend of smoking prevalence between 2003 and 2012). The Health Minister for

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<sup>53</sup> Ashok Kaul and Michael Wolf, The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis, Working paper series / Department of Economics No. 149, March 2014, available at <http://www.econ.uzh.ch>.

<sup>54</sup> Transcribed notes from the Meeting to Discuss the (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: A Trend Analysis, Working Paper, 20 March 2014, available at <http://www.kcl.ac.uk>.

<sup>55</sup> Ashok Kaul and Michael Wolf, The (Possible) Effect of Plain Packaging on Smoking Prevalence in Australia: A Trend Analysis, Working paper series / Department of Economics No. 165, June 2014 available at <http://www.econ.uzh.ch> (**Annex 9**).

South Australia stated in a press release dated 21 May 2014 that “*the State’s smoking rates ... have increased from 16.7 percent to 19.4 per cent over the last 12 months.*”<sup>56</sup> Significantly, the trend in the sub-group of 15-29 year-olds also reversed: between 2012 and 2013, the smoking prevalence of adolescents and young adults has increased by 1.3 percentage points.<sup>57</sup>

#### **d) NDSHS top-line results**

The Australian Institute of Health and Welfare (“AIHW”) recently released certain top-line data from its 2013 National Drug Strategy Household Survey (“NDSHS”), which is conducted every three years in Australia. The full report and data sets will not be published until “late 2014.”

The 2013 NDSHS top-line results report that daily smoking prevalence has dropped in the three years from 2010 to 2013 from 15.1% to 12.8%. Fieldwork for this study was conducted from July to November 2013. The reported overall decline continues the long-term downward trend in smoking prevalence that was observed in previous NDSHS studies. With respect to 12-17 year-olds, however, the NDSHS data show an increase in daily smoking prevalence: in 2010, the smoking rate for adolescents was 2.5%; in 2013 it was 3.4%.<sup>58</sup>

Between 2010 and 2013, there were a multitude of policy interventions, including the largest tobacco tax increase in Australian history, the ban of display of tobacco products at retail, and a number of additional smoking restrictions. Without further statistical analysis, the NDSHS as such cannot identify the effect of any one measure because it spans over a three year period. In this respect, Geoff Neideck, the director of the AIHW is quoted as saying: “*It is quite evident that there are a range of government policies to minimise the harms to do with smoking and alcohol. ... Plain packaging came in between 2010 and 2013, in what was a fairly strong drop in the daily smoking rate, but it would be a stretch to say this data shows that was a key factor.*”<sup>59</sup>

#### **e) Additional Australia data are forthcoming**

The Household, Income and Labour Dynamics in Australia (“HILDA”) Survey is an annual household-based panel study that began in 2001. The key distinction of this data set is that it is longitudinal; it follows the same panel members over time and tracks smoking prevalence along with many other demographic information.<sup>60</sup> The first HILDA survey

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<sup>56</sup> Minister Jack Snelling, News Release, 21 May 2014, available at <http://www.premier.sa.gov.au> (**Annex 10**).

<sup>57</sup> South Australia Health & Medical Research Institute, Key smoking statistics for South Australia - 2013, available at <http://www.sahmri.com>.

<sup>58</sup> Australian Institute of Health and Welfare, National Drug Household Survey 2013, available at <http://www.aihw.gov.au>.

<sup>59</sup> News.com.au, More Australian teenagers are choosing not to drink and smoke according to a major new report, 17 July 2014, available at [news.com.au](http://news.com.au).

<sup>60</sup> The Australian government has described this data set as follows: “*HILDA is a longitudinal study - this means we seek to tell the story of the same group of people over a period of time. The HILDA study uses a longitudinal design to put together a true, detailed story of Australians for decision makers to help plan for our future. It’s the only study of its kind in Australia.*” See <http://livinginaustralia.org/faqs>.

conducted after the implementation of “standardised packaging” in Australia was in the field beginning in July 2013. Based on previous practice, we expect that this wave of HILDA data will be released around December 2014. As mentioned above, later this year, the AIHW plans to release the full report on the NDSHS data.

#### 4. Chantler Summarily Dismisses the Importance of Australia Data

Despite the data emerging from Australia, Chantler summarily dismissed its relevance in his April 2014 report<sup>61</sup> (the “Chantler Report”): “*Australia does not constitute a trial because a number of things have happened together, including tax rises. Disentangling and evaluating these will take years, not months.*”<sup>62</sup> In his view, “*in Australia it will be difficult in due course to separate the effect of plain packaging from other factors such as changes in pack sizes introduced by the manufacturers, and price and tax increases.*”<sup>63</sup>

Chantler did not provide any further explanation for his views, which differed significantly from prior statements made by the UK government and tobacco control advocates as to the relevance of the Australia data. Nor did he provide any support for his view that it would be difficult to disentangle the effects of “standardised packaging” from other variables.

There are, however, well-established econometric techniques that can distinguish among the effects of multiple factors on a single outcome like smoking prevalence.<sup>64</sup> Given two years’ worth of data, a qualified econometrician should be able to test for the impact of “standardised packaging” in Australia, if any. Indeed, the Draft Regulations themselves would require the UK government to carry out a review of the legislation from time to time, an effort that would necessarily include an assessment of the extent to which its objectives are achieved.<sup>65</sup>

#### 5. The DH Relies Again on Pechey

The DH’s IA 2014 avoids any discussion of the Australia data and chooses to rely solely on the subjective guesswork of the Pechey exercise: “*The key variables that define the size of both these benefits and cost are the number of people quitting or not taking up smoking. Fundamentally these key variables are derived from the work of Pechey et al. as described*

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<sup>61</sup> Standardised Packaging of Tobacco – Report of the independent review undertaken by Sir Cyril Chantler, 3 April 2014.

<sup>62</sup> Chantler Report, summary paragraph 10.

<sup>63</sup> Chantler Report, paragraph 1.19.

<sup>64</sup> See, e.g., Nick Wilkins, Ayda Yurekli and The-wei Hu, Economic Analysis of Tobacco Demand, World Bank economics of tobacco control toolkit, Tool 3, p. 11; Magdalena Czubek and Surjinder Johal, Econometric Analysis of Cigarette Consumption in the UK, HMRC Working Paper Number 9, December 2010; Melanie A. Wakefield, Kerri Coomber, Sarah J. Durkin, Michelle Scollo, Megan Bayly, Matthew J. Spittal, Julie A. Simpson and David Hilla, Time Series Analysis of the Impact of Tobacco Control Policies on Smoking Prevalence Among Australian Adults, 2001–2011, Bulletin of the World Health Organisation, March 2014; Jon P. Nelson, *Cigarette Demand, Structural Change and Advertising Bans: International Evidence – 1970-1995*, Contributions to Economic Analysis & Policy, Volume 2, Issue 1, Article 10 (2003); European Commission DG Regio, Evaluating Socio-Economic Development, Sourcebook 2: Methods & Techniques Econometric Models, December 2003; Stephen L. Morgan and Christopher Winship, *Counterfactuals and Causal Inference, Methods and Principles for Social Research*, Cambridge University Press, Chapter 5, 2007.

<sup>65</sup> Draft Regulation 13.

previously and in Annex B.”<sup>66</sup> In doing so, the DH not only ignores all of the prior criticisms that it received in the 2012 Consultation as described above<sup>67</sup>, but compounds them with additional flaws. For instance:

- i. The DH uses Pechey’s overall median best guess estimate for New Zealand, Australia, the U.S., Canada, and the UK, rather than its median best guess estimate as to how much the measure would reduce smoking prevalence in the UK alone, which is significantly lower.<sup>68</sup> Why would the DH not base its assessment for the UK on the UK median? Is it because that would reduce the (speculative) benefits projection by more than 20%, thereby distorting its overall benefits by at least £4 billion? Would a focus on the UK median highlight the fact that 14 out of the 14 UK experts had competing interests?
- ii. Many of the participants in the Pechey exercise acknowledged that “standardised packaging” might lead to material increases in smoking prevalence, both among children and adults. Yet, the IA 2014 does not consider any scenario that factors in those assumptions.

And, despite all the weaknesses in the Pechey exercise, the DH is only able to muster a prediction that the measure **might** reduce overall smoking prevalence by 0.69 percentage points by **2025**.<sup>69</sup> Moreover, a reduction of that degree could easily be obtained with much less severe but certain measures.<sup>70</sup> In any event, there is good reason to question whether the 0.69 reduction can be substantiated.

First, both the UK government as well as UK tobacco control researchers have stated that the impact of “standardised packaging” in Australia on smoking behavior would be a critical factor for evaluating the policy. As discussed above, data from the experience in Australia are now available. More data will become available over the coming months.

While the data from Australia cannot justify imposing “standardised packaging” in the UK, the data are certainly a *necessary* component of a proper assessment. Absent other evidence regarding the actual impact on behavior, the prevalence data from Australia are the “*best information available*”<sup>71</sup> today to test the plausibility of the differing hypotheses regarding “standardised packaging.” Indeed, if the DH really believes that “standardised packaging” will have most of its effect on prevalence within the first two years, why would it not want to avail itself of the empirical data from Australia to check if the data confirm

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<sup>66</sup> IA 2014, paragraph 186 (emphasis added).

<sup>67</sup> See **Annex 7**, Comments on DH “Subjective Judgment Elicitation” Methodology.

<sup>68</sup> See Forest plot in Figure 1 at **Annex 11**.

<sup>69</sup> IA 2014, paragraph 29. According to the IA’s assumptions, the prevalence rate under the “no standardised packaging” option will be 18.96% in 2025, compared to 18.27% “with standardised packaging.”

<sup>70</sup> For instance, we estimate that a hypothetical above-inflation tax increase in the range of 0.6% to 1.6% annually over 10 years would have the same impact on smoking prevalence as the DH’s assumed impact of “standardised packaging.” We also believe that any of the alternative measures on which we have previously provided information to the DH could equally achieve the same or better results than the DH’s estimate. See **Annex 1**, Overview of key materials provided to the UK DH for consideration: Possible key less restrictive measures to “standardised packaging.”

<sup>71</sup> See **Annex 3** for an overview of applicable Better Regulations standards.

that belief? Excluding what may be the best evidence available is not a sound basis for policy making; nor will it allow the UK government to adequately test the proportionality of the measure.

*Second*, as discussed in more detail below, the IA 2014 fails to properly take into account the potential impact of the illicit trade on prevalence rates.

### **C. The IA 2014 Is Incomplete Because It Fails to Assess the Potential Impact of the Illicit Trade on Prevalence Rates**

On several occasions since 2008, the DH has stated that the potential impact of “standardised packaging” on the illicit trade is a major risk factor to consider in deciding whether to mandate “standardised packaging.” As numerous sources attest, the illicit trade undermines public health objectives, including by making tobacco more affordable and accessible to youth and other sub-populations who are sensitive to price. As the DH itself explained, the illicit trade “*creates a completely unregulated distribution network and makes tobacco far more accessible to children and young people.*”<sup>72</sup> The WHO has likewise observed that tobacco smuggling “*poses a serious threat to public health ... because smuggled cigarettes are sold at below market price. Cigarettes are available cheaply, thereby increasing consumption and undermining efforts to keep youngsters from smoking.*”<sup>73</sup> Indeed, in a survey conducted by Action on Smoking Health (“ASH”) and cited by the DH, researchers found that there was a “*strong association*” between age and purchase of illicit tobacco, with one in three smokers aged 16 to 24 indicating they bought cigarettes from illicit sources.<sup>74</sup>

In accordance with the UK government’s Better Regulation principles,<sup>75</sup> the DH should assess the ways in which proposed policy measures can backfire. The DH did not properly consider, however, how the measure’s potential impact on the illicit trade could undermine its purported public health objectives.

In the IA 2014, the DH accepts that “standardised packaging” “*is likely to enhance and diversify current risk that the UK faces from tobacco fraud.*”<sup>76</sup> It also states that “standardised packaging” is “*likely*”<sup>77</sup> to cause an increase in the duty unpaid market, and that there is “*a particularly large risk*” related to an increase in cross border shopping which “*cannot be mitigated.*”<sup>78</sup>

Yet, the DH has not addressed this risk and instead notes that “[t]he potential impact on the UK duty unpaid market remains unknown and unquantified.” Once again, the DH

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<sup>72</sup> Department of Health, Consultation on the future of tobacco control, 31 May 2008, paragraph 2.30.

<sup>73</sup> WHO, Subjects of possible protocols and their relation to the Framework Convention on Tobacco Control (A/FCTC/WG1/3), September 1999, p. 9, available at <http://apps.who.int>.

<sup>74</sup> DH, Consultation on the future of tobacco control, 31 May 2008, paragraph 2.34.

<sup>75</sup> See, e.g., HM Treasury, The Green Book, Appraisal and Evaluation in Central Government, July 2011, paragraph 2.6; Better Regulation Task Force, Principles of Good Regulation, 2003, p. 6.

<sup>76</sup> IA 2014, paragraph 126.

<sup>77</sup> IA 2014, paragraph 135.

<sup>78</sup> IA 2014, paragraph 131.

promises that “*potential changes in the illicit market and cross border shopping ... will be investigated after this consultation stage IA*”, while also claiming that there is “*no means of quantification.*”

In other words, the proposal lacks the substantiation necessary to quantify the “*likely*” risk that the measure will increase the illicit trade in tobacco products. This omission renders the IA 2014 incomplete and deprives it of any sufficient basis to determine whether the proposed measure is proportionate.

### **1. It is Possible to Quantify the Measure’s Impact on the Illicit Trade**

The DH claims that it has no means of quantifying the “*likely*” risk that the proposed measure will increase illicit trade, although it states that it will investigate this risk after this consultation concludes. But it offers no justification as to why it has failed to conduct that investigation already.

A double standard appears to be at work. For quantifying the impact of “*standardised packaging*” on smoking prevalence, the DH relies exclusively on Pechey’s subjective judgment elicitation process. Yet the DH dismisses the suggestion that it could quantify the measure’s likely impact on the illicit trade and the corresponding effect on smoking prevalence rates. Indeed, the DH could have used the SKIM study, a behavioral experiment involving UK smokers that we submitted to the DH in March 2013, which estimated a potential increase of illicit trade by more than 30%. The DH could have also used data from Australia.

Moreover, it could have quantified the effects that an increase in illicit trade would have on smoking prevalence rates. Tobacco control groups have developed models to describe such effects. ASH, for example, has presented a model to illustrate the effects of a *decrease* in illicit trade. The DH could have used the same basic model to study the effects of an *increase* in illicit trade.<sup>79</sup> But the DH did not conduct any such analysis, even though we provided the DH with relevant information and data for its consideration.<sup>80</sup>

### **2. The DH Did Not Evaluate Data from Australia Showing That Illicit Tobacco Trade in Australia Has Increased Since the Introduction of “Standardised Packaging”**

Using a widely accepted methodology, KPMG has concluded that illicit tobacco in Australia has reached record levels, increasing from 11.8% in July 2012 to 13.3% in June 2013 and reversing a trend established during the previous two years.<sup>81</sup> PMI provided the KPMG findings to the DH as part of the Chantler Review in January 2014, but the DH has not taken them into account.<sup>82</sup>

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<sup>79</sup> See **Annex 12**, Illicit Trade Feedback Loop.

<sup>80</sup> See **Annex 1**, Overview of key materials provided to the UK DH for consideration: Impact of plain packaging on illicit trade.

<sup>81</sup> KPMG, Illicit tobacco in Australia, 2013 Half Year Report, October 2013, available at <http://www.pmi.com>.

<sup>82</sup> Since then, KPMG published their 2013 full year results. In the twelve months leading to December 2013, the level of illicit consumption grew to 13.9% of total consumption, 2.1 percentage points higher than in

Chantler summarily dismissed the findings of KPMG based on his view that he did “*not have confidence in KPMG’s assessment of the size or changes in – the illicit market in Australia.*”<sup>83</sup> Many things are wrong with Chantler’s cursory review of the KPMG report, and the DH should not have followed suit:<sup>84</sup>

*First*, KPMG’s method is widely accepted<sup>85</sup> and has recently been validated by UK’s National Audit Office.<sup>86</sup>

*Second*, in clear contrast to Chantler, the DH does believe it is likely that “standardised packaging” will increase illicit trade.<sup>87</sup> The data from Australia are consistent with that belief. But then why not use the data to at least estimate the magnitude of such an increase in the UK?

In sum, the illicit trade is a major risk factor, and the DH has already concluded that “standardised packaging” is likely to increase illicit trade. Yet, the proposed measure does not adequately address the potential magnitude of this likely risk, which makes it impossible to evaluate the benefits and costs of the proposed measure, as UK regulatory standards require.<sup>88</sup>

#### **D. The Record is Insufficient to Justify a Finding that the Proposed Measure is Proportionate**

The DH has not properly assessed whether the proposed measure would constitute a proportionate interference with the tobacco companies’ fundamental rights and freedoms. As detailed above, the evidentiary record is so deeply flawed that it is objectively impossible to determine whether the proposed measure is proportionate. For that reason as well as others discussed earlier, the measure, if pursued, is likely to be struck down as unlawful.

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2012, and 0.6 percentage points higher than in the twelve months ending June 2013 (KPMG, *Illicit tobacco in Australia, 2013 Full Year Report*, 3 April 2014, available at <http://www.pmi.com>) (**Annex 13**).

<sup>83</sup> Chantler Report, paragraph 5.6. The Chantler Report cites to two other data sources as purported proof that the illicit trade in Australia is lower than KPMG’s estimates. However, one source (ACBPS data) is misrepresented and the other was accepted without critical scrutiny (Quit Victoria). Both of these sources provide seizure rates and not actual consumption rates of illicit tobacco. These rates differ significantly from consumption rates as even the most effective law enforcement undertaking seizes only a fraction of actual illicit tobacco.

<sup>84</sup> IA 2014, paragraphs 137-138.

<sup>85</sup> KPMG uses a robust methodology developed in conjunction with the European Commission Anti-Fraud Office (OLAF), and accepted and relied upon by the European Union, all 28 Member States, and the OECD.

<sup>86</sup> In its June 2013 “Progress in tackling tobacco smuggling Report”, the Comptroller and Auditor General of the National Audit Office compared HMRC’s estimates with industry (including KPMG) and academic figures. It concluded that these other sources are “*broadly supporting HMRC’s tax gap analysis*” and that “[i]ndustry figures support the scale and downward trend of HMRC’s market estimates for cigarettes since 2000.”

<sup>87</sup> See IA 2014, paragraphs 20, 83, 118, 120, 126, 132-133, 135, 176.

<sup>88</sup> IA 2014, paragraphs 116 and 135.

## VI. Conclusion

The proposal to require “standardised packaging” would be unlawful if enacted:

*First*, it would be an unlawful deprivation of property. The measure would deprive tobacco companies of the very substance of their valuable trademark rights. Since the DH does not make any provision to compensate the tobacco companies for this deprivation, the measure would be unlawful.

*Second*, the measure would violate the CTMR, which gives trademark owners the right to use their Community trademarks by “*identical means*” throughout the EU, regardless of frontiers. The measure would simultaneously prohibit tobacco companies from using Community trademarks in the UK and instead force them to use their brand names in a way that is diametrically opposed to how they are used throughout the rest of the EU. The proposal is therefore invalid as breaching the CTMR.

*Third*, Article 24(2) of TPD2 does not provide a valid basis to enact the measure. PMI and other tobacco companies are currently challenging the validity of Article 24(2), which purports to allow Member States to adopt stricter rules than those required by the TPD2 without ensuring the free movement of goods from other Member States that otherwise comply with TPD2’s harmonized rules. As the UK government is aware, the CJEU previously struck down another tobacco-related directive on similar grounds.

*Last*, the DH has not followed the UK government’s high standards for ensuring that there is an adequate evidence base to assess the proportionality of its proposed measures. The DH limited itself to a narrow piece of evidence that was – by virtue of its design and execution – flawed and non-transparent. At the same time, the DH has not taken adequate account of available data from Australia on the impact (if any) of “standardised packaging” in that jurisdiction. As a result, the record does not enable an objective determination of whether the proposed measure constitutes a lawful interference with fundamental rights and freedoms.

Each of these defects would constitute a separate and independent basis to invalidate the measure. For that reason, PMI respectfully submits that the UK government should exercise significant caution in deciding how to proceed.