

Cancer Research UK submission to the Consultation on the Norwegian proposal for standardised tobacco packaging and the implementation of Article 5.3 of the Framework Convention on Tobacco Control

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I. Introduction

About Cancer Research UK¹

1. Every year around 300,000 people are diagnosed with cancer in the UK and more than 150,000 people die from cancer. Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research. Together with our partners and supporters, our vision is to bring forward the day when all cancers are cured. As the largest fundraising charity in the UK, we support research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses. In 2012/13, we funded £351 million of medical research in institutes, hospitals and universities across the UK. The charity's pioneering work has been at the heart of the progress that has already seen survival rates in the UK double in the last forty years. We receive no government funding for our research.
2. Cancer Research UK is a registered charity in England and Wales (1089464) and in Scotland (SC041666). Registered as a company limited by guarantee in England & Wales No.4325234. Registered address: Angel Building, 407 St John Street, London EC1V 4AD.

3. Cancer Research UK welcomes comprehensive tobacco control measures worldwide, in line with the principles laid out in the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC).

Background information on Cancer Research UK's work in Tobacco Control

4. Cancer Research UK (CRUK) invests in a range of research from behavioural health research (e.g. the Health Behavioural Research Centre at UCL) to policy relevant translational research. We currently support the UK Centre for Tobacco and Alcohol Studies (UKCTAS) – a consortium of 13 University teams conducting research on tobacco and alcohol use and addiction. UKCTAS is one of five national public health research centres of excellence funded by the UK Clinical Research Collaboration. As member of the Collaboration we have provided approximately £2.4m to the initiative in its first 5-year phase, and we are providing a further £2.5m in the second five-year phase.
5. In addition to this, we have funded policy relevant translational research through our Tobacco Advisory Group (TAG) funding committee. The committee invests almost £1m a year in tobacco control policy research and advocacy. Over the last 5-years TAG has provided more than £1m of funding directly to the UK Centre of Tobacco Control (CTCR) at the University of Stirling. Among the projects funded were the first British pilot study²³ into the impact of standardised packaging in real world settings and a subsequent larger study on the impact of standardised packaging on female smokers, both undertaken by Dr Crawford Moodie at the CTCR⁴.
6. Furthermore, three of the 37 studies evaluated in the Systematic Review of standardised packaging of tobacco⁵, led by researchers at Stirling University, were directly funded by CRUK. A further three of the 17 of those included as part of the update review in September 2013 (now collectively referred to as the 'Stirling Review') were also directly funded by CRUK.
7. In 2014 CRUK secured matched funding from the Bupa Foundation, providing a total fund of £6m to develop and implement the Cancer Prevention Initiative (CPI). The CPI was designed to tackle cancer by funding cutting edge research into behavioural and lifestyle changes which prevent people getting cancer, and the policies which support this change. The creation of an in-house Policy Research Centre for Prevention (PRCP) is driving the translation of this research output into population impact through real-world policy change.
8. CRUK successfully campaigned for the introduction of standardised packaging of tobacco products in the UK, in partnership with the Smokefree Action Coalition (SFAC) – a coalition of more than 300 health and wellbeing organisations, including the British Medical Association and Royal Medical Colleges.
9. CRUK recognises the denormalisation of tobacco as a core pillar of our aspiration to see a tobacco-free UK.

Summary of Our Response

10. As an organisation that has successfully campaigned for the UK to implement standardised packaging of tobacco products, **we fully support Norway's efforts do the same**. We present the evidence given to inform the UK decision to implement this

measure, and provide relevant evidence that has arisen following similar international efforts to successfully implement such regulations.

11. **We echo the Ministry's support for standardised packaging, and we believe that all tobacco products should be subject to standardised packaging regulations.** As is the case in Australia, this should include cigars and pipe tobacco as well as cigarettes and roll-your-own tobacco, as legislated in the UK. We recognise the contribution of the measure towards fulfilling the long term vision of a tobacco free society and in preventing the use of tobacco products by reducing their appeal to young people. **We support standardised packaging as a cornerstone of any comprehensive tobacco control policy.**
12. We welcome the Ministry's assertion that the effects of the measure will primarily occur in the long term, encouraging tobacco denormalisation, as well as directly reducing the exposure of tobacco smoke to children.
13. We welcome the proposed regulations as contributing toward fulfilling Norway's obligations as a party to the FCTC and herein provide our position on the UK's interpretation and application of such obligations.
14. We reiterate the importance of countries taking a lead in the international community on this vital public health measure should not be understated, as Director-General of the WHO, Dr Margaret Chan, has made clear⁶.

II. Evidence to Support Standardised Packaging

The report of the Chantler Review

15. Cancer Research UK supports the conclusions of the 'Independent Review of the evidence for Standardised Packaging of Tobacco Products' (the Independent Chantler Review), which makes an overwhelmingly supportive case for the introduction of standardised packaging based on the public health gains that can be achieved. As referenced in the Ministry's evaluation, chiefly, that:

"...there is sufficient evidence...that the introduction of standardised packaging, as part of a comprehensive policy of tobacco control measures, would be very likely, over time, to contribute to a modest but important reduction in smoking prevalence, especially in children and young adults."

Australia, the UK experience and other evidence

16. The cumulative findings of academic research – coupled with official figures from Australia – leads us to the conclusion that **there can be no doubting the efficacy of standard packs in reducing the appeal of tobacco products to young children.** There is substantial evidence that advertising and promotion draw young people into smoking^{7,8,9} and that packaging is an important part of tobacco promotion¹⁰. To inform the UK's consultation on standardised packaging, the Department of Health commissioned a systematic review¹¹ of all the available evidence for its impact. Leading CRUK researchers were involved in the review. A total of 37 studies were included meeting stringent methodological and relevance criteria. After the review was published, research in Australia^{12,13,14}, the UK^{15,16,17}, Norway¹⁸, Brazil¹⁹, Canada²⁰, the USA²¹, France and Germany²², has supported its findings. A review from the UK Centre for Tobacco Control

and Alcohol Studies in September 2013²³ detailed a total of 54 studies on standard packaging. They consistently demonstrated that standard packs reduce the appeal of smoking.

17. CRUK statistical analysis of Citigroup research ('Australia Data Provides Ammunition for Plain Packaging Elsewhere')²⁴ demonstrated the following:

"There was a very small increase in youth smoking (ages 12-17) of 0.9% but this was not statistically significant and therefore may just be due to random variation between the samples. The proportion of 12-17 year olds that had never smoked remained very high at 95%. We will need to continue monitoring this data as these children grow up and move into the 18-24 year old age group, in order to see whether the introduction of standardised packaging has helped to ensure that they are less likely to start smoking as adults. Encouragingly for those currently aged 18-24 there was a significant increase in the proportion that had never smoked along with a continued decrease in the proportion that smoke every day. The figures also show that there was a significant decrease in daily smoking rates for all ages between 25-59. The trends therefore indicate that the introduction of standardised packs is likely to have helped to ensure that smoking rates in Australia are now at a record low."

18. Following successful Australian implementation, this author wishes to refer the Ministry to the recent evaluations of the Australian plain packaging implementation, as contained in the *Tobacco Control* journal of April 2015²⁵. One such study²⁶ concluded:

"The specific objectives of plain packaging were achieved and generally sustained among adult smokers up to 12 months after implementation."

Another²⁷ stated:

"These findings provide some of the strongest evidence to date that implementation of PP with larger GHWs (is) associated with increased rates of quitting cognitions, microindicators of concern and quit attempts among adult cigarette smokers."

19. Following standardisation in Australia the industry reported a small (0.28 per cent) increase in sales year on year without reporting the increase in the Australian population between 2012 and 2013. Adjusted for population, tobacco sales per person by their measure of consumption would in fact have fallen, from 920.4 per person in 2012 to 906.9 in 2013²⁸. Adjusting official Australian Treasury figures for the population growth in Australia of 1.7 per cent show a 5 per cent drop in cigarettes sold per head of population in the first year that standard packs were introduced²⁹. The Australian Department of Health has released figures showing that total consumption of tobacco and cigarettes in Australia in the first quarter of 2014 was the lowest ever recorded, as measured by estimated expenditure on tobacco products:

- \$5.135 billion in September 1959;
- \$3.508 billion in December 2012 (when standardised packaging was introduced); and

- \$3.405 billion in March 2014.
20. Australian Treasury figures show that tobacco clearances (including excise and customs duty) fell by 3.4 per cent in 2013 relative to 2012 when tobacco plain packaging was introduced. Clearances are an indicator of tobacco volumes in the Australian market³⁰.
 21. In July 2014 figures from the Australian Institute of Health and Welfare³¹ showed that smoking prevalence (daily smoking) in Australia fell from 15.1 per cent to 12.8 per cent (of those aged 14 and over) between 2010 and 2013. This is a 15 per cent reduction in the period. The survey was conducted before the large tax rise in December 2013, meaning that the standardised packaging was the only major tobacco control policy to be introduced during this period. The results also show that less young people are taking up the habit. The proportion of 18-24 year olds who had never smoked increased significantly between 2010 and 2013 (from 72% to 77%)³².
 22. Early research from Australia revealed that smokers using standard packs were 70 per cent more likely to say they found their cigarettes less satisfying. Furthermore, smokers using standard packs were 81 per cent more likely to rate quitting as a higher priority in their lives than smokers using branded packs³³. A study also showed a 78 per cent increase in the number of calls to smoking Quitlines³⁴. A further study showed that, among socioeconomically disadvantaged smokers, standard packs were associated with significantly reduced 'positive smoker characteristics' and reduced purchase intentions³⁵.
 23. An observational study of café strips in Australia, looking at personal pack display, found that 81.4 per cent of tobacco packs were displayed face-up. This highlights how tobacco pack marketing endures outside of the retail environment and continues to be seen in an unregulated environment – indiscriminate of age³⁶. A previous study looking at the impact of standardised packaging found that pack display in cafes, restaurants and bars with outdoor smoking areas fell by 15 per cent after the introduction of standard packs³⁷.
 24. A survey conducted on behalf of the British Heart Foundation³⁸ which was undertaken in the UK and Australia following the Australian implementation of the measure, compared the attitudes of 2,500 under-18s to cigarette packs and the health warnings they carry.

The polling found that:

- Only 36 per cent of UK teenagers were deterred from smoking by cigarette packs, compared to half (48 per cent) of teenagers in Australia, where packs were almost entirely covered by graphic warnings (i.e. standardised packaging).
 - In Australia 59 per cent of under-18s thought the new packs would make people their age less likely to smoke and 66 per cent of Australian teens thought that standard packs should be introduced elsewhere in the world.
 - 10 per cent of teenagers in the UK made the incorrect assumption that certain cigarette brands are healthier than others – twice as many as Australian teens.
25. Another Australian study looking at tobacco product development – alongside the implementation of standardised packaging³⁹ – found unprecedented levels of product

development in the months leading up to the introduction of the measure. The author concludes that governments working toward standardised packaging should be aware of likely industry activity between legislation being proposed, passed, and implemented.

26. In Australia, the Cancer Council Victoria’s “Plain Facts”⁴⁰ website is an excellent repository of information both of the research on the impact of standardised packaging and for critiques of a number of tobacco-industry funded pieces of research and media coverage. This response will not repeat the information hosted on this website in full, but we wanted to highlight the availability of this as a resource.

The standardisation of packaging

27. On the specifics of the packaging CRUK included the following in its response to the UK consultation on regulations:

- It should be made clear that text giving details about how to contact the producer could not be used to promote the ‘quality’ of, or ‘satisfaction’ derived from tobacco products, in line with manufacturer’s descriptors.
- We believe that ‘bevelled or rounded edges’ for tobacco packs should be prohibited because they are a design feature which serve no purpose, other than to enhance the sensory appeal of tobacco products.
- We believe that ‘shoulder hinge’ opening mechanisms should be prohibited. Such opening mechanisms – laterally along the surface of the pack – split health warnings, risking a reduction in their intended effect.
- We believe that the dimensions of the packs should be regulated as to ensure the minimum size for health warnings of height not less than 44mm and width not less than 52mm – as mandated by the Tobacco Products Directive – can be implemented.
- We recommend that the brand name of the cigarette should not be allowed to appear on the cigarette; the principle of standardisation is weakened by allowing brand identity to remain on the cigarettes themselves. The brand name is not required to assist in supply chain controls, and therefore serves no purpose other than a promotional one.

III. The Industry Rebuttal

28. We would expect the tobacco industry to challenge the implementation of these measures in Norway, as in England, and we would advise the Ministry of the evidence surrounding the key opposition arguments:

Illicit trade

29. The tobacco industry continues to claim that the level of illicit trade in Australia has increased since, and as a result of, the introduction of standardised packaging. For example, British American Tobacco told investors in March 2014 that total illicit activity in Australia had risen by more than 30 per cent since the introduction of standardised

packaging⁴¹. The tobacco industry in Australia also claims an increase in tobacco sales from 21.015bn sticks in 2012 to 21.074bn in 2013⁴², which the industry and its front groups in the UK have claimed demonstrates that standardised packaging was not working.

30. The primary purpose of the Chantler Review was to examine the public health impact of the policy, however it also unpicked the major tobacco industry arguments relating to claims of increases in illicit tobacco trade following the introduction of standardised packaging. The UK House of Commons Home Affairs Select Committee, in its report on the illicit tobacco trade published in June 2014, stated:

*“We believe that the decision on standardised packaging should be driven by health reasons and the imperative need to reduce the numbers of young people who start smoking. We note the statement of Sir Cyril Chantler to the effect that he was not convinced that standardised packaging would bring about an increase in the illicit market; even if this were the case, we believe that the proper response would be a more vigorous effort on enforcement rather than any lessening in the Government’s drive towards introducing standardised packaging”.*⁴³

31. A number of studies commissioned by the tobacco industry have claimed that standardised packaging in Australia was not achieving its aims and having negative consequences – particularly with reference to the illicit tobacco trade. Officials in the UK and Australia have repeatedly dismissed such claims, while public campaigning – through a series of tobacco industry adverts – have concurrently been ruled as misleading. The Chantler Review consolidates many of these expert opinions, indicating that tobacco industry commissioned and funded data does not reflect the reality of the situation and their information cannot be relied upon⁴⁴.
32. Indeed, the Australian Government and customs officials have rejected tobacco industry claims that illicit trade in Australia has risen since the introduction of standardised packaging⁴⁵ and have described the methodology of tobacco industry commissioned reports on the illicit trade as “flawed”⁴⁶.
33. A number of studies commissioned and funded by the tobacco industry have been unpicked and discredited by both the public health community and the conclusions of the Independent Chantler Review. Furthermore, claims made in tobacco industry campaign material have been repeatedly denounced as “misleading” by the UK advertising regulator.

Incompatibility with the Tobacco Products Directive (TPD)

34. We would like to draw the Ministry’s attention to a co-funded report between CRUK and Action on Smoking and Health (ASH)⁴⁷, attached as an appendix to this response, which concludes that there are no legal difficulties of standardised packaging in relation to compatibility with the TPD. One of its authors, Professor Alemanno of HEC Paris, said:

“... we believe that any challenge by the tobacco industry against standardised packaging under European law is unlikely to succeed.”

Inefficacy

35. For decades the tobacco industry has undertaken activities that sought to misinform, protect against liability claims and avoid government regulation. UK public health organisations remain concerned by the tobacco industry's ongoing attempts to distort scientific evidence and cast doubt on legitimate research into the effects of tobacco use; such as questioning the definition – and extent – of the addictiveness of tobacco, and challenging the links between second hand smoke and lung cancer^{48,49,50}. The same tactics were employed in order to attempt to create doubt as to the efficacy and unintended consequences of the introduction of standard packs in the UK. In reality, the evidence the tobacco industry's arguments have relied upon lack both relevance and quality^{51,52}. 77 of 143 pieces of the transnational tobacco corporations' cited evidence submitted to the UK consultation on standardised packaging⁵³ were used to promote their claim that standardised packaging "won't work". Of these 77, just 17 addressed standardised packaging: 14 were industry connected and none were published in peer-reviewed journals⁵⁴.
36. Tobacco companies have compounded the misleading effect of their distortion of the evidence base, through mass advertising campaigns focussed on opposing standardised packaging. For example, in July 2012 Japan Tobacco International (JTI, Gallaher in the UK) launched a £2m investment in an advertising initiative to contribute to the debate on standardised packaging in the UK⁵⁵. Following complaints from a number of organisations – including CRUK – the UK Advertising Standards Authority (ASA), in three separate adjudications, ruled that the adverts had breached the Committee on Advertising Practice Code, (CAP edition 12) with respect to the following points: 3.1, misleading advertising (March 2013)⁵⁶; 3.1 & 3.3, misleading advertising and 3.7, substantiation (April 2013)⁵⁷; 3.1, misleading advertising and 3.7, substantiation (August 2013)⁵⁸. In July 2014, a fourth JTI advert was ruled to have been misleading, in respect of parts 3.1 and 3.3 of the CAP edition 12⁵⁹.
37. One of the "misleading" adverts – and a running theme of tobacco industry opposition to the measure, as outlined above – focused on the claim that standardised packaging would result in an increase to the illicit trade in tobacco products. An impact assessment on the effect of standardised packaging written by HM Revenue & Customs (HMRC), reported:

"We have seen no evidence to suggest the introduction of standardised packaging will have a significant impact on the overall size of the illicit market or prompt a step-change in the activity of organised crime groups".⁶⁰

Notably HMRC have in fact highlighted that oversupply by manufacturers continues to play a part in facilitating tobacco smuggling; for example they estimate that the aggregate actual supply of some brands of hand rolling tobacco to some countries exceeded legitimate demand by 240 per cent in 2011⁶¹. In their June 2014 report, on their inquiry into tobacco smuggling, the UK Home Affairs Select Committee concluded:

"It is astonishing that no UK tobacco manufacturer has ever been fined for the oversupplying of products to high-risk overseas markets... the penalties available are too weak and enforcement too rare"⁶².

IV. FCTC Article 5.3

Background

38. Cancer Research UK strongly supports the World Health Organization Framework Convention on Tobacco Control (WHO FCTC)⁶³ – the world’s first international public health treaty. We believe that effective implementation of the FCTC by ratifying nations will decisively change the international landscape of tobacco control and will stem the tobacco epidemic, protecting future generations worldwide.
39. The aim of Article 5.3 of the WHO FCTC is to ensure that tobacco control policies are protected from interference from an industry whose primary goal is to keep people smoking in order to generate profits. The Article states:

“In setting and implementing their public health policies and with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law”⁶⁴

As the Ministry has noted, the guidelines for the implementation of Article 5.3 of the WHO FCTC recognise that:

“There is a fundamental and irreconcilable conflict between the tobacco industry’s interests and public health policy interests.”⁶⁵

The UK interpretation

40. The success the UK has had in implementing comprehensive tobacco control is due, in part, to effectively protecting public health policy from the influence of the tobacco industry – consistent with the guidelines to implementation of FCTC 5.3. This progress has been coupled with awareness raising of the role of the tobacco industry in attempting to block, amend or delay the progress of these regulations.
41. As a mechanism for protecting public health policy from tobacco industry interference, we therefore support the most complete implementation of Article 5.3. An example of gold standard, we refer to the UK’s interpretation of its obligations extending to overseas embassies and posts. In a recent article Professor Ruth Malone, writing in the Tobacco Control Journal, wrote:

*“While some government agencies, mostly health-focused, have instituted policies about contact with industry representatives, no government has fully publicised and implemented policies throughout government to insulate the policymaking process from tobacco company ‘shenanigans’... “In one **example of a government providing clear guidance to overseas embassies and posts regarding Article 5.3**, the UK bars ‘activities with the specific purpose of promoting the sale of tobacco or tobacco related products; encouraging investment in the tobacco industry; attending or otherwise supporting receptions or high profile events, especially those where a tobacco company is the sole or main sponsor and/or which are overtly to promote tobacco products or the tobacco industry; endorsing or recommending any tobacco company; endorsing projects which are funded directly or indirectly by the tobacco industry; etc.’ **This may be the first such guidance not developed primarily via the health sector of a government**, and it is significant in light of stories of*

embassies protecting the interests of the multinationals against domestic policy in host countries, or ignoring the public health implications of industry policy involvements”.

42. Parties to the FCTC are obligated to submit reports on implementation, with the latest reporting period in April 2014. As examples of meeting implementation, the UK submission highlighted the following:

- In May 2009, the then Secretary of State for Health wrote to the Prime Minister and Cabinet colleagues bringing their attention to article 5.3 of the WHO FCTC, attaching the relevant guidelines.
- ‘Healthy Lives, Healthy People: A tobacco control plan for England’ (2011) includes a chapter entitled ‘Protecting tobacco control from vested interests’. The plan states that to ensure further transparency, the Government is committed to publishing the details of all policy-related meetings between the tobacco industry and Government departments. (This excludes meetings to discuss operational matters to reduce the illicit trade in tobacco and bilateral meetings between tobacco manufacturers and HM Revenue and Customs).
- In the future, organizations engaging with the Department of Health on tobacco control, for example by responding to consultation exercises, will be asked to disclose any links with, or funding received from, the tobacco industry. Local authorities are encouraged to follow the Government’s lead in this area, and to take necessary action to protect their tobacco control strategies from vested interests.

43. The Local Government Declaration on Tobacco Control recognises the role of government, at all levels, in meeting FCTC 5.3 obligations. The declaration has been signed by more than 70 councils in England since its launch in May 2013. And endorsed by leading figures including the Public Health Minister, the Chief Medical Officer and Public Health England.

E-cigarettes

44. The growth of tobacco industry investments in e-cigarettes also has the potential to create problems regarding compliance with 5.3 obligations. We are concerned that tobacco industry-owned e-cigarette companies may be used as a ‘Trojan Horse’ to re-enter debates on public health and threaten the principles of the Framework Convention on Tobacco Control to protect public health policy from the pernicious influence of the tobacco industry.

V. Declaration of Interests

45. Cancer Research UK, consistent with its Vision and Mission, opposes the promotion and use of tobacco in all its forms, and wishes to do everything it can, as far as reasonably practicable, to avoid links with the tobacco industry. We have strict guideline which detail that all staff, including employees, contractors, agency staff, volunteers, secondees, students and consultants should not work with the tobacco industry, either directly, or through a third partner. Cancer Research UK will not accept applications from research teams in receipt of tobacco industry funding.

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LEGAL OPINION ON THE COMPATIBILITY OF THE UK PROPOSALS TO INTRODUCE STANDARDISED PACKAGING ON TOBACCO PRODUCTS WITH THE EU TOBACCO PRODUCTS DIRECTIVE

Alberto Alemanno and Amandine Garde

Action on Smoking and Health (ASH) and Cancer Research UK have asked us to provide a Legal Opinion on the compatibility of the UK draft **Standardised Packaging of Tobacco Products Regulations**ⁱ with the revised EU Tobacco Products Directive (TPD) and, more in general, EU Law. Our Opinion contains three main sections:

- the first section sets out the scene and places the UK debate on standardised packaging within the Tobacco Control Plan for England and introduces the UK proposals;
- the second section focuses on the legislative history and the provisions of the EU Tobacco Products Directive on standardised packaging; and
- the third section contains the core of our legal analysis in that it focuses on the conditions that the UK should comply with if it wishes to introduce standardised packaging in its territory in a manner compatible both with the TPD and the EU Treaties.

I. Setting the scene: the UK proposal to introduce standardised packaging of tobacco products

1. The epidemiology of smoking

The tobacco epidemic is one of the biggest public health threats the world has ever faced, killing nearly six million people a year. More than five million of those deaths are the result of direct tobacco use, while more than 600,000 are the result of non-smokers being exposed to second-hand smoke. Approximately one person dies every six seconds due to tobacco, accounting for one in 10 adult deaths. Up to half of current users will eventually die of a tobacco-related disease, including cancer, lung diseases, and cardiovascular diseases. Tobacco users who die prematurely deprive their families of income, raise the cost of health care and hinder economic development.⁽¹⁾

ⁱThis memo considers in particular the draft regulations at Appendix B in the [consultation on standardised packaging of tobacco products: draft regulations](#), which set out the proposed requirements for standardised packaging, should it be introduced.

Even though nearly 80% of the more than one billion smokers worldwide live in low- and middle-income countries, where the burden of tobacco-related illness and death is heaviest, tobacco use remains one of the main sources of death and non-communicable diseases in Europe: the European Union (EU) estimates that *'smoking causes 700,000 deaths a year, more than the combined number caused by car and work accidents, AIDS, suicides, homicides and drugs'*.⁽²⁾ Despite considerable progress made in recent years, the number of smokers in the EU is still high – 28% of the overall population and 29% of young Europeans aged 15-24 smoke. 94% of smokers take up smoking before they are 25 years of age, and around 50% die prematurely (some 14 years earlier) and have more life years in poor health.⁽²⁾

There are still more than 8 million smokers in England, where *'smoking causes more preventable deaths than anything else – nearly 80,000 in England during 2011. There's also an impact on smokers' families: each year, UK hospitals see around 9,500 admissions of children with illnesses caused by secondhand smoke'*.⁽³⁾

2. The importance of prevention

The addictive nature of tobacco use and the specific problems which it raises reinforce the importance of prevention, and in particular the need to create enabling environments on the basis of comprehensive, co-ordinated, multi-sectoral and multi-level strategies, as required by the Framework Convention on Tobacco Control (FCTC)⁽⁴⁾ and the World Health Organization (WHO) Action Plan for the Prevention and Control of Non-Communicable Diseases 2013-2020.⁽⁵⁾

The FCTC is the first global public health Treaty adopted under the auspices of WHO. The Convention entered into force on 27 February 2005. As of September 2014, 179 states are parties to the FCTC. Both the EU and its 28 Member States have signed and ratified the Treaty and are therefore legally bound by its provisions. The FCTC is based on evidence and addresses both the demand and the supply sides of tobacco consumption.ⁱⁱ

3. The 2011 Tobacco Control Plan for England

The UK Government has undertaken to try and reduce smoking rates by the end of 2015 to:

- 18.5% or less for adults (compared to 21.2% for April 2009 to March 2010) - meaning around 210,000 fewer smokers per year;
- 12% or less for 15 year olds (compared to 15% in 2009); and

ⁱⁱ See [Articles 6 to 14 and Articles 15 to 17 respectively of the WHO FCTC](#), supplemented by the Protocol to Eliminate Illicit Trade in Tobacco Products, signed in November 2012, and a series of Guidelines (seven to date).

- 11% or less for pregnant women, measured at the time of giving birth (compared to 14% over 2009 to 2010).⁽³⁾

To this effect, it published *'Healthy Lives, Healthy People: A Tobacco Control plan for England'* in March 2011, which includes commitments to:

- implement legislation to end tobacco displays in shops
- look at whether the plain packaging of tobacco products could be an effective way to reduce the number of young people who take up smoking and to support adult smokers who want to quit, and consult on options by the end of the year
- continue to defend tobacco legislation against legal challenges by the tobacco industry, including legislation to stop tobacco sales from vending machines from October 2011
- continue to follow a policy of using taxation to maintain the high price of tobacco products at levels that impact on smoking prevalence
- promote effective local enforcement of tobacco legislation, particularly on the age of sale of tobacco
- encourage more smokers to quit by using the most effective forms of support, through local stop smoking services
- publish a three-year marketing strategy for tobacco control.⁽⁶⁾

This multi-sectoral strategy is intended to tackle the different determinants of smoking. As such, it is very much in line with the FCTC. It also has a particular focus on young people:

'While nicotine keeps tobacco users physically dependent, there are a wide range of social and behavioural factors that encourage young people to take up smoking and that make it harder for tobacco users to quit. The Government's approach to improving public health includes tackling the wider social determinants of health and it aims to build people's self-esteem, confidence and resilience, right from infancy. To promote health and wellbeing, we will work to encourage communities across England to reshape social norms, so that tobacco becomes less desirable, less acceptable and less accessible. We want all communities to see a tobacco-free world as the norm and we aim to stop the perpetuation of smoking from one generation to the next. To reduce smoking uptake by young people, we all need to influence the adult world in which they grow up. We must also remove the considerable social barriers that smokers face when they are trying to quit.'⁽⁷⁾

4. Standardised packaging in the UK Tobacco Control Plan

The rest of this report focuses on one of the components of the UK's tobacco control strategy: the introduction of standardised packaging of tobacco products.

Timeline

In its 2011 Tobacco Control Plan, the Department of Health undertook to consult on ‘*options to reduce the promotional impact of tobacco packaging, including plain packaging, before the end of 2011*’.⁽⁸⁾ In particular, it stated that it would look at whether the plain packaging of tobacco products could be effective in reducing the number of young people who take up smoking and in supporting adult smokers who want to quit: ‘*the Government wants to make it easier for people to make healthy choices but wants to understand whether there is evidence to demonstrate that plain packaging would have an additional public health benefit. We will explore the competition, trade and legal implications, and the likely impact on the illicit tobacco market of options around tobacco packaging.*’⁽⁹⁾

The Government ran a consultation on standardising the packaging of tobacco products between April and August 2012, for views on whether standardised packaging could reduce the appeal of tobacco, make health warnings more effective, make packaging less misleading about health effects and change how children and young people think about smoking.⁽¹⁰⁾

At the time, the Government explicitly stated that it was ‘*keeping an open mind on this issue*’, and had not ‘*made any proposals yet*’.⁽¹⁰⁾ A report summarising the responses to the consultation was published in July 2013,⁽¹¹⁾ accompanied by an Impact Assessment Report⁽¹²⁾ and an Equality Impact Assessment Report.⁽¹³⁾ The Government also commissioned an independent academic review of the evidence supporting plain packaging.⁽¹⁴⁾

In total, the Government received 2,444 detailed responses (alongside 665,989 campaign responses). As could have been expected, strongly differing views were expressed in this consultation: 53% of the respondents who provided detailed feedback argued in favour of introducing standardised packaging – including some 190 health organisations, as opposed to 43% against. ‘*Having carefully considered these differing views*’, the Secretary of State for Health, Jeremy Hunt, decided to ‘*wait until the emerging impact of the decision can be measured before we make a final decision on this policy in England. [...] Standardised packaging therefore remains a policy under consideration.*’⁽¹⁵⁾

On 28 November 2013, the Public Health Minister, Jane Ellison, made a statement to the House of Commons in which she declared that it was time to ‘*examine the emerging evidence base*’ and that standardised tobacco packaging would be brought in after the review of existing evidence if ‘*we are satisfied that there are sufficient grounds to proceed*’, including public health benefit.⁽¹⁶⁾ The review was entrusted to paediatrician Sir Cyril Chantler who was asked to look at whether there was likely to be an effect on public health, particularly for children, if standardised tobacco packaging were to be introduced.⁽¹⁷⁾ It is important to note that the focus of the Chantler Review is placed exclusively on the evidence and not on the legal issues surrounding the introduction of standardised packaging.⁽¹⁸⁾

Sir Cyril Chantler sought to conduct his review on the principles of transparency and independence, and relied on an independent secretariat. He delivered his report on 3 April

2014.⁽¹⁹⁾ Although Sir Cyril Chantler did not reopen the public consultation on standardised packaging that the UK government previously organised, he decided to publish a call for the collection of all evidence available. Thus, Public Health England published its submission to the Chantler Review on 13 January 2014, expressing its strong support for the introduction of standardised packaging in the UK: *'standardised packaging will be fundamentally important in helping to reduce the incidence and prevalence of smoking, and there is significant evidence to support its introduction'*.⁽²⁰⁾ Sir Cyril Chantler also drew evidence from a range of sources he considered necessary and appropriate, including a visit to Australia in March 2014 to study the implementation of plain packaging there.

By building on the pre-existing Stirling review⁽¹⁹⁾ – *'the most extensive and authoritative piece of work on the issue of standardised packaging yet undertaken'*, his review provides an independent view which will help the Government make a decision on whether to go ahead with standardised tobacco packaging.⁽²¹⁾

While the report does not provide a detailed definition of *'standardised packaging'*ⁱⁱⁱ, its analysis largely refers to and builds upon the scheme in Australia, which became the first country to legislate for standardised packaging in 2011.^{iv}

The Government also tabled an amendment to the Children and Families Bill, which was then being considered in the House of Lords. The amendment provides powers to bring forward regulations to introduce standardised packaging if the Government decides to do so following Sir Cyril's review and consideration of the wider issues raised by this policy.⁽²²⁾ In particular, the amendment provides that regulations could be adopted if they may contribute to any of the following:

- a. discouraging people from starting to use tobacco products;
- b. encouraging people to give up using tobacco products;

ⁱⁱⁱ The 2012 consultation proposed the following approach to standardised packaging: (i) All internal and external packaging to be in a prescribed colour/s (ii) All text on the pack, including brand names, to be in a standard colour and typeface (iii) No branding, advertising or promotion to be permitted on the outside or inside of packs, attached to the package or on individual tobacco products themselves. For this purpose 'branding' includes logos, colours or other features associated with a tobacco brand (iv) Any foils within a pack to be of a standard format and colour with no text permitted (v) Packs to be of a standard shape and opening and possibly manufactured with particular materials (vi) Only the following information or markings are to be permitted on packs: a brand name ; a product name ; the quantity of product in the packaging : the name and contact details of the manufacturer ; one barcode to facilitate sale and stock control ; health warnings, as currently required ; tar, nicotine and carbon monoxide yield information, as currently required ; product identification marking, as currently required ; fiscal mark requirements, as currently required ; markings not visible to the naked eye to assist with the identification of genuine, duty-paid products, or other features to prevent fraud (vii) Any wrapper around the pack to be transparent and colourless, without any other markings visible to the naked eye.

^{iv} On 1st December 2012, Australia became the first country to require plain packaging of all tobacco products. Generic drab brown colour and identical plain text fonts noting only the brand and product type have replaced the use of all brand logos and colours. Additionally, the size of required graphic pictorial health warning labels have been increased: they must now cover 75% of the front and 90% of the back of the package with additional text warnings on the package sides; they must also include the national quit line number. Misleading and deceptive product descriptors such as 'light' and 'mild' are also prohibited: see the Tobacco Plain Packaging Act 2011 (Cth), section 19 (Australia) and the Tobacco Plain Packaging Regulations 2011 (Cth), regulation 2.2.1 (Australia). On the Australian experience with plain packaging, see, e.g. J. Liberman. Plainly Constitutional: The Upholding of Plain Tobacco Packaging by the High Court of Australia. *Journal of Law and Medicine* 39 (2013) 361, and M. Rimmer. The High Court of Australia and the Marlboro Man: The Battle over the Plain Packaging of Tobacco Products. In T. Voon, A. Mitchell, and J. Liberman, *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues* (2014). Chapter 17. Routledge

- c. helping people who have given up, or are trying to give up, using tobacco products not to start using them again;
- d. reducing the appeal or attractiveness of tobacco products;
- e. reducing the potential for elements of the packaging of tobacco products other than health warnings to detract from the effectiveness of those warnings;
- f. reducing opportunities for the packaging of tobacco products to mislead consumers about the effects of using them;
- g. reducing opportunities for the packaging of tobacco products to create false perceptions about the nature of such products;
- h. having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products.⁽²²⁾

Following the adoption of this amendment on 13 March 2014, provisions in section 94 of the Children and Families Act 2014 enable the Secretary of State to regulate the retail packaging of tobacco products, if he or she considers that the regulations as a whole may contribute to reducing the risk of harm to, or promoting the health or welfare of, children. In making the decision he or she may also take into account whether the regulations would reduce the risk of harm to adults. Ministers may also specify requirements for the products themselves, for example: the appearance of individual cigarettes.

The Chantler Review was published on 3rd April 2014. Sir Cyril concluded that: “...*there is enough evidence to say that standardised packaging is very likely to contribute to a modest but important reduction in smoking... Given the dangers of smoking, the suffering that it causes, the highly addictive nature of nicotine, the fact that most smokers become addicted when they are children or young adults and the overall cost to society, the importance of such a reduction should not be underestimated.*”⁽²³⁾ The Public Health Minister, Jane Ellison MP, said in a written statement that the report found standardised packaging “very likely to have a positive impact” on public health. She went on to say: “In the light of the report and the responses to the previous consultation in 2012, I am minded to proceed with introducing regulations to provide for standardised packaging” and that she wished to “proceed as swiftly as possible”. She also reported that the Government’s Chief Medical Officer, Professor Dame Sally Davies, had written to her supporting the conclusion of the Chantler review and supporting the introduction of standardised packaging.⁽²⁴⁾

Before reaching a decision on whether to introduce standardised packaging of tobacco products, the UK Government published on 26 June 2014 a *Consultation on the introduction of regulations for standardised packaging of tobacco products*. The purpose of this consultation was to seek the views of interested people, businesses and organisations, with a focus on gaining any additional information relevant to standardised packaging that had arisen since the 2012 consultation.⁽²⁵⁾

The consultation included draft regulations illustrating how requirements for standardised packaging would work in practice. The draft regulations set out inter alia proposed requirements for the packaging of cigarettes and hand-rolling tobacco, and requirements for

the appearance of individual cigarettes should standardised packaging be introduced.^v Alongside the consultation, an updated consultation-stage Impact Assessment and Equalities Analysis were also published that have been - insofar as is relevant - considered in our Legal Opinion.

The Standardised Packaging of Tobacco Products Regulations

The UK draft regulations laid down a set of requirements for the packaging of cigarettes and hand-rolling tobacco, as well requirements for the appearance of individual cigarettes should standardised packaging be introduced. They find their legal basis in sections 94 and 135(2) and (3) of the Children and Families Act 2014 and section 2(2) of the European Communities Act 1972.

The requirements introduced by the draft regulations apply measures relating to the presentation and appearance of products and their packaging set out in Articles 13 and 14 of the EU Tobacco Products Directive. These include, for example, those relating to the shape and material used in cigarette and handrolled tobacco packs, the type of lid used for cigarette packs, the minimum quantity (cigarettes) or weight (handrolled tobacco); and prohibition of elements or features which are misleading.

The draft regulations also require the use of specified standard colours for all external and internal packaging and only permit specified text in a standard typeface. In so doing, these provisions introduce a form of standardised packaging analogous to that enacted in Australia, well beyond what the EU TPD prescribes. The consultation closed on 7 August 2014 and the UK government notified the draft regulations to the Commission on 29 August 2014. The main content of the regulations as notified to the EU are as follows⁽²⁶⁾:

Pack Colour (regulations 3 and 7)

- *The outside surfaces of packs (external packaging) would be drab brown with a matt finish.*
- *The inside surfaces of packs (internal packaging) would be white or drab brown with a matt finish.*

Permitted text and features (Schedules 1, 3)

- *Text on packaging would be in a grey Helvetica typeface with a specified maximum size.*
- *Brand and variant names may appear once on each of the front, top and bottom surfaces of cigarette packs, once on each of the front and back surfaces and on the surface hidden beneath the flap of hand-rolling tobacco pouches.*
- *A bar code may appear once on a pack or pouch to facilitate sale and stock control.*

^v While the Government has yet to make any final decisions on whether to introduce standardised packaging, the draft regulations are included at appendix B of the Consultation document

- *A producer's contact details may appear once on a pack or pouch.*
- *The pack or pouch may include a measurement mark and a trade description (for example: "20 cigarettes" or "30g hand-rolling tobacco").*
- *If a pack of hand-rolling tobacco includes filters or cigarette papers inside the pack, then the pack may have text giving this information (for example: "includes cigarette papers and filters" or "includes cigarette papers").*

Cigarette packets (Regulation 4)

- *Cigarette packets must be cuboid and made of either a carton or soft material. If packets can be re-closed or re-sealed, then they must either have a flip-tip lid or be a shoulder box with a hinged lid.*
- *A pack of cigarettes must contain a minimum of 20 cigarettes.*

Packets of Hand-rolling tobacco (Regulation 8)

- *Hand-rolling tobacco packets must be cuboid, cylindrical or in the form of a pouch.*
- *A pack of hand-rolling tobacco must contain at least 30 grams of tobacco.*

Other provisions (Schedules 3 and 4 and Regulations 11 and 12)

- *Pack surfaces must be smooth, with no embossing or irregularities of texture.*
- *Wrappers must be completely clear and transparent.*
- *Inserts or other additional material not integral to the packaging would be prohibited.*

Individual cigarettes (Regulation 5)

- *Cigarettes would be white with a cork effect or white tip and may have text indicating the brand name (in a specified typeface, size and location).*

The draft regulations would also implement Articles 13 and 14 of the Tobacco Products Directive (Directive 2014/40/EU) (see Regulations 4, 8 and 10 of the draft regulations).

The rationale for and the evidence supporting the imposition of standardised packaging

Standardised packaging aims to reduce the attractiveness and appeal of tobacco products, increase the noticeability and effectiveness of mandated health warnings, reduce the ability of retail packaging to mislead consumers about the harms of smoking, and help change smoking-related attitudes, beliefs, intentions and behaviour. The more standardised the packaging of tobacco products, the less visually appealing the products are.

Plain packaging as a form of standardised packaging

As a preliminary remark, it is important to note that packaging standardisation is a matter of degree, and that standardised packaging does not necessarily equate with 'plain packaging'.⁽²⁷⁾ This understanding is confirmed by the EU Tobacco Products Directive that,

although it falls short of introducing ‘*full standardisation*’ (i.e. plain packaging), it expressly recognises that the individual Member States (emphasis added to text here and subsequently in underline and bold) ‘*should, under certain conditions, retain the power to impose **further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules***’. Accordingly, Member States could, for example, introduce provisions providing for ***further standardisation of the packaging*** of tobacco products, provided that those provisions are compatible with the TFEU, with World Trade Organization WTO obligations and do not affect the full application of this Directive’.⁽²⁸⁾

As defined in law by Australia ‘*plain packaging*’ (also referred to as ‘*generic*’ packaging) represents the most extreme form of package standardisation, as tobacco products are put in drab, purposefully unattractive packaging, devoid of branding (other than name) or promotional information. It can only bear the brand names displayed in a mandated size, font and place.⁽²⁹⁾ In Australia, the enacted plain packaging scheme includes some restrictions on size and shape and the pack is in brown/olive packaging and mat cardboard. There are no special foils, tapes, and laminating or special print effects. Packages are dominated by large and prominent (graphic and textual) health warnings.

There is a range of other less intrusive forms of standardisation than plain packaging as defined by Australia. Thus, any attempt at limiting the freedom to design a package through the imposition of some presentation standards, such as a given size, shape, colour and presentation characteristics, automatically translates into a form of pack standardisation: as a result of these requirements, the appearance of the products, or at least part of it, may end up being harmonised across a given segment of products. For example, the duty to affix mandatory graphic and/or pictorial health warnings on a package inevitably produces the effect of standardising the presentation of any given product. This is due to the fact that, as a result of these requirements, the size, colour, font and often also the positioning of those warnings are determined by law. As they reduce the ability of manufacturers to design the presentation of their products, all forms of packaging standardisation are often referred to, especially by the tobacco industry, as ‘*space appropriation measures*’.

A range of measures have already been imposed at EU level which standardise certain aspects of tobacco packaging, not least mandatory textual and pictorial warnings on all tobacco packaging. As illustrated above, the standardisation requirements envisaged in the UK go much further than those measures.

A look at the images below suffices to identify the major differences between the UK proposed pack of cigarettes and the one required by the EU.^{vi}

^{vi} An illustration of how a cigarette pack may look if the draft regulations were introduced is included at appendix C of the [Consultation on Standardised packaging of tobacco products: draft regulations](#)

Pack as enacted by the EU TPD



Pack as envisaged by the UK draft regulations



Standardised packaging as a further restriction on the advertising of tobacco products

Given the prominent role played by the appearance, imagery and general packaging of tobacco products, policy makers should consider the extent to which they should reduce the ability of tobacco manufacturers to market their products as they wish. In particular, as regulators have become aware of the power of marketing to induce consumer choices, they are reflecting on how they should offset those marketing techniques. Whilst the regulation of product packaging may play an important role in providing important information to consumers, it may also attempt to dissuade consumption.

The rationale underpinning all forms of package standardisation is to reduce the attractiveness of the relevant products: firstly, by conveying negative information about the products available to consumers and, secondly, by reducing the ability of manufacturers to design and present them as they wish. These measures rely on the assumption that, given the proven association between marketing efforts and growing consumption, the introduction of standardised forms of packaging may lower the prevalence of the consumption of the relevant product at either the population or the individual level or both.⁽³⁰⁾

Packaging is an important element of advertising and promotion. Tobacco pack or product features are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or on individual cigarettes or other tobacco products.⁽³¹⁾ As a result of the wide-ranging restrictions imposed on the advertising, the sponsorship and other forms of promotion for tobacco products, packaging design has become one of the last remaining opportunities for tobacco manufacturers to promote their products and brands to consumers.⁽³²⁾

The FCTC, read in conjunction with the Guidelines for implementation of Article 11 on packaging and labelling and Article 13 on advertising, promotion and sponsorship⁽³³⁾ presents plain packaging as having the potential to eliminate the effect of advertising and promotion on packaging. Thus, it calls on its Parties to consider *‘adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others’*.^{vii}

^{vii} See [Guidelines for implementation of Article 11 of the WHO FCTC](#), at paragraph 46. See also [Guidelines for implementation of Article 13 of the WHO FCTC](#), at paragraph 16 (advertising, promotion and sponsorship): The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer’s name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products’. Moreover, if plain packaging is not yet mandated, paragraph 17 invites Parties to consider imposing packaging restrictions which ‘cover as many as possible of the design features that make

These calls were reiterated in WHO's latest report on the global tobacco epidemic 2013, which incidentally focuses on enforcing bans on tobacco advertising, promotion and sponsorship.⁽³⁴⁾ In this report, WHO explicitly stated that *'package design serves an increasingly critical role in promoting tobacco use as other tobacco advertising, promotion and sponsorship activities are restricted or prohibited'*.⁽³⁵⁾ Consequently, and in light of the growing body of evidence establishing that the standardisation of packaging can be an effective tobacco control measure, WHO has taken a clear stance in favour of plain packaging: *'[p]arties should consider adopting plain (or generic) packaging requirements to eliminate the advertising and promotional effects of packaging. Product packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products more attractive to consumers.'*⁽³⁶⁾

The existing evidence on plain packaging

The 2013 WHO Tobacco Report highlights certain research findings on plain packaging. In particular, it states that requiring plain packaging – without colour, pictures or distinctive typefaces, other than required health warnings – minimises the ability to promote brands.⁽³⁷⁾ Furthermore, plain packaging enhances the impact of health warnings and other packaging and labelling measures.⁽³⁸⁾ Finally, many youth consider that plain packaging is unattractive and that it reinforces negative attitudes toward smoking.⁽³⁹⁾ However, this report does not purport to provide an exhaustive analysis of the evidence base supporting plain packaging.

To date, two systematic reviews have attempted to assess the evidence on the impact of plain packaging of tobacco products. Firstly, the Cancer Council of Victoria published a report in April 2011 (updated in August 2011).⁽⁴⁰⁾ Secondly, the systematic review, commissioned by the UK Department of Health as part of its consultation on plain packaging (see above), was published in July 2012, highlighting the findings from 37 studies on the three potential benefits of plain packaging identified by WHO: appeal, perceptions of harm, and salience and effectiveness of health warnings; as well as what the available literature had found about smoking-related attitudes, beliefs, intentions and behaviour in respect to plain packaging, and facilitators and barriers to plain packaging.⁽¹⁴⁾ It was subsequently updated (though this was not commissioned by the Department of Health); the update, published in September 2013, identified 17 studies published between August 2011 (the cut-off date for study inclusion in the original systematic review) and mid-September 2013, reinforcing the findings of the earlier review.⁽⁴¹⁾

Both reviews clearly support the introduction of plain packaging as an effective tobacco control measure. Overall, the evidence concurs in suggesting that plain packaging would reduce the appeal of cigarettes and smoking; enhance the salience of health warnings on packs; address the use of packaging elements that mislead smokers about product harm; and contribute to a change in smoking-related attitudes, beliefs, intentions and behaviour.

tobacco products more attractive to consumers such as animal or other figures, "fun" phrases, coloured cigarette papers, attractive smells, novelty or seasonal packs'.

If one looks more specifically at the review of evidence commissioned by the UK Department of Public Health, the following elements emerge:

- As far as the appeal of tobacco products is concerned, studies comparing responses to plain and branded packs have consistently found that plain packs reduce the appeal of the pack, of the cigarettes contained within it, and of smoking in general.
- As far as the salience of health warnings on packs is concerned, plain packs are perceived as detracting less than other packs from the health warning. Furthermore, the dullness of the packs enhances the seriousness and believability of warnings.
- As far as perceptions of product harm are concerned, plain packs are perceived as more effective than branded packs. The findings are mixed, as perceptions vary according to the colour of the plain pack: in general, darker coloured plain packs are seen as more harmful, and lighter coloured plain packs less harmful, than branded cigarettes. Moreover, descriptors such as *'gold'* or *'smooth'* also affect response: in general, plain packs without descriptors are perceived as more harmful than packs with descriptors, thus suggesting that descriptor terms have the potential to mislead consumers about harm when used both on plain packs or on branded packs.
- As far as smoking-related attitudes, beliefs, intentions and behaviour are concerned, the systematic review found that the overall pattern of results is mixed but tends to be supportive of plain packaging as having a deterrent effect on smoking. In particular, studies have found that when young adults put their own cigarettes in plain packs they are more likely to think about quitting, want to quit and engage in cessation-related behaviours.

The evidence review conducted by Sir Cyril Chantler largely confirms the benefits which plain packaging would have on public health. In particular, his report highlighted the importance of the Stirling evidence as being the consistency of its results on appeal, salience and perceptions of harms, and most notably that standardised packaging is less appealing than branded packaging. This evidence is direct and not reliant on stated intentions. Thus, by reducing its appeal, standardised packaging would affect smoking behaviour.⁽⁴²⁾ The Review concludes in no uncertain terms: *'Although I have not seen evidence that allows me to quantify the size of the likely impact of standardised packaging, I am satisfied that the body of evidence shows that standardised packaging, in conjunction with the current tobacco control regime, is very likely to lead to a modest but important reduction over time on the uptake and prevalence of smoking and thus have a positive impact on public health.'*⁽⁴³⁾

This Legal Opinion does not purport to provide an exhaustive review of existing evidence on plain packaging. This would fall beyond our expertise. However, we discuss relevant evidence wherever necessary in our legal analysis of the compatibility of the

UK draft Standardised Packaging of Tobacco Products Regulations with the recently adopted revised EU Tobacco Products Directive and EU law more generally.

The rest of this report focuses on the extent to which EU law constrains the development of a scheme – such as the one proposed by the UK draft Standardised Packaging of Tobacco Products Regulations – that would introduce the standardised packaging of tobacco products on its territory. After presenting the relevant provisions of the Tobacco Products Directive (II), it evaluates the extent to which they affect the freedom of Member States, and the UK more specifically, to impose standardised packaging measures – understood as *‘plain packaging’* – of tobacco products on their territories.

II. Plain packaging in the EU Tobacco Products Directive

Before analysing in detail the legal implications stemming from the introduction of standardised packaging as a tobacco control tool in the individual Member States of the Union,⁽³²⁾ it is necessary to briefly contextualise this policy option within the broader framework of EU tobacco control.

1. Introduction to EU tobacco control

EU tobacco control efforts have historically been marked by a strong regulatory involvement of the EU, coupled with recommendations to Member States and EU-wide anti-smoking campaigns.⁽⁴⁴⁾ This is because, as of today, virtually all legislation on labelling, advertising and product regulation enacted by the EU has been based on the internal market legal basis provided by Article 114 of the Treaty on the Functioning of the European Union (TFEU). This provision empowers the EU to replace, by a qualified majority vote, divergent national legislations with a common rule applicable across the whole territory.⁽⁴⁵⁾ Yet, since the objective pursued by tobacco control policies, such as labelling, advertising and product regulation restrictions, is to reduce tobacco consumption rather than to promote the free movement of tobacco, reliance on this legal basis may appear, at least *prima facie*, somehow inconsistent. The reason behind such a choice lies in the limited competences enjoyed by the EU in the area of public health. Although the protection of public health is one of the basic requirements that the EU has to take into account in the enactment of any of its policies or activities,⁽⁴⁶⁾ including its internal market policy,⁽⁴⁷⁾ Member States remain generally competent to adopt public health measures.⁽⁴⁸⁾ However, the EU has thus far not hesitated to rely on the internal market legal basis to provide a strict legal regime for both the advertising and production of tobacco products.

The EU tobacco control policy rests on two main regulatory instruments: the EU Tobacco Products Directive (TPD) and the Tobacco Advertising Directive (TAD).^{viii} Since their adoption, the EU has become a party to the FCTC, thus becoming for the first time an actor alongside its 28 Member States on the public health scene at global level.

2. The genesis of the 2014 TPD and plain packaging

In order to go beyond the FCTC's minimal requirements,⁽⁴⁹⁾ and in an effort to closely implement its Guidelines, the EU adopted on 14 March 2014 a revised TPD aimed at strengthening and modernising its existing tobacco control policy.^{ix} The original TPD, which

^{viii} [Directive 2003/33, OJ 2003 L152/16: \(Articles 3 and 4 more specifically\)](#). Only publications intended for professionals in the tobacco trade and publications from non-EU countries which are not principally intended for the EU market are exempted from the cross-border advertising and sponsorship ban the Tobacco Advertising Directive imposes.

^{ix} The new Directive entered into force in May 2014. A transposition period of two years for Member States to bring national legislation into line with the revised Directive means that most of the new rules will apply in the first half of 2016. However, the Directive also foresees a transitional period for all product categories to give manufacturers and retailers time to sell off their existing stock insofar as it complies with the old Directive or other relevant legislation.

was adopted in 2001, famously introduced far-reaching tobacco control measures, such as voluntary graphic health warnings and a ban on misleading descriptors (such as *'mild,' 'light'* or *'low tar'*). Moreover, it reinforced several pre-existing pack space appropriation measures by, for example, increasing the size of text health warnings; and establishing maximum tar, nicotine, and carbon monoxide levels (commonly referred to as TNCO) for cigarettes.

Yet, *'new international, scientific and market developments'* – including the entry into force of the FCTC – led the EU to verify whether the original TPD *'still fully guarantees'* its original objectives: to facilitate the functioning of the internal market in the tobacco products sector while ensuring a high level of health protection. This is the dual rationale behind the revised TPD as they originally emerged from the Public Consultation Document, published by the European Commission in 2010,^x and were confirmed by the adopted revised TPD.⁽⁵⁰⁾

Besides broadening the scope of the Directive, such as to include electronic cigarettes, herbal cigarettes, water pipes, and paraphernalia, the envisaged revisions contemplated the introduction of equally ground-breaking policy tools, such as plain packaging, aimed at further strengthening existing rules. However, the first mention of plain packaging in an EU document occurred in the Second Report on the Application of the TPD, where the Commission wrote: *'in order to decrease the smoking initiation and to protect EU consumers on an equal basis in all Member States the introduction of generic (black and white) standardised packaging for all tobacco products could be explored as a possibility to reduce their attractiveness'*.^{xi} The term *'plain packaging'* was first employed in the 2009 Council Recommendation on smoke-free environment,⁽⁵⁰⁾ inviting the Commission to *'analyse the legal issues and the evidence base for the impact of plain packaging, including on the functioning of the internal market'*.⁽⁵¹⁾ This term has been used since then as defining the most radical form of standardisation of the package.^{xii}

3. Plain packaging in the public consultation document on the revision of the TPD

When the EU Commission announced its intention to revise the TPD, it published a document illustrating the need for this revision and listing possible areas of intervention: (1) scope; (2) smokeless tobacco products; (3) consumer information; (4) reporting and registration of ingredients; (5) regulating ingredients; and (6) access to tobacco products. For

^x European Commission. [Public Consultation Document on the Possible Revision of the Tobacco Products Directive 2001/37/EC](#). The need for a revision has also been highlighted by the European Parliament, the Member States and other stakeholders, as well as by the Commission itself in relation to its commitment to promote work on tobacco ingredients at the time of the adoption of the REACH Regulation. European Commission. [Second Report on the Application of the Tobacco Products Directive](#). COM(2007) 754 final; 2007; p.3

^{xi} Ibid., p.11

^{xii} Sir Cyril Chantler suggests in his report that although the terms *'standardised packaging'* and *'plain packaging'* are often used interchangeably, the *'latter may involve fewer restrictions on, for example, size and shape of packs than fully standardised packaging'*. While this might be true in the future, the Australian example, by representing today the most standardised form of packaging in the world, is often equated with plain packaging. The EU documents accompanying the preparation of the TPD confirm this understanding. See, e.g. European Commission (2014): [MEMO/14/134. Questions & Answers: New rules for tobacco products](#). ('The new Directive specifically allows Member States to introduce further measures relating to standardisation of packaging or plain packaging').

each of those areas, the Directorate-General for Health and Consumers (DG SANCO) of the European Commission envisaged a number of measures to strengthen the current regulation by clustering them into three policy options depending on the degree of change envisioned (from ‘no change’ to ‘revision of the directive with the objective of strengthening product regulation’). In addressing areas 3 and 6, the Commission contemplated for the first time the introduction of plain packaging as a policy option that the EU legislator may consider as part of its revision of the TPD. The consultation document was preceded by a study preparing the ground for a DG SANCO impact assessment.⁽⁵²⁾ This document examined the various options for amendment identified by the Commission and was followed by a public consultation process.^{xiii}

4. The notion of plain packaging as envisioned in the public consultation document

In contemplating for the first time the introduction of plain packaging as a policy option that the EU legislator might consider as part of its revision of the TPD, the Commission provided a first definition:

‘[P]lain or generic packaging would standardise the appearance of tobacco packaging. Manufacturers would only be allowed to print brand and product names, the quantity of the product, health warnings and other mandatory information such as security marking. The package itself would be plain coloured (such as white, grey or plain cardboard). The size and shape of the package could also be regulated.’^{xiv}

This definition is in line with the definition provided by the Guidelines for the implementation of Article 11 and Article 13 of the FCTC,⁽³³⁾ which refer to the potential of plain packaging to eliminate the effect of advertising and promotion on packaging.⁽⁵³⁾ The stated objective of generic packaging is to undermine the allure of smoking, especially for adolescents, in the hope that smoking up-take rates may be reduced.⁽⁵⁴⁾ In particular, plain packaging is considered in the Public Consultation Document as one of the policy options available to the EU legislator to attain three different objectives:

1. Firstly, this policy tool might help overcome the existing disparities in labelling, which stem from the current voluntary pictorial warnings regime, since this regime has led some — but not all — Member States to make pictorial warnings

^{xiii} European Commission. [Public Consultation Document on the Possible Revision of the Tobacco Products Directive 2001/37/EC](#), at p. 22. While the Commission presents this consultation as ‘an example of the great interest of the general public and stakeholders in the EU policymaking process’, the high number of submissions received (around 85,000) reveals misuses of the consultation mechanism. Indeed, not only were 2/3 of the contributions received from two Member States (Italy and Poland), but out of the 96% responses submitted by (self-declared) citizens more than half consisted in duplicates and ‘form’ responses. *Id.* at p.8 and 9.

^{xiv} European Commission. [Public Consultation Document on the Possible Revision of the Tobacco Products Directive 2001/37/EC](#). The need for a revision has also been highlighted by the European Parliament, the Member States and the stakeholders, as well as by the Commission itself in relation to its commitment to promote work on tobacco ingredients at the time of the adoption of the REACH Regulation. European Commission. [Second Report on the Application of the Tobacco Products Directive](#). COM(2007) 754 final; 2007; p.7

mandatory in their own jurisdictions.^{xv}

2. Secondly, plain packaging would enable the EU legislator to regulate packaging as an advertising tool, which seems to have become crucial since *'tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image'*.^{xvi}
3. Thirdly, plain packaging could improve consumer information by preventing the existing TNCO quantitative labelling from being misread by consumers who might *'think that lower levels indicate that a product is less risky to their health'* and thus *'decide to smoke or increase their consumption... in preference of quitting'*.^{xvii}

To sum up, the EU ascribed to plain packaging two well-defined policy roles in its tobacco control policy. Firstly, by overcoming existing regulatory divergence among tobacco products, it could have acted as an internal market-enhancer. Secondly, by detracting attention from packages and by preventing packaging from suggesting that some products are less harmful than others, it might also have served as a tool intended to prevent misleading marketing practices.

5. Reactions to plain packaging in the Commission consultation of December 2010

The consultation generated more than 85,000 contributions from a wide range of stakeholders, including citizens, industry, NGOs, governments and public authorities. The responses were carefully, yet slowly given their significant number, analysed and a report was prepared by DG SANCO. Respondents in favour of mandatory pictorial warnings and plain or generic tobacco packaging stressed that these measures would eliminate the advertising and marketing effects utilised by industry and would provide equal protection of European citizens. By contrast, the opponents to these measures argued that implementing mandatory pictorial warnings and generic packaging would have little to no impact on the uptake of smoking, especially among youth. Opponents also expressed legal concerns about intellectual property and suggested that generic and plain packaging could increase illicit trade in tobacco.⁽⁵⁵⁾

^{xv} Yet, it is not clear whether plain packaging would supplement or replace the pictorial warnings.

^{xvi} European Commission. [Public Consultation Document on the Possible Revision of the Tobacco Products Directive 2001/37/EC](#). The need for a revision has also been highlighted by the European Parliament, the Member States and the stakeholders, as well as by the Commission itself in relation to its commitment to promote work on tobacco ingredients at the time of the adoption of the REACH Regulation. European Commission. [Second Report on the Application of the Tobacco Products Directive](#). COM(2007) 754 final; 2007; p.6

^{xvii} *Ibid.*, p.7

6. Plain packaging in the Commission's Proposal of 19 December 2012

Despite much speculation about whether the EU would embrace plain packaging, the EU Commission eventually decided not to include this policy option in its proposal for a revised TPD. In order to understand the reasons that have led the Commission not to choose plain packaging as its preferred policy option, one has to examine the impact assessment accompanying the preparation of the Commission proposal.

Impact assessment of the options relating to plain packaging in the Commission Proposal

In this document, the Commission acknowledges that *'also in the area of packaging and labelling, the disparities are expected to grow in coming years as Member States continue to take further measures, e.g. to adopt pictorial health warnings, introduce cessation information and/or further standardise tobacco packaging in line with the guidelines for implementing Articles 11 and 13 of the FCTC'*.⁽⁵⁶⁾ In particular, after examining the initiatives announced by the UK,^{xviii} Ireland, Belgium, Finland and France in relation to these measures, it predicts that *'it is likely that at least some of them will go forward at national level in the absence of a common EU approach'*.^{xix} Moreover, the Commission highlights that Member States' interest in plain packaging is also reflected in a Council Recommendation of 2009 inviting the Commission to analyse the legal issues and the evidence base for the impact of plain packaging, including its effect on the functioning of the internal market.⁽⁵¹⁾

In light of the above considerations, the Commission contemplated, in line with its original working document subject to public consultation, plain packaging as one of the policy options to be developed under the section *'packaging and labelling'*. In this area of intervention, the Commission noted that the current provisions are outdated (e.g. size of the warnings, display of quantitative TNCO-values) and that there is heterogeneous development in Member States (e.g. pictorial warnings). It also recognised that there was a need to implement FCTC obligations and commitments; and to address the potential of packaging and labelling, firstly, to mislead consumers and, secondly, to encourage people to start or maintain smoking.

To address these concerns, the Commission identified the following policy options:

- Option 0: No change;^{xx}
- Option 1: Mandatory enlarged picture warnings;^{xxi}

^{xviii} See the first part of this Opinion for the a discussion of the measures envisaged by the UK

^{xix} Ibid

^{xx} That meant that current labeling rules were maintained, i.e. a general text warning of not less than 30% and an additional text warning of not less than 40%; Member States could choose to use a combined warning (picture and additional text warning) instead of the additional text warning (40%)

^{xxi} That meant combined warnings (picture plus text) of 75% displayed on both sides of the packages of tobacco products, presented in rotation. TNCO levels on the packages would have been replaced with descriptive information on content, emissions and risks. Display of cessation information (e.g. quit-lines, websites) is added to the packages. Tobacco products other than FMC and RYO would have been exempted.

- Option 2: Option 1 plus harmonise certain aspects of packets and prohibit promotional and misleading elements,^{xxii}
- Option 3: Option 2 plus ‘full plain packaging’.⁽⁵⁷⁾

Both Options 2 and 3 imply the introduction of plain packaging in the EU but to a different extent. Option 2 would lead the EU to harmonise certain requirements for packages, such as cuboid shape, minimum number of factory manufactured cigarettes (FMC)^{xxiii} per package, and the size of the warnings; and it would allow the Member States to regulate ‘*the area not regulated by the TPD or other Union legislation, including adopting provisions providing full standardisation of packaging of tobacco products (i.e. plain packaging) as far as these provisions are compatible with the Treaty*’. Option 3 would lead instead to the EU mandating ‘*a standardised colour, font, size and position of brand name and brand variant on packages (plain packaging) and a readable health warning on each FMC stick*’. In other words, while Option 2 would allow Member States to adopt plain packaging as far as this is compatible with the EU internal market, Option 3 would lead to the adoption by the EU of a fully harmonised, EU-wide plain packaging scheme.

After having assessed the economic, social and health impact of each of these policy options and compared their individual score one against the other, the Commission preferred Option 2: the adoption of mandatory enlarged picture warnings alongside the harmonisation of certain aspects of packets and FMC appearance, whilst prohibiting promotional and misleading elements.

Despite the more beneficial economic and health effects brought about by Option 3 (the introduction of EU-wide plain packaging) over Option 2,⁽⁵⁸⁾ the EU Commission chose the latter. In its view, ‘*full plain packaging (Policy Option 3) would be most effective in terms of removing national disparities*’, and would help to reduce administrative burdens by fully unifying labelling rules, whereas requiring mandatory pictorial warnings and/or harmonising certain aspects of the package shape and prohibiting promotional and misleading elements (Options 1 and 2) would contribute to a lesser extent to this objective. Most of the Member States responding to the public consultation were in favour of enlarged mandatory pictorial warnings, while the positions on plain packaging were more diverse. Overall, the Commission decided to opt for Option 2, which it considered – for the time being at least – the most appropriate policy option for the EU.

The role of plain packaging in the Commission Proposal

In line with the choices made in the impact assessment, the final proposal adopted by the

^{xxii} That meant Option 1 plus: i) The tobacco labelling and packaging and the tobacco product itself could not include any promotional and misleading elements (e.g. misleading colours, symbols, slim FMC); ii) setting certain requirements for packages (e.g. cuboid shape, minimum number of and FMC per package) as well as for the size of the warnings Member States are allowed to regulate the area not regulated by the TPD or other Union legislation, including adopting provisions providing full standardisation of packaging of tobacco products (i.e. plain packaging) as far as these provisions are compatible with the Treaty. The Commission would report on experiences gained with respect to surfaces not governed by the TPD five years after the transposition of the TPD.

^{xxiii} This is a cigarette, produced by a tobacco manufacturer, capable of being smoked as such.

Commission⁽⁵⁹⁾ mandates enlarged picture warnings and harmonises certain aspects of packets and FMC appearance, whilst prohibiting promotional and misleading elements. It also expressly recognises Member States' power 'to regulate the area of the package not regulated by this Directive or other Union legislation'. As a result of this proposal, tobacco packaging may become even more standardised, with plain packaging a possible result.⁽⁶⁰⁾

In the explanatory memorandum accompanying the publication of the proposed TPD, the Commission states:

'Under the proposal, Member States would retain their power to regulate the area of the package not regulated by this Directive or other Union legislation, including implementing provisions providing full standardisation of packaging of tobacco products (including colours and font), as far as these provisions are compatible with the Treaty. The Commission will report on experiences gained with respect to surfaces not governed by the Directive five years after its transposition deadline.'⁽⁶¹⁾

This conclusion seems to be based upon the following two recitals included in the text of the legislative proposal:

*'(40) A Member State that deems it necessary to maintain more stringent national provisions for aspects falling inside the scope of this Directive should be allowed to do so, for all products alike, on grounds of overriding needs relating to the protection of public health. A Member State should also be allowed **to introduce more stringent provisions**, applying to all products alike, on grounds relating to the **specific situation** of this Member State and provided the provisions are **justified by the need to protect public health**. More stringent national provisions should be **necessary and proportionate**, not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Stricter national provisions require **prior notification to, and approval from, the Commission** taking into account the high level of health protection achieved through this Directive.*

*(41) Member States should remain free **to maintain or introduce national legislations applying to all products alike for aspects falling outside the scope of this Directive**, provided they are compatible with the Treaty and do not jeopardise the full application of this Directive. Accordingly, **Member States could, for instance, maintain or introduce provisions providing standardisation of packaging of tobacco products provided that** those provisions are **compatible with the Treaty, with WTO obligations** and **do not affect the full application of this Directive**. A **prior notification** is required or technical regulations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and on rules on Information Society services.'*

According to the ordinary legislative procedure, this text was examined by the European Council and the European Parliament (EP), and both proposed amendments in relation to the policy option of plain packaging.^{xxiv}

7. The legislative process of the TPD and the plain packaging amendments

On 12 September 2012 at the EP plenary meeting, an amendment proposed by Glenis Willmott and Linda McAvan (the EP rapporteur) on behalf of the S&D Group to introduce plain packaging (as well as further ingredients restrictions) was rejected.^{xxv}

The chronology and content of this amendment offers interesting insights.

- On Monday 12 September 2012, individual political Groups in the EP decided to present draft motions for resolutions on European Union position and commitment in advance of the UN high-level meeting on the prevention and control of non-communicable diseases.⁽⁶²⁾
- On Tuesday 13 September 2012 two different motions were presented:
 - One signed by ALDE Group, S&D Group, Greens/EFAGroup, ECR Group, GUE/NGL Group.
 - One signed by EPP Group.
- On Tuesday 13 September 2012, all political groups agreed on a draft joint motion for a resolution replacing the previous two.
- The three above-mentioned draft resolutions did not include any reference to plain packaging as such, but referred to the FCTC and the TPD in general terms.
- 8 amendments were then tabled to the joint resolution by individual MEPs on behalf of respective political Groups.
- **Amendment 1** signed by G. Willmott and L. McAvan (S&D UK MEPs) proposed plain packaging, larger health warning label and ingredients restrictions. This was the proposed text:

*'Emphasises the **need for an immediate**, effective revision of the Tobacco Products Directive, taking into account the European Union's commitment to the Framework Convention on Tobacco Control and **the possibility of introducing standardised packaging***

^{xxiv} For information on the revision process of the TPD, see also the [Commission's dedicated webpage](#)

^{xxv} In particular the political Groups of the EPP, ECR, EFD, NI, part of Alde and of S&D opposed the proposal

and large pictorial health warnings for tobacco products and of restricting the use of certain additives

8. The political agreement of 18 December 2013: towards a new TPD

Pending the vote in the EP Plenary and formal adoption by the Council, an agreement was reached at COREPER level on 18 December 2013. It was a direct outcome of the last trilogue between the EP and EU Member States on this text.

Similarly to the EU Commission proposal (and notably Policy Option 2 of the impact assessment), the agreed text expressly allows Member States to introduce *inter alia* plain packaging. It must however be observed that it does so both in the preamble – as the Commission’s proposal did – as well as in the text of the Directive.⁽⁵⁹⁾

The relevant recital provided as follows:

‘(40) Tobacco products and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should retain, under certain conditions, the power to impose further requirements in certain respects to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules.’

Accordingly, Member States could, **for instance**, introduce provisions providing for further standardisation of packaging of tobacco products provided that those provisions are compatible with the Treaty, with WTO obligations and do not affect the full application of this Directive.

Article 24 translated this idea in prescriptive terms by stating:

*‘2. This Directive shall not affect the right of a Member State to maintain and introduce further requirements, **applicable to all products placed on its market**, in relation to standardisation of packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection achieved through this Directive. Such measures shall be **proportionate** and may **not constitute a means of arbitrary discrimination or a disguised restriction on trade** between Member States. They shall be **notified** to the Commission together with the grounds for maintaining or introducing them.’*

9. The adopted revised EU TPD and plain packaging: the text of 26 February 2014 adopted on 14 March 2014⁽⁶³⁾

The text agreed in December 2013 was substantially upheld in the final revised TPD. In particular, Article 24 reads as follows:

‘Article 24

Free movement

1. Member States **may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article,** prohibit or restrict the **placing on the market** of tobacco or related products which comply with this Directive.

2. **This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.’**

This is the provision that – together with the rules of the EU Treaties⁽⁶⁴⁾ – will help determine the legality of national schemes introducing inter alia standardised packaging. Therefore, in order to determine the compatibility of the UK draft Standardised Packaging of Tobacco Products Regulations with EU law, it is necessary to closely interpret this specific provision.

While neither the EU legislator nor the EU judiciary have yet provided an interpretation of Article 24 of the revised TPD, an initial indication of how to interpret this provision can be found in the Q&A document that the Commission published on 26 February 2014. To the question ‘[c]an Member States introduce plain packaging?’, the EU Commission provides the following response: ‘while the new rules mean that health warnings will cover a substantial part of the total surface of cigarette packages, **a certain space will remain available for branding**’.^{xxvi}

Recital 53 of the preamble of the TPD clarifies the exact margin of discretion that is left to the Member States in disposing of this “space”. It states that: ‘...**in light of the different degrees of harmonisation achieved by this Directive,** the Member States should, under

^{xxvi} Sir Cyril Chantler suggests in his report that although the terms ‘standardised packaging’ and ‘plain packaging’ are often used interchangeably, the ‘latter may involve fewer restrictions on, for example, size and shape of packs than fully standardised packaging’. While this might be true in the future, the Australian example, by representing today the most standardised form of packaging in the world, is often equated with plain packaging. The EU documents accompanying the preparation of the TPD confirm this understanding. See, e.g. European Commission (2014): [MEMO/14/134. Questions & Answers: New rules for tobacco products](#). (‘The new Directive specifically allows Member States to introduce further measures relating to standardisation of packaging or plain packaging’).

certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules’.

In line with Article 24, this recital reminds us of a general principle of EU law: in those areas in which the EU harmonisation is not full, Member States remain free to maintain or introduce ‘further requirements in certain respects’. Among the areas in which the Member States can take unilateral action within the framework of the current directive, the legislator mentions ‘the presentation and the packaging’ of tobacco products. As these are two areas in which the EU provides ‘a first set of basic common rules’, Member States are therefore allowed ‘to, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive’.⁽⁶⁵⁾

This suggests that an EU Member State that decides to propose the introduction of a form of package standardisation that goes beyond the presentation and packaging requirements provided for the TPD (i.e. Chapter II of the TPD), will in principle be allowed to do so. Therefore, provided that it respects the conditions listed above, an individual Member State can determine not only the colour of the package but also its shape, surface and brand variants by thus further limiting the ability of the tobacco manufacturers to use the package as a ‘billboard’.⁽⁶⁶⁾ Thus, for instance, while the EU TPD regulates the appearance of tobacco products by requiring a cuboid shape⁽⁶⁷⁾ and prohibiting their resemblance to a food or cosmetic product,⁽⁶⁷⁾ an EU Member State may further constrain the shape of the product, for example by banning *inter alia* the use of rounded or bevelled edges on packs. Although recital (28) TPD expressly authorises this feature – by judging it ‘acceptable’ –, Article 14 only prescribes a cuboid shape without providing any further indication in relation to the use of bevelled or rounded edges. In these circumstances, it is argued that – given the lack of legally binding nature of the recital of a directive – a Member State could validly limit this possibility by prohibiting bevelled and rounded edges, provided that it could comply with the requirements established by primary law and that will be illustrated in the following section. In short, the proposed prohibition – being restrictive to the free movement of tobacco products – must pursue a legitimate objective (presumably public health), non-discriminatory (it must apply to both imported and domestic products), proportionate (to its declared objective).

Similarly, given that the EU TPD introduces a minimum number of cigarettes per pack (‘at least 20’), a Member State may prohibit a higher number and in particular the option of additional, known in Australia as ‘loosie’, cigarettes. This marketing strategy of including extra cigarettes for free has been used in Australia since the introduction of plain packaging accompanied by the use of variant names such as ‘+loosie’. While variant names such as ‘Malboro+loosie’ could be registered, their use could be prohibited as part of the national standardised packaging scheme. Likewise, the UK government could also, in line with

Article 13 of the TPD, expressly prohibit the use of other misleading branding names. In particular, it could prohibit the use of the terms ‘*natural*’, ‘*organic*’, ‘*without additives*’, ‘*without flavours*’ or ‘*slim*’, as well as others such as ‘*smooth*’, ‘*gold*’ and ‘*silver*’. This is true insofar as all these terms may encourage consumption by ‘*creating an erroneous impression about its characteristics, health effects, risks or emissions*’.⁽⁶⁷⁾ In particular, in line with Article 13.1 lett. (b), they seem to suggest that ‘*a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle properties*’. It is important to observe that the use of misleading terms on the package has been prohibited since the entry into force of the original TPD on 18 July 2001, but Member States may reiterate and further refine this prohibition by providing a list of prohibited brand names.

In determining the compatibility of a national plain packaging scheme such as the one envisaged by the UK government, one therefore needs to determine whether, and under which conditions, a Member State may introduce ‘*further requirements... in relation to the standardisation of the packaging of tobacco products*’, including issues related to colour, shape, surface and brand variants.

III. The compatibility of the draft Standardised Packaging of Tobacco Products Regulations with EU law

In analysing the compatibility of the draft UK Standardised Packaging of Tobacco Products Regulations with EU law, it is necessary to systematise the major packaging requirements they introduce by taking as a point of reference the TPD.

The new TPD mandates that health warnings shall cover a substantial part of the total surface of tobacco packages. However, a certain space will remain available for branding these products. In particular, Article 10(1)(c) of the TPD requires that each unit packet and any outside packaging^{xxvii} of tobacco products shall carry combined health warnings covering 65% of both the external front and back surface of the unit packet, and any outside packaging. The remaining 35% of the pack is therefore – under the newly adopted TPD – a space that can freely be used by the tobacco manufacturers to brand their products, subject to the limits set both by the provisions contained in the TPD itself and by the provisions of the EU Treaties.

However, as foreseen in Article 24 of the TPD, tobacco manufacturers may have to comply with **further requirements** that could be introduced by Member States in relation to the standardisation of the packaging of tobacco products, subject to compliance with the EU Treaties, which could inter alia prevent them from making use of the remaining 35% of the package as they would wish. As discussed above, since the presentation and packaging of the tobacco products are aspects that have not been fully harmonised by the EU legislator, Member States enjoy a wide margin of manoeuvre in determining the degree – and related features – of the package standardisation which they intend to implement in their own jurisdiction. In particular, as expressly suggested by the preamble of the TPD, they are free to require the manufacturers to use a particular colour in the remaining space of the pack, as well as to determine further restrictions to the shape (e.g. bevelled edges) and size (e.g. prohibition of ‘+loosie’) of the pack. That is where the major requirements for standardised packaging advanced by the UK find application: pack colour (drab brown with a matt finish)⁽⁶⁸⁾ and permitted text and features (font, colour, size of the brand and number of appearances of the brand variant).⁽⁶⁹⁾ Yet the UK requirements for packaging standardisation do not only affect the remaining (35%) surface of the pack. The draft regulations introduce also further characteristics of the pack, such as surface (smooth without embossing), of the wrappers (which must be clear and transparent), of the inserts (which are prohibited) and the packs cannot make noise or produce a smell not normally associated with tobacco packaging. They also mandate a colour for the individual cigarettes (white with a cork effect or white tip) as well as specified typeface, size and location of their text indicating the brand name.

All these requirements are additional to – and therefore go beyond – those mandated by the TPD and thus qualify as ‘*further requirements*’ within the meaning of Article 24 of the TPD,

^{xxvii} According to Recital 24 of the preamble of the TPD, ‘outside packaging’ means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging.

with two sole exceptions: the shape of the pack⁽⁷⁰⁾ and those prohibiting promotional or misleading labelling⁽⁷¹⁾ These requirements contained in the UK draft regulations seem to merely implement Article 13 and 14 of the TPD respectively. To minimize the burden for tobacco manufacturers, the UK government envisages the implementation of its requirements for standardised packaging in May 2016 to coincide with the transposition deadline for the TPD.

While it is true that the new TPD specifically allows Member States to introduce further measures relating to the presentation and packaging of tobacco products such as those described above, such measures are subjected to a set of conditions on which the rest of our analysis focuses. Even without such an explicit recognition, Member States would have been free to introduce stricter packaging rules, including standardised packaging requirements. Indeed, in areas of shared competence and in the absence of EU common, harmonised rules, Member States are, in principle, free to act provided they do so within the limits laid down in the EU Treaties. These limits largely coincide with the conditions that are enshrined in Article 24 of the TPD and constrain the freedom of Member States to introduce *'further requirements'*, including plain packaging. We will therefore start discussing the scope of these conditions, before assessing whether other provisions of EU law may also limit the freedom of Member States, and the UK more specifically, to introduce measures intended to standardise the packaging of tobacco products on their territories. In so doing, we will be examining whether the UK requirements envisaged by Standardised Packaging of Tobacco Products Regulations are compatible with EU law. It should be noted, however, that the Standardised Packaging of Tobacco Products Regulations will not suffice to implement the TPD as this requires a broader set of requirements for tobacco manufacturers that go beyond the presentation, packaging and sale of tobacco products for example with respect to rules on ingredients.

1. The conditions listed in the TPD which Member States must comply with

According to its Article 24(2), the newly adopted TPD *'shall not affect the right of a Member State to maintain or introduce further requirements [...] in relation to the standardisation of the packaging of tobacco products'*. However, the exercise of this prerogative is subject to respecting a set of conditions. In particular, the additional national requirements must:

- a. be *'applicable to all products placed on its market'*;
- b. be *'justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive'*;
- c. be proportionate;
- d. may not constitute *'a means of arbitrary discrimination or a disguised restriction on trade between Member States'*; and
- e. *'be notified to the Commission together with the grounds for maintaining or introducing them'*.

We propose to examine these conditions in turn, focusing specifically on the question whether the various requirements envisaged by Standardised Packaging of Tobacco Products Regulations are compatible with those conditions laid down by EU law. In so doing, we will consider the evidence available in relation to the effectiveness of standardised packaging on public health by relying in particular on the Chantler Review.

(a) Applicable to all products placed on its market

By requiring that the introduction of plain packaging should apply to all tobacco products, irrespective of their origin, this condition is intended to avoid discrimination against imported goods in violation of Article 34 TFEU.^{xxviii} Its rationale therefore is to ensure that national products are not placed at a competitive advantage over imported products.

The *Philip Morris* judgement⁽⁷²⁾ delivered in September 2011 by the EFTA Court provides some guidance on this point.⁽⁷³⁾ The central question in this case was whether the Norwegian ban on the display of tobacco product was in breach of the free movement of tobacco products. The Court held that, ‘*by its nature*’, a visual display ban of tobacco products was not only liable to favour domestic products over imported ones, as consumers tend to be more familiar with the former,⁽⁷⁴⁾ but also that such a discriminatory effect would be particularly significant with regards to the market penetration of new products.⁽⁷⁵⁾

Against this backdrop, one may wonder whether the introduction of a set of requirements aimed at standardising the packaging of tobacco products such as the one envisaged by the UK would be capable of producing similar effects. While it may appear *prima facie* true that any form of standardisation of the package that go beyond what the EU requires may crystallise the national market for tobacco products, by limiting the ability of lesser known products or new ones to thrive into that market, it must be observed that in the EU there is an increasingly passive market of tobacco products. While such products can still lawfully be placed on the EU market, the EU and its Member States nonetheless have a duty to regulate this market to steer existing and potential consumers away from smoking in light of the costs of smoking and existing evidence linking marketing and consumption patterns.^{xxix} In these circumstances, the argument could be made that a domestic standardised packaging scheme would apply equally to all tobacco products placed on the domestic market, that it would not favour home-manufactured cigarettes and that it would not therefore have any discriminatory effects towards imported products – thus satisfying the first condition listed in Article 24(2) of the revised TPD. Indeed, none of the requirements envisaged by Standardised Packaging of Tobacco Products Regulations, being applicable to all tobacco products, seems

^{xxviii} Article 34 TFEU provides that ‘quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States’. As is well-known, the Court has interpreted the scope of this provision particularly broadly in a long line of cases starting with its seminal *Dassonville* decision: measures having an equivalent effect cover all ‘trading rules enacted by Member States, which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade’: Case 8/74 *Procureur du Roi v Dassonville* [1974] ECR 837, at p.852.

^{xxix} The obligation of the EU to take into account a high level of human health protection in the definition and implementation of all its policies is strongly enshrined in the Treaties: see in particular Articles 9, 114(3) and 168(1) TFEU

discriminatory in nature. Given their limited use,⁽⁷⁶⁾ the exemption provided for cigars and pipe tobacco does not alter this conclusion.

(b) Justified on grounds of public health

According to Article 24(2) of the revised TPD, a Member State may only introduce national measures which are '*justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive*'. The exact significance of this provision is not particularly straightforward. One could distinguish two elements.

Firstly, it refers to **national measures** which must be justified on grounds on public health. This is a classical free movement statement: if Member States introduce national measures which restrict the free movement of goods, these measures must be justified by a mandatory requirement, i.e. a public interest of sufficient importance to satisfy the CJEU or a national court that it can provide a ground for derogating from the fundamental principle of free movement. Member States must also adduce evidence that the measure is proportionate, as discussed below. Public health has been one of the most often invoked grounds of derogation by Member States, when defending national measures challenged on the basis that they infringed the general free movement provisions of the EU Treaties, and Article 34 on the free movement of goods and Article 56 on the free movement of services more specifically.

At the same time, however, Article 24(2) of the revised TPD refers to the obligation resting **on the EU** to take a high level of public health protection in the definition and the implementation of all its policies.⁽⁶³⁾ This '*mainstreaming*' obligation implies, at its core, that the EU should not pursue a high level of public health protection only via ear-marked, distinct policies, but that it must do so systematically via all its policy areas, including the internal market, as clearly stated in Article 114(3) TFEU.^{xxx} The TPD, both in its original and revised versions, has at its heart a high level of public health protection. In particular, and as discussed above, it is intended to create a more passive market in tobacco products in order to reduce smoking rates across the EU, and in particular the uptake of smoking by children and young people.

One way of reconciling the two sections of the provision under review is to discuss the extent to which Member States are allowed to exceed the level of public health protection mandated by the EU TPD by adopting supplementary measures on their territories, such as the imposition of a plain packaging or other forms of packaging standardisation of tobacco products. If so, the answer seems to be rather straightforward: the Impact Assessment Report which the Commission published alongside its proposal for a revised TPD, clearly acknowledges that plain packaging has the potential to increase public health outcomes.⁽⁵⁶⁾ Even though the EU may not have been in a position to choose the option which would have

^{xxx} On the mainstreaming of public health concerns at EU level, see A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010), at p. 73.

led to the imposition of a full plain EU-wide packaging scheme (Option 3) – a high level of protection does not mean the ‘*highest*’ level of public health protection – this should not necessarily mean that Member States could not impose a plain packaging scheme on their territories: Article 24(2) clearly suggests otherwise (subject to the national measures in question being proportionate).

The Impact Assessment undertaken by the UK on its draft regulations unequivocally establishes the public health objectives which are being pursued. It states that: “Research evidence suggests that standardised packaging of tobacco products would contribute to the Government’s public health policy objectives by reducing the appeal of cigarettes, packs and brands, increasing the salience of health warnings, making perceptions of product harm and strength more accurate and reshaping smoking-related attitudes, beliefs, intentions and behaviour.⁽⁷⁷⁾ In other words, standardised packaging is capable of contributing to the attainment of the public health objective through a sub-set of goals: reduced attractiveness of the pack, increased salience of warnings, enhanced perception of harm. Each of these elements act as a proxy which proves the suitability of standardised packaging to attain its legitimate objective: public health. In the very same document, the UK government also demonstrates that all impacts have been considered and the measures proposed are therefore proportionate.⁽⁷⁸⁾

(c) Be proportionate

Member State action that departs or goes beyond what the EU requires, such as would be the case if the UK introduced standardised packaging on its territory, must satisfy a proportionality test which is similar to the test applied to EU-wide measures. According to established case law, an act is proportionate when it is suitable and necessary to achieve its declared goal.⁽⁷⁹⁾ In particular, the principle of proportionality requires:

- that measures adopted should not exceed the limits of what is suitable or appropriate in order to attain the legitimate objective pursued by the legislation in question (suitability limb); and
- where there is a choice between several appropriate measures, that recourse must be had to the least onerous method (necessity limb).

Because of the potentially disruptive effect that national measures may have on the EU internal market, EU courts tend to engage in a more intensive review when determining whether restrictive measures adopted by a Member State are suitable or necessary than when examining the proportionality of EU action.^{xxxii} Moreover, unlike what would occur should EU courts examine the legality of an EU-wide plain packaging scheme under EU law,

^{xxxii} See, on this point, A. Alemanno, *The Shaping of EU Risk Regulation by EC Courts* (Jean Monnet Working Paper 18/2008); P. Craig, *EU Administrative Law*, (Oxford University Press, 2nd edition, 2012), at p. 688-689 and 704-706.

national standardised packaging schemes would be examined solely in light of the objective of protecting public health under both the suitability and necessity tests. This is likely to lead the interpreter, be it the CJEU or a national court applying EU law, to engage in a closer analysis of the effectiveness of plain packaging in reducing tobacco consumption.

However, although the burden of proof bears on the acting Member State who has to adduce evidence or data in support of the contested measure, the national authorities cannot – in principle – *‘be deprived of the possibility of establishing that an internal restrictive measure satisfies those requirements, solely on the ground that that Member State is not able to produce studies serving as the basis for the adoption of the legislation at issue’*.⁽⁸⁰⁾ This would seem to suggest that, despite a more intrusive standard of judicial review, national measures should still survive, at least in principle, the proportionality scrutiny even in the absence of *‘hard’* evidence supporting them. This argument finds support in light of the existing evidence supporting the effectiveness of standardised packaging. While Sir Cyril Chantler conceded in his Review that no evidence allowed him *‘to quantify the size of the likely impact of standardised packaging’*, he concluded that it *‘is very likely to lead to a modest but important reduction over time on the uptake and prevalence of smoking’*.⁽⁸¹⁾ The Impact Assessment⁽¹²⁾ performed by the UK government made an attempt at quantifying the net benefit stemming from the proposed standardised packaging. While conceding that *‘quantification of the likely scale of the impact on smoking take up and prevalence is difficult in the absence of directly comparable precedents’*, it stated that *‘there is experience in the UK and internationally of other tobacco control interventions, particularly those involving tobacco advertising, promotion and marketing to provide insight into expected impacts of introducing standardised packaging’*. In particular, independent academic research was commissioned by UK Department of Health to gather an expert view on the likely scale of impact of standardised packaging from a range of tobacco control experts from around the world. The consensus (based on the median of reported views) of these experts is that the intervention would be expected to generate after two years:

- a decline in the proportion of 11-15 year olds who have ever smoked of three percentage points (from a baseline of 27% at the time of the research); and
- a decline in adult smoking prevalence of one percentage point (from a baseline of 21% at the time of the research), as more people find themselves able to quit.

By relying upon the TPD Impact Assessment,⁽⁸²⁾ the UK Impact Assessment estimates that around one tenth of this gain might plausibly be achieved by the TPD without standardised packaging. The rest of the gain provides our central estimate of the incremental gain attributable to standardised packaging.

The two limbs of the proportionality test are considered in turn and applied to the UK’s proposal to standardise the packaging of tobacco products.

Suitability

Under the first limb of the proportionality test, the question is whether a given intervention is suited to attain its declared objective. In the case of plain packaging, the objective pursued by the UK will be public health. More specifically, underlying the Government's choice will be the aim to decrease tobacco initiation among young people by reducing the attractiveness of tobacco products. Regardless of the exact objective adduced by the relevant Member State when choosing it, the suitability assessment of a national plain packaging scheme is set to lead the interpreter to assess the measure's effectiveness in achieving its public health objective.

Several difficulties exist when scrutinising the suitability of any public health intervention. This is mainly due to the difficulty in establishing a causal link between the resulting packaging and its expected outcome. The most direct experiment to test the actual impact of standardised packaging on the uptake of smoking amongst children would be a randomised controlled trial, i.e. a comparison of the uptake of smoking in children exposed to cigarettes in non-standardised branded packaging and in standardised packaging to see which group had the greatest propensity to take up smoking. However, to do so would require not only a suitably large and isolated population free of known confounding factors that influence smoking and prevalence, but also to expose a randomised group of children to nicotine exposure and possible addiction.⁽⁸³⁾ As Sir Chantler clearly stated, such an approach is neither possible nor ethical: *'given the highly addictive and harmful nature of smoking, such an experiment could, rightly, never receive ethical approval.'*⁽⁸⁴⁾

These difficulties are further compounded by the fact that any of the public health objectives previously mentioned (e.g. reduction of tobacco initiation, tobacco prevalence, public health gains) cannot be pursued by individual measures taken in isolation. There is no *'silver bullet'* in tobacco control: only a multi-sectoral policy may help facilitate tobacco prevention, which makes the effectiveness of a specific intervention all the more difficult – if not impossible – to quantify.⁽⁸⁵⁾ Therefore, the contribution which a plain packaging scheme could make to public health objectives should not be assessed in isolation: it should be considered as part of a coherent set of measures which the Department of Health has elected to adopt as part of its 2011 Tobacco Control Plan for England, including bans on the display of tobacco products at points of sale, increased taxation on tobacco products, public health campaigns, as well as other tobacco control measures included in the Children and Families Act such as making proxy purchasing an offence.

The EFTA Court, when called upon to assess the suitability of visual display ban of tobacco products at point of sale, held in its *Philip Morris* decision that *'where the EEA State concerned legitimately aims for a very high level of protection, it must be sufficient for the authorities to demonstrate that, even though there may be some scientific uncertainty as regards the suitability and necessity of the disputed measure, it was reasonable to assume that the measure would be able to contribute to the protection of human health'*.⁽⁷³⁾ As a result of the introduction of such an innovative approach to the suitability analysis of the contested measure, any court interpreting EU law, be it that of a Member State or of the EU,

should grant a wide margin of manoeuvre to Member States in selecting the tobacco control measures it wishes to implement, including plain packaging, even though their effects cannot be conclusively established. This case law is particularly relevant to the case of plain standardised packaging insofar as this measure has been applied to date for a limited period of time and only in one jurisdiction (Australia).^{xxxii} In any event – in light of the reasons discussed above, its effectiveness in reducing consumption is difficult to demonstrate conclusively.⁽⁸⁶⁾ Moreover, it is well known that the effect of any form of public health intervention tends to appear gradually and over time. More critically, the specific effects of health control policy are difficult to discern from those stemming from the overall policy. In these circumstances, any court should recognise – as the EFTA Court did in its *Philip Morris* decision – some general ability of a given policy tool to achieve its public health objective. It is suggested that the Court should check the reasoning put forward by a Member State to justify its national measure, without however substituting its assessment to that of the national legislature too readily in fields as complex as public health protection, and tobacco control more specifically.⁽⁸⁷⁾

Necessity

The second limb of the proportionality test implies an inquiry into the necessity of the measure adopted by the Member State: it cannot go beyond what is necessary to achieve its declared objective.⁽⁸⁸⁾ In practical terms, the necessity limb requires verification of whether there could be less restrictive measures that also achieve the declared goal. If these alternative policy options are available, the relevant Member State is bound to choose the least intrusive of all equally effective means. This examination inevitably requires a comparative analysis between the measure under examination and other policy options available. In a sector such as public health, this analysis is extremely difficult to carry out in light of the holistic approach which is required from competent public authorities. Which policy options should be considered? How should they be measured and compared, and with reference to what benchmark, when assessing the necessity of the chosen measure? Can it be said that the proposed standardised packaging scheme is the only measure that appears appropriate to cope with the danger posed by tobacco use, particularly by young people? Are there other forms of standardised packaging that could achieve the same level of protection while being less intrusive of tobacco manufacturers?

As previously discussed, the European Commission addresses this sort of questions when conducting an Impact Assessment of its proposals. In the case at hand, the Commission decided not to require plain packaging only after having examined all policy options which could be adopted at the EU level, including plain packaging. One may therefore wonder to what extent the policy options identified and the evidence gathered for each of them by the Commission may shape the necessity assessment by the interpreter. While EU Courts already refer to the analysis contained in an Impact Assessment when they are called upon to

^{xxxii} According to the Chantler Review, comprehensive surveys showing changes in prevalence since the introduction of plain packaging in Australia are not yet available. A survey from the Australian Institute of Health and Welfare is expected to report results of overall prevalence in October 2014 and estimates for youth prevalence are expected in August 2015.

examine the necessity of an EU measure,⁽⁸⁹⁾ it is not clear whether they could rely on the very same evidence when called upon to verify the necessity of a national measure. In our view, it is likely that EU Courts, should they be called upon to examine the necessity of any national standardised packaging scheme, may take the Commission's Impact Assessment into account in determining how that measure scores as compared to other policy options. It appears less likely that EU Courts will consider the impact assessment performed by the United Kingdom to support its measure. This is true for at least two reasons. First, the requirements for standardised packaging envisaged by the UK substantially overlap with those the Commission examined in its Impact Assessment, which may therefore offer a useful analysis. Second, the UK impact assessment does not explicitly examine – unlike the one performed by the EU – the proportionality of the policy option considered.⁽⁹⁰⁾ At the same time, one must consider that also the EU Impact Assessment of standardised packaging falls short of providing a complete analysis. It only focuses on the impacts of the different policy options, including plain packaging, on the assumption that they could be adopted at EU level, not by a Member State. While it is obvious that the scale of their effects may change, it is submitted that the evidence gathered in relation to their individual ability to achieve the declared objective could be useful also in relation to the UK requirements.

Thus, should EU Courts refer to the Impact Assessment Report accompanying its proposal for a revised TPD, they will find that standardised packaging promises important health benefits, whilst its economic effects remain difficult to determine.⁽⁹¹⁾ In its Impact Assessment, the Commission highlighted the many benefits that plain packaging may bring about in terms of health gains as compared to other policy options involving less standardisation of the packaging of tobacco products. In particular, it explicitly recognises that *'although no studies based on real life experiences are available at this stage, many recent studies indicate that plain packaging not only increases the noticeability and effectiveness of health warnings, but also reduces substantially the attractiveness and appeal of tobacco packaging, the product, particular brands, and smoking (both to smokers and potential smokers) as well as false beliefs about the risks associated with different brand variants'*.⁽⁹²⁾ As a consequence, the study concludes that *'plain packaging may help to reduce tobacco consumption and smoking prevalence, in particular by discouraging young people from taking up smoking, by reducing tobacco consumption among young adult smokers'*.⁽⁹³⁾

Yet, the necessity test does not require the policymaker to choose the most effective policy option in achieving its declared goal. Rather, it is its cost-effectiveness when measured against other policy options that determines whether the chosen policy option, i.e. standardised packaging, is necessary to attain its objective. In determining the cost-effectiveness of a national standardised packaging scheme, one has to consider a dimension that was inevitably lacking from the Impact Assessment: its limited territorial nature (i.e. the UK and not the EU). The costs of a national standardised packaging scheme may disrupt – to some extent at least – the functioning of the internal market: tobacco products will have to be specifically packaged for the UK market, thus hindering the free movement of goods across the EU. However, in establishing the necessity of standardised packaging, the interpreter may suggest that, given the current circumstances characterising the EU market for tobacco

products (i.e. a passive market), a standardised packaging scheme is arguably necessary to achieve its objective.⁽⁹⁴⁾ Moreover, the UK may also insist on its duties and obligations as they derive from its commitments under the FCTC (as it did in its proposal), which explicitly encourages its parties to implement *inter alia* standardised packaging.^{xxxiii} Finally, the interpreter may also decide to assess the necessity of the proposed standardised packaging not only as a single measure but also as one component of a wider legislative intervention, including for instance the criminalisation of proxy purchasing and other measures, as discussed above. In so doing, it may want to refer to the Impact Assessment accompanying the UK proposal.

(d) Not a means of arbitrary discrimination or disguised restriction on trade between Member States

This condition overlaps with the first condition, namely that the measure must be applicable to all products placed on the Member State's market. On the basis of the analysis we have provided above, we conclude that the introduction of a standardised packaging scheme on tobacco products in the UK would fulfil this condition and would not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States: the scheme would apply equally to all tobacco products, irrespective of their origin.

(e) Be notified to the Commission

The modalities of the notification to the Commission of the *'further requirements [...] in relation to the standardisation of the packaging of tobacco products'* are defined in the adopted TPD. In the absence of a more specific procedure, the relevant Member State is subject to the notification regime established by Directive 98/34.⁽⁹⁵⁾

Directive 98/34 sets up a procedure which imposes an obligation on Member States to notify to the Commission and to each other all the draft technical regulations concerning products as well as Information Society Services before they are adopted in national law. As such regulations could create unjustified barriers to the free movement of goods between Member States, their notification in draft form and subsequent evaluation of their content in the course of the procedure may promote transparency and control with regard to those regulations.^{xxxiv} As the CJEU has confirmed, Directive 98/34 has a general aim of *'eliminating or restricting obstacles to trade, to inform other States of technical regulations envisaged by a State, to give the Commission and the other Member States time to react and to propose amendments for lessening restrictions to the free movement of goods arising from the envisaged measure and to afford the Commission time to propose a harmonising directive'*.⁽⁹⁶⁾ Moreover, the wording of the directive is clear that it provides for a procedure for EU control of draft

^{xxxiii} This is discussed more fully in the first part of this opinion

^{xxxiv} See Recitals 2 to 10 of the Preamble of the EU TPD

national regulations whose date of their entry into force is made subject to the Commission's agreement or lack of opposition.⁽⁹⁷⁾

A proposal to adopt standardised packaging constitutes a draft technical specification subject to the notification requirement under the provisions of Directive 98/34. In effect, a *'technical specification'* is defined as *'a specification contained in a document which lays down the characteristics required of a product [...] including the requirements applicable to the product as regards [...] packaging, marking or labelling [...]'*.⁽⁹⁷⁾

Importantly for our purposes, the CJEU has held that a breach of the obligation to notify renders the technical regulations concerned inapplicable, so that they are unenforceable against individuals.⁽⁹⁶⁾ It is therefore important that any standardised packaging measures the UK is considering notifying to the Commission should be in accordance with the provisions of Directive 98/34 if these measures are to be successfully applied and enforced against tobacco industry operators on the national territory.

2. Other legality concerns relating to the interaction between EU law and national law

(a) EU Trademark Law

All forms of standardisation of the package of tobacco products, including plain packaging, raise significant legal concerns in relation to intellectual property rights, notably trademark law.⁽⁹⁸⁾ This is all the more true for plain packaging, such as that envisaged by the UK government, as it entails the removal not only of all the design elements typically displayed on cigarette packs, but also of the use of the characterising features of brand names (e.g. *'Marlboro'*, *'Camel'*...). In particular, it requires that the distinctive typeface, colour and font size of tobacco signs, which tobacco manufacturers typically register all these signs as trademarks, be replaced by a standard plain format.

Article 2 of Directive 2008/95 (*'Trademark Directive'*)⁽⁹⁹⁾ provides that *'a trade mark may consist of any signs capable of being represented graphically, particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, provided that such signs are capable of distinguishing the goods or services of one undertaking from those of other undertakings'*.⁽¹⁰⁰⁾ An analogous provision is contained in Article 4 of Regulation 207/2009 (*'Trademark Regulation'*).⁽¹⁰¹⁾

Given the likelihood that these EU trademark provisions could be invoked to oppose the introduction of a tobacco control measure such as standardised packaging, the following paragraphs analyse the compatibility of the Standardised Packaging of Tobacco Products Regulations with EU trademark law.

The UK plain packaging scheme may raise the following three legal concerns:

- it may jeopardise the main function of trademarks;
- it may infringe trademark's rights; and
- it may infringe the unitary character of trademark.

Does plain packaging jeopardise the main function of trademarks?

Trademarks make it easier for the public to take educated purchase decisions. It is for this reason that, in order to be registrable, trademarks should effectively distinguish the goods or services of one company from those of other companies.⁽¹⁰²⁾ This has been recognised by the EU courts as well as by the decision practice of the Office for Harmonization in the Internal Market ('OHIM').⁽¹⁰³⁾

This fundamental function may be threatened should trademarks not be visible, or even available, to consumers when selecting a product. This is exactly what standardised packaging – as set out in the requirements proposed by the UK government – would create, as all of the distinctive elements displayed on the box would be removed. This new measure may therefore threaten consumers' ability to make reasoned choices, as there would be little difference — besides the brand names — between the different cigarette boxes marketed by tobacco companies.

The concerns related to the loss of distinctiveness appear heightened if examined in the light of CJEU findings made in proceedings involving the legality of the TPD. In this case the CJEU was called upon to examine the extent to which the prohibition of descriptors such as 'light', 'ultra-light', 'low-tar' and 'mild' could infringe the fundamental right to property, including intellectual property and trademark rights. After confirming that this provision prohibits the use of trademarks incorporating the above descriptors, the Court noted that tobacco producers may continue using other distinctive signs on the packs. In particular, it held that *'[w]hile that article entails prohibition, in relation only to the packaging of tobacco products, on using a trade mark incorporating one of the descriptors referred to in that provision, the fact remains that a manufacturer of tobacco products may continue, notwithstanding the removal of that description from the packaging, to distinguish its product by using other distinctive signs'*.⁽¹⁰⁴⁾ According to an *a contrario* interpretation of this finding, it may seem that a measure that does not allow tobacco producers to use signs capable of distinguishing their products might negatively impact on the main function of their trademarks.⁽¹⁰⁵⁾

Yet the above finding could not be invoked to claim that standardised packaging is not compliant with EU trademark law. The distinctiveness of a trademark is relevant when it comes to granting registration, with the result that signs devoid of distinctive character will not be protected.⁽¹⁰²⁾ However, this does not mean that public law measures that have a negative impact on the distinctive character of already registered trademarks are necessarily contrary to EU law as there is not a general prohibition on restricting the use of distinctive elements under EU law. The UK proposal expressly states that the standardisation

requirements that it puts forward do not affect the ability to register trademarks and designs for tobacco products.⁽¹⁰⁶⁾

Does plain packaging infringe trademark rights?

In order to determine if standardised packaging is contrary to EU trademark law, it is necessary to investigate if and to what extent it encroaches upon the rights offered by trademark registration. Article 5 of the Trademark Directive and Article 9 of the Trademark Regulation lay down the scope of protection given by a trademark registration. It is generally believed that these provisions do not offer their owners a positive right to use the protected sign, but a negative right to prevent third parties from using it.⁽¹⁰⁷⁾ Indeed, the right to use a sign does not arise from registration at all, but from the freedom to carry out commercial activities in the market.⁽¹⁰⁸⁾ As a matter of fact any person interested in trading is free to start using trademarks for distinguishing his or her products and services, provided that such signs do not infringe upon earlier exclusive rights owned by third parties.

This reading is disputed by some commentators, who consider it too formalistic: by permitting a right of registration but at the same time denying a right of use — it is argued — such an interpretation may annihilate the whole aim of registration, which is to offer owners a right of exclusive use.⁽¹⁰⁹⁾ Yet the above disputed reading was endorsed by Advocate General Geelhoed in his Opinion on the validity of the TPD, where he stated that:

‘[T]he essential substance of a trademark right does not consist in an entitlement as against the authorities to use a trademark unimpeded by provisions of public law. On the contrary, a trademark right is essentially a right enforceable against other individuals if they infringe the use made by the holder’.⁽¹⁰⁹⁾

Following this interpretation, it would seem that standardised packaging — which would be implemented by *‘provisions of public law’* — would not breach trademark rights as it does not authorise third parties to exploit tobacco signs, but merely consists of a restriction on right owners’ ability to use their own signs. Despite the loss of distinctiveness of tobacco trademarks, rights holders could still exercise the right to prohibit the misappropriation of their signs by unauthorised third parties.

Thus, the fact that trademark rights are essentially negative rights under EU law should permit Member States, including the UK, to pursue and adopt public policies, such as measures aimed at protecting public health. The validity of this conclusion finds further support in the WTO Panel in the *EC – Trademarks and Geographical Indications (Australia)*,⁽¹¹⁰⁾ a case opposing the US and the EU regarding the former’s coexistence regime between geographical indications and trademarks.^{xxxv} In that case, the Panel held that a *‘fundamental feature of intellectual property protection inherently grants Members freedom*

^{xxxv} The EU and its Member States are WTO Members and thus they must respect WTO agreements including TRIPS and the interpretations given by WTO adjudicatory bodies

to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement’.⁽¹¹⁰⁾

The unitary effect of Community trademark law

A final concern raised by the introduction of any form of standardisation of the package, including that advanced by the UK, relates to one of the main principles of EU trademark law: the so-called ‘unitary effect’ of the Community Trademark. According to this principle, the EU trademark is a unique title granted by the Office for the Harmonization in the Internal Market that is valid in all the twenty-eight EU Member States. According to this principle, as enshrined in Article 1(2) of the Trademark Regulation,⁽¹¹¹⁾ a Community Trademark has ‘an 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’.^{xxxvi} In other words, the Community Trademark consists of a unique title that is valid in all 28 Member States, meaning that its use cannot – in principle – be prohibited in individual countries. The introduction of standardised packaging requirements at a national level, by preventing or limiting the use of Community Trademarks in some Member States but not others, might clash with the unitary character of the Community Trademark system. Article 22 of the Trademark Regulation provides for a sole exception to this principle by stating that a Community Trademark may be licensed for the whole or part of the Union. Although the Trademark Regulation does not foresee other exceptions to the principle of unitary effect allowing individual Member States to prohibit the use of Community Trademarks licensed for the EU as a whole, it is argued that this does not automatically imply that standardised packaging violates this principle and, should this be the case, that this principle could not suffer from other derogations. One must observe that standardised packing does not amount to a total prohibition of the trademark, but merely to a restriction to its use in on the tobacco products’ packs. Moreover, Article 110(2) of the Community Trademark – by foreseeing the possibility to limit the use of a EU trademark in one or more EU Member States^{xxxvii} – seems to suggest that it is actually possible to limit the unitary character of the EU trademark.⁽¹¹²⁾

In these circumstances, it is submitted that the unitary character of the EU trademark does not represent an obstacle to the introduction of a standardised packaging by an individual Member State, such as the UK.

(b) EU fundamental rights

^{xxxvi} This provision applies unless otherwise provided in the Trademark Regulation (see Recital 3).

^{xxxvii} This provision reads as follow: This Regulation shall, unless otherwise provided for, not affect the right to bring proceedings under the civil, administrative or criminal law of a Member Sate or under provisions of Community law for the purpose of prohibiting the use of a Community trade mark to the extent that the use of a national trade mark may be prohibited under the law of that Member State or under Community law.

The EU is ‘founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights’.⁽¹¹³⁾ As a result, the EU and its Member States when interpreting, applying or implementing EU law must comply with fundamental rights. More specifically, Article 6 of the Treaty on European Union identifies three main sources of EU fundamental rights: the EU Charter of Fundamental Rights (EU Charter), the European Convention on Human Rights and Fundamental Freedoms (ECHR), and the general principles of EU law resulting from the constitutional traditions common to the Member States.

Virtually all attempts of tobacco manufacturers to challenge the legality of EU and national tobacco control measures have been accompanied by the invocation of a breach of their fundamental rights. In particular, tobacco manufacturers have argued that EU and/or national measures regulating the content, presentation (including the packaging and the labelling), advertising or promotion of their products infringe several of the fundamental rights they derive from EU and/or national law, not least: the freedom of expression and information, the freedom to choose an occupation and the right to engage in work, the freedom to conduct a business, and the right to property.⁽¹¹⁴⁾ All these rights are protected by the EU legal order. Nevertheless, none of them is absolute: they may be restricted on grounds of public health protection.⁽¹¹⁵⁾ The CJEU has granted a particularly broad margin of discretion to the EU and the national legislatures in deciding which measures should be put in place as part of the EU and national tobacco control strategies. This is not to suggest, however, that policy makers can dispense with the proportionality assessment involved in balancing competing rights against each other.

The right to property and the freedom to conduct a business

The right to property and the freedom to conduct a business are often invoked *in tandem*. In a consistent line of decisions delivered before the EU Charter became legally binding, the CJEU highlighted that neither of those rights constituted an unfettered prerogative but had to be viewed in light of their social function. They could therefore be restricted provided that the restrictions imposed corresponded to objectives of general interest pursued by the EU; and that they did not constitute, as regards the aim pursued, a disproportionate and intolerable interference with the very substance of the rights thus guaranteed.⁽¹¹⁶⁾ The Court unequivocally applied these principles in the *British American Tobacco* judgment where it rejected any suggestion that the EU had unlawfully interfered with the right to property of tobacco manufacturers and their freedom to pursue a trade or profession by adopting the TPD:

‘As regards the validity of the Directive in respect of the right to property [...] the only effect produced by Article 5 of the Directive is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets to show their trademarks without prejudicing the substance of their trade mark rights, the purpose being to ensure a high level of health protection when the obstacles created by national laws on labelling are eliminated.’⁽¹¹⁷⁾

The Court also emphasised that imposing a limitation on the freedom to trade and pursue a profession was no more than the consequence of the restriction upon the exercise of the right to property, so that the two restrictions merged. Thus, the reasons justifying the restriction upon the manufacture and distribution of tobacco products were the same as those justifying the restrictions placed upon the use of property. Moreover, as EU institutions enjoy a margin of discretion in the choice of the means needed to achieve their policies, traders are unable to claim that they have a legitimate expectation that an existing situation which is capable of being altered by decisions taken by those institutions within the limits of their discretionary power will be maintained. In particular, no informed trader is entitled to expect that patterns of trade will be respected.⁽¹¹⁸⁾ Finally, by virtue of the principle of proportionality, measures imposing financial charges on economic operators are lawful provided that the measures are appropriate and necessary for meeting the objectives legitimately pursued by the legislation in question.⁽¹¹⁹⁾

Following the entry into force of the Lisbon Treaty, the Court has maintained this approach, except that it relies directly on the EU Charter rather than on the unwritten general principles of EU law.^{xxxviii}

In light of the Court's case law, tobacco manufacturers affected by tobacco control measures are unlikely to succeed in their claims if they submit that their fundamental right to property, including intellectual property, and fundamental freedom to pursue their business are infringed because they have to bear some of the economic burden of measures imposed to restrict tobacco use. Therefore, should the UK impose the standardised packaging of tobacco products, preventing the use of brands on tobacco products, it is arguable that the very substance of the right to property and the freedom to trade would not be affected.^{xxxix} Tobacco manufacturers would continue to benefit from the protection that intellectual property law offers traders from the unauthorised use of their trademarks by third parties.⁽¹²⁰⁾

^{xxxviii} For a recent example of how the Court balances competing interests when invoking the EU Charter, and in particular Article 16 (freedom to conduct a business) and Article 17 (right to property), see Case C-283/11 *Sky Österreich* [2013] ECR I-28. In this judgment, the Grand Chamber confirmed that the EU legislature was entitled to give priority, in the necessary balancing of the rights and interests at issue, to overriding requirements of public interests over private economic interests, on the condition that the restriction was proportionate, i.e. that a fair balance had been struck between several rights and fundamental freedoms protected by the EU legal order with a view to reconciling them (at paragraph 60). On the facts of the case, the Court concluded that the EU legislature could limit the freedom to conduct a business and the right to property 'to give priority, in the necessary balancing of the rights and interests at issue, to public access to information over contractual freedom' (at paragraph 66). See by analogy in relation to alcoholic beverages, Case C-544/10 *Deutsches Weintor* [2012] ECR I-526.

^{xxxix} Article 52(1) of the EU Charter requires that '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', thus recognising that there are 'limitations on limitations' to fundamental rights and freedoms under the 'essential core' doctrine: any limitation on fundamental rights – even proportionate ones – must never undermine the 'very substance' of a fundamental right. This sets an absolute limit to all governmental power by identifying an 'untouchable' core within a right. However, the role of this doctrine remains unclear in EU law: R. Schütze, *EU Constitutional Law* (CUP, 2012), at p.419.

Freedom of expression

Tobacco manufacturers have also argued that restrictions on tobacco advertising and sponsorship violate their right to free commercial expression.⁽¹²¹⁾ Freedom of expression is of a different nature, as it does not pertain to the products, the services or the brands manufacturers place on the market, but to the commercial discourse they develop in order to promote their consumption.

Under Article 10 of the ECHR, ‘everyone has the right to freedom of expression’,⁽¹²²⁾ and this provision has been held to apply not only to artistic and political but also to commercial expression,⁽¹²³⁾ on the ground that consumers have the right to receive information on the goods and services available to them on a given market: ‘for the citizen, advertising is a means of discovering the characteristics of goods and services offered to him’.⁽¹²⁴⁾ Nevertheless, freedom of expression may also be restricted on public health and other public interest grounds provided that the restriction in question is proportionate.⁽¹²⁵⁾ Thus, in the *Tobacco Advertising II* judgment, the Court rejected the argument put forward by tobacco manufacturers that the contested TAD constituted an unlawful interference with their right to free commercial expression. After recalling its settled case law that the EU legislature should be granted a broad margin of discretion in areas entailing political, economic and social choices on its part, and in which it was called upon to undertake complex assessments,⁽¹²⁵⁾ the Court concluded that even assuming that the measures laid down in Articles 3 and 4 of the Directive prohibiting advertising and sponsorship had the effect of weakening freedom of expression indirectly, the measures they imposed were not disproportionate. The legality of a measure such as the ban on tobacco advertising and sponsorship can be affected only if the measure is ‘*manifestly inappropriate*’ having regard to the objective which the competent institutions seek to pursue.⁽¹²⁶⁾ That the judiciary grants a broad margin of discretion to the legislature – be it the EU legislature or the national legislature⁽¹²⁷⁾ – is all the more necessary, ‘*in a field as complex and fluctuating as advertising*’.⁽¹²⁷⁾

The Court has tended to grant an extremely broad margin of discretion to the EU legislature in determining how far it would restrict fundamental rights to ensure a high level of public health protection. It is highly commendable that the Court has not substituted its assessment to that of the legislature.^{x1} Tobacco control regulation does involve complex assessments which result not only from the scientific understanding of specific health risks but also from the social and political evaluation of those risks.⁽¹²⁸⁾ EU political institutions are better equipped than the Court to determine how competing interests should be balanced against each other. This does not mean, however, that the EU legislature has a *carte blanche*: it bears the burden of proving that the measures it has adopted are suitable and necessary to achieve their objective of reducing the health and social burden resulting from tobacco use in the EU.

^{x1} The respective role of judges and administrators are fundamentally distinct and should remain so: J. Jowell, ‘Beyond the Rule of Law: Towards Constitutional Judicial Review’, *Public Law* (2000) 671, at p.681.

Discretion does not mean arbitrariness.^{xli} If the Court's decision in *Tobacco Advertising II* may be criticised for its failure to engage as effectively as it could have with existing evidence demonstrating the proportionality of the advertising ban, the outcome of the case is nonetheless compelling.⁽⁸⁷⁾ The FCTC has called on its Parties to introduce comprehensive bans on tobacco advertising, promotion and sponsorship so that the consumption of tobacco products is reduced.⁽³¹⁾ Thus, it is legitimate for the EU and its Member States as parties to the FCTC to limit the freedom of industry operators to promote cigarettes and other tobacco products whose consumption is inherently harmful to health. Advertising bans and packaging restrictions are therefore intended to support the creation of a '*passive market*' for tobacco products: if such products can still lawfully be placed on the EU market, the EU and its Member States nonetheless have a duty to regulate this market to steer existing and potential consumers away from smoking in light of the costs of smoking and the evidence linking marketing and consumption patterns. The legality of a measure such as the ban on tobacco advertising and sponsorship can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institutions seek to pursue.⁽¹¹⁷⁾

Shifting the paradigm: using fundamental rights as a 'sword'

The shortcomings of the fundamental rights discourse developed by industry operators, where fundamental rights are invoked as a '*shield*', i.e. by the tobacco industry as a way to systematically challenge tobacco control measures, are even more glaring if assessed in light of the arguments supporting the use of fundamental rights as a '*sword*', i.e. by legislators as a vehicle for better health as part of their tobacco control strategies.^{xlii}

If the ECHR does not contain specific provisions on health, the EU Charter does: Article 35 provides that '*a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*'. Furthermore, the right to health can be considered as falling within the general principles of EU law in light of the fact that all Member States have ratified the two UN Treaties offering its most comprehensive expression, namely: Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and Article 24 of the Convention on the Rights of the Child (CRC).^{xliii} Therefore, the question is not so much whether the right to health is protected by the EU legal order, but what this right entails and how it can be operationalised to support effective tobacco control strategies, including the adoption of plain packaging schemes.

^{xli} English courts have expressed this point elegantly: 'The protection of public health is a very important counter-balance to unrestricted commercial expression. It is not a factor affording to a decision maker an unfettered discretion.' (McCombe J. in *The Queen v BAT UK et al*, [2004] EWHC 2493 (Admin), at paragraph 32.

^{xlii} This argument was first made and is developed more fully in A. Alemanno and A. Garde (2013). [Regulating Lifestyles in Europe: How to Prevent and Control Non-Communicable Diseases Associated with Tobacco, Alcohol and Unhealthy Diets?](#) Swedish Institute for European Policy.

^{xliii} One should note that before the adoption of the ICESCR and the CRC, Article 25 of the Universal Declaration of Human Rights already provided: 'everyone has the right to a standard of living adequate for the health and the well-being of himself and of his family'. The right to health has also been expressed in a range of other UN Treaties, including the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, the International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families, and the Convention on the Rights of Persons with Disabilities. For a comprehensive discussion of the right to health in international law, see J. Tobin, *The Right to Health in International Law* (OUP, 2012).

The concept of health is defined very broadly as ‘a state of complete physical, mental and social well-being’, rather than merely the absence of disease or infirmity.⁽¹²⁹⁾ As such, this definition, which was explicitly endorsed by the CJEU in its *Working Time Directive* judgment,⁽¹³⁰⁾ extends the right to health beyond the provision of medical care to encompass the right to prevention, treatment and control of diseases. This is not to say, however, that the right to health is a right to be healthy; rather, it is ‘*a right to the highest attainable standard of health*’,⁽¹³¹⁾ subject both to an individual’s biological, social, cultural and economic preconditions and the State’s available resources. In particular, the right to health requires that States ensure ‘*the prevention, treatment and control of epidemic, endemic, occupational and other diseases*’,⁽¹³²⁾ that they ‘*develop preventive health care*’⁽¹³³⁾ and that they ‘*combat disease and malnutrition*’.⁽¹³⁴⁾

In recent years, a growing number of international law documents have confirmed that States can invoke the right to health in order to promote healthier lifestyles and support their tobacco control strategies. Thus, the FCTC refers explicitly to Article 12 of the ICESCR in its Preamble. This supports the argument that several scholars have put forward that tobacco control is an integral component in the protection of the right to health.⁽¹³⁵⁾ Not only is the burden of the tobacco pandemic not fairly distributed – tobacco consumption rates being much higher among poor communities both within and among States. But exposure to tobacco prevents the fulfilment of the right to health, as well as several health-related rights, including the right to life, the right to a clean environment and the right to information. Tobacco control measures, including the adoption of standardised packaging schemes, are therefore arguably intended to implement the commitments of public authorities to respect, protect and fulfil these rights.⁽¹³⁵⁾

In light of the interdependence and indivisibility of international human rights, the realisation of the right to health is indispensable for the enjoyment of all the other rights, and achieving the right to health is dependent on the realisation of many other human rights. The other rights which could be invoked in relation to tobacco control include the right to life, the right to a clean environment, the right to information,⁽¹³⁶⁾ the right to education, and the umbrella principle requiring that all actions concerning children shall be taken in their best interest.^{xliv}

Embracing a fundamental-rights approach to tobacco control would not only strengthen the basis for the adoption of effective smoking prevention and control measures, but it would also highlight the need to reduce social disparities in health between different population groups, providing equality of opportunity for all to enjoy the highest attainable standard of health.⁽¹³⁷⁾

^{xliv} In its General Comment N° 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration, the Committee on the Rights of the Child stated: ‘one needs to bear in mind that the purpose of assessing and determining the best interests of the child is to ensure the full and effective enjoyment of the rights recognised in the Convention and its Optional Protocols, and the holistic development of the child’ (at paragraph 82).

While virtually all attempts made by the tobacco industry to challenge the legality of measures adopted at national or EU level to regulate tobacco products have been accompanied by the invocation of a breach of fundamental rights, as discussed above, this does not imply that the law cannot be used as a tool to promote the right to health and several other fundamental rights protected by the EU legal order. Some encouraging signs can be found in the recent case law of EU Courts. For example, in its *Deutsches Weintor* decision,⁽¹³⁸⁾ the CJEU specifically relied on Article 35 of the EU Charter to dismiss the claims of alcoholic beverages industry operators that the EU legislature had exceeded the limits on its margin of discretion by banning the use of health claims on all beverages containing more than 1.2% alcohol by volume.⁽¹³⁹⁾ This decision supports the argument that fundamental rights may be invoked not only as a shield by industry operators to protect their private economic interests, but also as a sword by competent regulatory authorities – be it the EU or its Member States – when regulating, in the general public interest, the activities of these very operators.^{xlv}

^{xlv} It is noteworthy that the wording of Article 35 of the EU Charter is less prescriptive than Article 12 of the International Covenant on Economic, Social and Cultural Rights (as broadly interpreted by General Comment N°14 (2000) and Article 24 of the UN Convention on the Rights of the Child, the two main sources of the right to health in international law. Nevertheless, Article 35 should be interpreted in their light for coherence purposes.

IV. Conclusion on the compatibility of a UK plain packaging scheme on tobacco products with the TPD

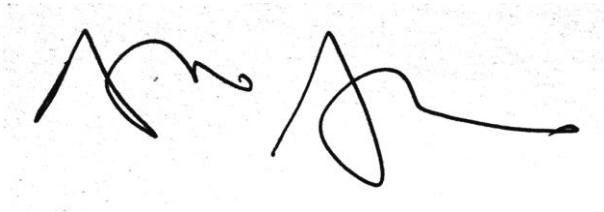
The drivers behind the enactment of standardised packaging legislation at the national level are similar to those that might lead the EU to adopt these requirements. In the area of tobacco, all Member States are parties to the FCTC. In particular, Article 11 and Article 13 of the Convention and their implementing Guidelines encourage them to develop effective restrictions on the labelling and advertising of tobacco products. In principle, in the absence of EU regulatory action, Member States are free to adopt standardised packaging schemes within their own jurisdictions,⁽¹⁴⁰⁾ provided that they comply with the conditions laid down in the TPD and in the EU Treaties.

Our analysis suggests that the UK Department of Health enjoys a broad margin of discretion to introduce a standardisation scheme of tobacco products, such as the one it proposed in the framework of the 2014 Consultation, on its territory. The evidence supporting standardised packaging keeps accumulating. The Chantler Review adds to the calls for standardised packaging, and does so in no uncertain terms – though it recognises the inherent limitations of the evidence policy makers have at their disposal. As it points out in its concluding remarks, *‘it is important to note that proponents of standardised packaging include the World Health Organization, Public Health England, local Directors of Public Health and a host of experts involved in the field of human health’*, i.e. *‘long-time devoted members of the public health community’*.⁽¹⁴¹⁾ The UK’s proposed regulations and its Impact Assessment draw on this evidence and present it as clearly as possible bearing the conditions the TPD and the EU Treaties lay down to determine the validity of a national scheme standardising tobacco products.

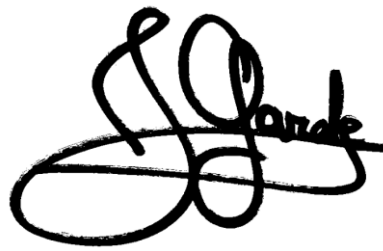
A broad margin of discretion does not mean that the UK will not have to justify its measures if they are challenged before the CJEU or before national courts on the basis of EU law: as we hope we have shown, discretion does not equate with arbitrariness. Consequently, the Government should be fully aware of the conditions the TPD and the EU Treaties lay down and how these conditions are likely to be interpreted by the CJEU or by national courts. In particular, it needs to be aware of the importance of framing existing evidence within the limits of the proportionality test – and its two limbs of suitability and necessity – to increase its chances of success. We have argued that there is ample scope to do so successfully, in light of the evidence supporting the introduction of standardised packaging schemes as effective tobacco control measures and more specifically the explicit calls of the international public health community on the Parties to the FCTC to consider implementing such schemes, even in their most restrictive form of plain packaging.

In this Legal Opinion, we have focused on the compatibility of the UK draft Standardised Packaging of Tobacco Products Regulations with EU law. We concluded that all the packaging requirements they propose are compatible with both the EU TPD and, more generally, EU law. However, the introduction of standardised packaging in

the UK is set to raise legal concerns not only under EU law (and in particular under free movement, trademark and fundamental rights law), but also under other legal orders. In particular, as illustrated by the numerous pending litigations brought against Australia, the Standardised Packaging of Tobacco Products Regulations are likely to be challenged under WTO law⁽¹⁴²⁾ and investment regimes applicable to the UK. Similarly, the introduction of these regulations may be challenged in judicial review actions based on English law, not least on the basis of the Human Rights Act 1998 as interpreted by English courts.^{xlvi}

Handwritten signature of Alberto Alemanno, consisting of a stylized 'A' followed by a series of loops and a long horizontal stroke.

Alberto Alemanno

Handwritten signature of Amandine Garde, featuring a large, stylized 'G' and 'A' followed by the name 'Garde' in a cursive script.

Amandine Garde

14 November 2014

^{xlvi} In relation to tobacco control, see for example *The Queen v BAT UK et al* [2004] EWHC 2493 ... (Admin).

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- (124) *Casado Coca v Spain*, para 51; see also *Krone Verlag GmbH & Co. KG v Austria*, para 31. This statement is all the more relevant in light of the role which advertising has been granted in EU internal market law.
- (125) Article 10(2) of the ECHR, which explicitly provides for the possibility to restrict the freedom of expression, differs from Article 11 of the EU Charter.
- (126) See Case C-491/01 *British American Tobacco* [2002] ECR I-11453, at paragraph 123.

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