DH Consultation on Implementation of the revised Tobacco Products Directive (2014/40/EU)
Response from Action on Smoking and Health

About ASH

1. ASH (UK) is a health charity set up by the Royal College of Physicians in 1971, working towards the elimination of harm caused by tobacco. ASH receives core funding from the British Heart Foundation and Cancer Research UK and has received project funding from the Department of Health for work to support delivery of the Government's tobacco strategy for England. ASH does not have any direct or indirect links to, or receive funding from, the tobacco industry.

2. ASH wishes to engage further with the Government on the areas impacted by the Implementing and Delegated Acts and will complete the online form referenced in Section 9 to this effect.

Question 1: Should the Government request peer review of any reports submitted by the tobacco industry in relation to certain additives contained in a priority list of additives?

3. ASH strongly supports the Government requiring (not requesting) peer review of any reports submitted by the tobacco industry in relation to additives, and recommends that the costs of such review should always be borne by the industry.

4. The tobacco industry has a long history of suppressing information it holds on the harm caused by its products, and of commissioning research to support its policy positions and resist regulation, generally published without an adequate statement of methodology and without peer review. The general approach of the tobacco industry to the evidence of harm caused by smoking has been well described as the *"manufacture of uncertainty"*, for example over the health effects of secondhand smoke.[1]

5. A recent academic article reviewed submissions from British American Tobacco and Japan Tobacco International to the UK Government's July 2013 consultation on standardised packaging. The article concluded that:

> *"First, the TTCs* [transnational tobacco companies] *misquoted published studies, thereby distorting the main messages of these studies. For example, the TTCs sometimes omitted important qualifying information when quoting from published studies. Second, the TTCs undermined evidence by employing experts to review published studies for methodological rigor and value in ways that did not conform to normal scientific critique approaches ('mimicked scientific critique'). So, for example, the experts considered each piece of evidence in isolation for its ability to support standardised packaging rather than considering the cumulative weight of the evidence. Finally, the TTCs engaged in 'evidential landscaping'. That is, they promoted research that deflected attention from standardised packaging (for example, research into social explanations of smoking behaviour) and omitted internal industry research on the role of packaging in marketing."* [2]

[1] Well summarised in Tobacco Explained: The truth about the tobacco industry ... in its own words, by Clive Bates and Andy Rowell. Published by the World Health Organization

[2] Ulucanlar S, Fooks G, Hatchard J, Gilmore A. Representation and Misrepresentation of Scientific Evidence in Contemporary Tobacco Regulation: A Review of Tobacco Industry Submissions to the UK Government Consultation on Standardised Packaging. PLoS Medicine March 25 2014. DOI: 10.1371/journal.pmed.1001629

6. ASH concludes that no research published or commissioned by the tobacco industry, or its funded front groups and surrogates, should be taken at face value, and therefore peer review should be required. Since the tobacco industry uses such research to defend its highly profitable market, it follows that it should meet proportionate costs of such peer review.

7. In order to ensure a consistency of approach, and ensure that it is carried out in the most efficient and effective way, peer review should be overseen by the European Commission, which should also be responsible for recouping the costs from the tobacco industry.

Question 2: The Government intends to implement this provision of the Directive [TPD Article 8.8 – Images of packs targeting consumers] to mean images, targeted at consumers, that are used to promote the sale of products, such as retailer websites offering products for sale. Do you agree with this approach?

8. ASH agrees with the Government's approach in principle, but in practice there are potential loopholes. Tobacco advertising was effectively prohibited in the UK by the Tobacco Advertising and Promotion Act 2002, and retail displays under the Tobacco Advertising and Promotion (Display) (England) Regulations 2010 and the Tobacco Advertising and Promotion (Display of Prices) (England) Regulations 2010 (implemented between 2012 and 2015), and similar legislation covering the devolved jurisdictions. There remain a small number of cases in which images of tobacco products may appear in the media, for example in illustrating a news story, in music videos, films or TV programmes. It is important that such residual opportunities for displaying tobacco products should not be used to circumvent the regulations prohibiting advertising. There is also independent evidence that the tobacco industry has been engaged in covert marketing of its products through online resources such as YouTube.[3]

9. ASH would like to draw the Government's attention to the World Health Organization's guidelines for the implementation of Article 13 of the Framework Convention on Tobacco Control, dealing with tobacco advertising and sponsorship. Paragraph 29 to 30 of the guidelines states that:

> *"29. Implementation of a comprehensive ban on tobacco advertising, promotion and sponsorship should not prevent legitimate journalistic, artistic or academic expression or legitimate social or political commentary. Examples include news images with coincidental tobacco-related content in the background, the depiction of historical personalities or presentation of views on regulation or policy. Nevertheless, appropriate warnings or disclaimers may be required.*
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> *30. In some cases, journalistic, artistic or academic expression or social or political commentary may contain elements that are not justified for editorial, artistic, academic, social or political reasons and must be regarded as advertising, promotion or sponsorship rather than genuine editorial, artistic or academic content or genuine social or political commentary. This is obviously the case if an insertion is made for commercial, tobacco-related reasons, for example, paid placement of tobacco products or images in the media. Recommendation Implementation of a comprehensive ban on tobacco advertising, promotion and sponsorship need not interfere with legitimate types of expression, such as journalistic, artistic or academic expression or legitimate social or political commentary. Parties should, however, take measures to prevent the use of journalistic, artistic or academic expression or social or political commentary for the promotion of tobacco use or tobacco products".*

[3] Elkin L, Thomson G, Wilson N. Connecting world youth with tobacco brands: YouTube and the internet policy vacuum on Web 2.0. Tob Control doi:10.1136/tc.2010.035949

10. ASH recognises that there may be cases of legitimate use of images of tobacco products in print, broadcast and online media, where such products are not TPD2 compliant. These might include both historic images and images from countries outside Europe. We do not believe that further legal obligations should be placed on media organisations to ensure TPD2 compliance, but we do believe that these organisations should be regulated by Codes of Practice that include provisions to ensure that they use tobacco imagery responsibly. For example, after the draft the Sun newspaper repeatedly used plain white packs to illustrate stories about standardised packaging regulations, despite having been informed on many occasions that such images were grossly misleading, and only ceased doing so following a complaint to the independent newspaper and magazine regulator, IPSO.

11. ASH therefore recommends that the Government:

- Write to relevant media regulators (including IPSO, Ofcom and the British Board of Film Classification) to ensure that they are aware of the provisions of the TPD2;
- request that they review their Codes of Practice to ensure that they contain adequate provisions in relation to use of tobacco imagery following transposition of the TPD2 to UK law; and
- consider how to improve investigation of and, where appropriate, prosecution of online use of tobacco imagery for covert marketing purposes.

Question 3. The TPD2 stipulates where health warnings should appear on packs including that the general warning should appear on the lateral surface. The Government propose to transpose "lateral" (Article 9) as "secondary" (defined as the next two largest surfaces of the pack, after the front and the back surfaces) in our domestic legislation. Can you tell us of any packaging shapes where this interpretation would not be the most effective approach/would not work as intended?

12. ASH has no knowledge of packaging shapes where the proposed interpretation would not work as intended. We would also recommend that if such shapes exist, in order to ensure proper compliance with the TPD2, the presumption should be that the tobacco industry should modify the shapes to ensure that the Government's proposed interpretation can be applied.

Question 4. The TPD2 requires Member States to choose between the warning "Smoking kills" or "Smoking kills – quit now". The Government is minded to require that tobacco products be labelled with the warning "Smoking kills – quit now" to align with UK smoking cessation messaging. Do you have any information/evidence that would inform this choice?

13. There is evidence that the impact of health warnings declines over time,[4] more noticeably with text than with picture warnings.[5] The message 'Smoking Kills' has been on the front of packs in the UK since TPD1 was implemented in 2002. The graphic warnings on the front of packs are a strong reminder to smokers of the harm caused by smoking, and research shows such 'fear appeals' are more effective when accompanied by messages providing information about how to avoid the threat highlighted by the 'fear appeal'.[6] Including the message 'quit now' adds a call to action to smokers, which acts as a positive reinforcement to the information on where to quit

[4] Hammond, D. Tobacco Labelling & Packaging Toolkit. A Guide to FCTC Article 11. Waterloo, ON: Tobacco Labelling Resource Centre, 2009. Available from: http://www.tobaccolabels.ca/tobaccolab/iuatldtook February 2009.

[5] White V. Bariola E. Faulkner A. Coomber K. Wakefield M. Graphic health warnings on cigarette packs: how long before the effects on adolescents wear out? Nicotine and Tobacco Research, September 2014. doi: 10.1093/ntr/ntu184

[6] Strahan E. White K. Fong G. et al. Enhancing the effectiveness of tobacco package warning labels: a social psychological perspective. Tob Control. 2002 11(3): 183–190. doi: 10.1136/tc.11.3.183

which will also be included on the pack. Therefore the option "Smoking kills – quit now" is our preference.

14. The Sambrook report for the European Commission[7] concluded that *"The optimum renewal period for the warning messages is broadly seen as every 2-5 years. If a rotation period of 12 months is adopted, then the warnings / images should be reviewed after 4 years (allowing each message to be used at least twice)."*

15. The evidence is clear that the health warnings need to be revised and renewed within five years if they are to remain effective. Therefore it is essential that the Commission puts in place delegated acts in accordance with Article 27 to review and update all the health warnings in a timely manner to ensure that warnings can be revised at least every five years. This would require updated text (and picture) warnings to be in place by 20 May 2021, and every five years thereafter.

16. This is particularly important with the general text messages on the side of packs, as there are only two options, so renewal and rotation of the warnings is not possible. Australia has 13 new information messages on the health effects of chemicals in tobacco smoke which can appear on the side of cigarette packs and cartons and on most loose tobacco packs, replacing the single information message previously required.[8] ASH recommends that when the text messages are revised the European Commission follows the Australian model and replaces the two messages with multiple alternatives to allow proper rotation to prevent the impact of the messages on the side of packs wearing out.

Question 5: Are there any pack shapes for cigarettes, Roll Your Own (RYO) and waterpipe tobacco on the market, other than pouches and squat cylindrical tins/tubs, where there may be technical difficulties in applying any of the new health warnings under Articles 9 and 10?

17. ASH has no knowledge of packaging shapes where there would be difficulties in applying health warnings as proposed. As per question 3, if such shapes exist, in order to ensure proper compliance with the TPD2, the presumption should be that the tobacco industry should modify the shapes to ensure that the Government's proposed interpretation can be applied.

Question 6: To ensure the combined health warnings are applied evenly across each brand of tobacco product, it is proposed that images should appear on between 1/24 (4.15%) and 1/12 (8.33%) of products and each set of images in the TPD2 picture library should be rotated on an annual basis. Are there any additional costs, above and beyond the current regime, imposed by this proposal?

Question 7: The draft regulations require producers/manufacturers to ensure the correct heath warning is applied to tobacco products. We are minded to treat retailers who repackage tobacco products at the point of sale the same as producers. For example, loose tobacco packaged at point of sale, should comply with the full labelling provisions, including the rotation of the combined health warning. Do you agree with this approach?

We also seek further details on the costs and practicalities of such businesses meeting these requirements.

[7] Sambrook Research International. A review of the science base to support the development of health warnings for tobacco packages. A report prepared for the European Commission, Directorate General for Health and Consumers. Brussels, European Commission, 2009.
[8] Competition and Consumer (Tobacco) Information Standard 2011 Australian Government, 2011

18. ASH is not able to comment on possible additional costs of these proposals, but since they appear to meet the requirements for effective health warnings, it would be appropriate for the tobacco industry to be required to meet any such costs that may occur.

19. We strongly agree with the proposed approach that retailers who repackage tobacco products at the point of sale should be treated the same as producers. From a public health perspective, there is no relevant difference between tobacco products packaged by a manufacturer and products repackaged by a retailer. To allow repackaged products to be sold without the packaging regulations applied to other products would be to create an important and unjustified loophole in the legislation.

20. ASH does not believe that it is necessary or most effective for the rotation of picture warnings across the EU to be harmonised to ensure the same picture warnings are used by all Member States simultaneously, as suggested by the European Commission.

21. Up to date evidence is that picture warnings that elicit strong emotional reactions are most effective[4], and that while picture warnings sustain their impact longer than text warnings[9], their impact diminishes after five years.[5] The picture warnings currently in use in the EU were published in May 2005, have been in use in the UK since October 2008, and are tired and out of date. They are being replaced with new picture warnings from 20 May 2016[10] which are unimaginative by comparison with best practice elsewhere, for example in Australia[11] and Brazil.[12]

22. As stated in our answer to Q.4 it is essential the health warnings, both text and picture, are regularly rotated, and revised at least every five years, taking into account not just scientific and market developments but also best practice in other jurisdictions. It is essential that the Commission puts in place delegated acts in accordance with Article 27 to ensure that updated picture warnings will be in place by 20 May 2021, and every five years thereafter.

Question 8: The Government is minded to derogate individually wrapped cigars and cigarillos from the full labelling regime, requiring only the general warning 'Smoking kills' or 'Smoking kills – quit now'; one of the text warnings from the combined warning list but no picture; and a reference to the smoking cessation information. Do you agree with this approach?

23. ASH considers the proposed list of Article 11 derogations to be the limit that the Government should be prepared to consider. Rather than simply allowing the first derogation (where "it is impractical to apply the full labelling regime") the onus should be put on the tobacco industry to show why it cannot adapt existing packaging so that the full regime can be applied. The presumption should be that packaging should be adapted, rather than that a derogation should be applied to current packaging.

24. It is essential that there is a reference to the smoking cessation information on all tobacco products. Warning labels include information for smokers who want to quit about where to find help have been shown to increase the number of smokers who try to quit.[4]

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[9] Hammond D, Fong GT, Borland R, et al. Text and graphic warnings on cigarette packages: findings from the ITC Four Country Survey. Am J Prev Med. 2007; 32:202–209. doi: 10.1016/j.amepre.2006.11.011.
[10] Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco product. OJEU 17 December 2014.
[11] Health Warnings Australian Government Department of Health, Dec. 2012
[12] Health Warnings - Brazil Tobacco Labelling Resource Centre

Question 9: The Government is seeking evidence and information on the supply chains currently used to distribute tobacco products in the UK, such as the number of links in the chain and the number of businesses affected.

Question 10: The Government would welcome initial views on how track and trace security markings may impact on business, and what the key issues for business will be.

25. ASH supports *requirements on,* rather than *requests to,* the tobacco industry to supply much greater information on the operation of its supply chain, its marketing strategies and spending, and on its pattern of sales. We note that the industry has been extremely reluctant to supply such information in the past. This is now a necessary condition for:

    - effective action against illicit trade, through tight supply chain controls, as required by the WHO Framework Convention on Illicit Trade Protocol (WHO FCTC ITP) and the TPD2
    - the establishment, as recommended by the WHO FCTC ITP, of a licensing scheme covering tobacco wholesalers and retailers
    - public spending on tobacco control to be targeted on communities with the highest rates of tobacco consumption.

26. ASH considers a robust tracking and tracing system to be an essential element in an effective strategy to combat the illicit tobacco trade, at a national, European and global level. Particularly given the extensive evidence of past complicity in illicit trade by the major tobacco manufacturers,[13] such a system is needed to ensure effective control of the supply chain. If such a system imposes costs on the tobacco manufacturers, they should be required to meet such costs.

27. ASH also considers the following to be essential requirements for a unique identifier suitable for use in the tracking and tracing of tobacco products:

    a. A marking for each package of tobacco products that should be unique and non-predictable.
    b. A data carrier that contains the unique identifier and other information available at the time of manufacturing, such as place and time of production. This data carrier should be suitable for high speed production and international exchange, storing and reading of data. Two dimensional bar codes, for instance, are machine readable and widely used in an international environment on many consumer products, such as food, alcohol, pharmaceuticals and tobacco products.
    c. A link and parent-child relationships (called aggregation) between different packaging units that allow, for instance, traceability of pallets without scanning all master cases, cartons and packs that are inside the pallet. We consider that this could be best achieved by a *single* system that operates across each level of packaging, rather than adding a separate pack based system to the systems already used by the tobacco industry for higher level units.
    d. Recording of any shipping and receiving events along the supply chain, for instance the recording of the departure of the pallet at the manufacturing site and the arrival of the consignment at trader x in country y.
    e. Internationally accepted standards to describe the main characteristics of the products (such as country of manufacture, product description, date of manufacture), to encode

[13] Most recently, in November 2014, British American Tobacco (BAT) was fined £650,000 by HMRC for over-supplying hand-rolled tobacco to Belgium, following a House of Commons Public Accounts Committee report which criticised HMRC for not taking tougher action on industry misconduct.

the data in the data carrier, to record events along the supply chain among the supply chain partners.

f. The storage of the data and events along the supply chain in an *independent* database controlled by competent government authorities. At global level, we would expect in the first instance that there would be a number of databases that could be used to share data and could be accessed by relevant authorities from any jurisdiction. In the longer term, we would support moving to a single international database, and we consider that the use of a single database across the EU would be likely to speed this process up.

28. The UK has committed to ratification of the WHO FCTC ITP[14] and it is therefore essential that we support the introduction of a tracking and tracing system that meets both the requirements of Article 15 of the TPD2 and Article 8 of the WHO FCTC ITP. The Protocol requires that the obligations of the tracking and tracing system shall not be delegated to the tobacco industry. Article 8.2 states that the tracking and tracing system must be *"controlled by the Party"*. Article 8.12 states that obligations assigned to a Party shall not be performed by or delegated to the tobacco industry and Article 8.13 states that each Party shall ensure that its competent authorities, in participating in the tracking and tracing regime, interact with the tobacco industry and those representing the interests of the tobacco industry only to the extent strictly necessary in the implementation of this Article.

29. We also note that the tobacco industry is attempting to promote its own track and trace system, Codentify. There has so far been no full independent assessment of the security of Codentify, indeed the Codentify patent documentation states that *"the production codes can easily be imitated or cloned",* which suggests that it suffers from major security weaknesses as a candidate tracking and tracing system. [15] Codentify appears to be both inadequate in its function and, through its links to industry, fails to meet the criteria established in the Illicit Trade Protocol and is inconsistent with Article 5.3.[16] It is essential that the UK ratifies the Protocol as soon as possible, as well as transposing the TPD2 into UK law, and that the UK Government ensures any standards set for track and trace systems are fit for purpose and ensure independence from the tobacco industry.

Question 11: If a registration scheme were introduced for cross-border distance sales, the Government is minded to require the nomination of an individual to be responsible for verifying that the product complies with the provisions in the UK regulations, before the product is supplied to the consumer. Do you agree with this approach?

30. ASH believes that sales of tobacco products to individual consumers should be prohibited, as set out in our answer to Question 12 below. However, if a registration system is preferred, then we would strongly urge that a nominated individual should be responsible for ensuring regulatory compliance. This is likely to be the simplest and most effective means to ensure that the major tobacco manufacturers and other businesses in their supply chain meet their legal obligations. If there is no direct individual responsibility, the tobacco industry is likely to continue its past failure to comply with regulations and subsequent efforts to avoid liability.

Question 12: Should cross-border sales of tobacco products to consumers be prohibited?

Question 13: Should cross-border distance sales of e-cigarettes and refills to consumers be prohibited?

[14] HMRC and UK Border Force. Tackling illicit tobacco: From leaf to light The HMRC and Border Force strategy to tackle tobacco smuggling. March 2015.
[15] Framework Convention Alliance. Does the tobacco industry have a tracking and tracing system that governments can use? May 2015.
[16] Joossens L. Gilmore AB. The transnational tobacco companies' strategy to promote Codentify, their inadequate tracking and tracing standard. Tob Control doi:10.1136/tobaccocontrol-2012-050796

Question 14: What systems to verify the age of customers are available to, or currently used by, businesses involved in distance sales to other EU Member States?

31. ASH can see no good reason to permit cross-border distance sales of tobacco products to consumers. Such sales largely function as a means to avoid tobacco taxes and other tobacco control regulations in the UK. Therefore we would recommend that they be prohibited. If there is a problem in discriminating between cross-border and domestic distance sales then we would prefer that all distance sales be prohibited.

32. The principle set out above should not be applied to the cross-border, or domestic, distance sale of electronic cigarettes. The results of surveys commissioned by ASH show[17]:

    - An estimated 2.6 million adults in Great Britain currently use electronic cigarettes
    - Nearly two out of five users are ex-smokers and three out of five are current smokers – therefore there is very little use by never smokers
    - The main reasons given for electronic cigarette use by current users are to help them quit smoking and prevent relapse.

33. Since the available evidence strongly supports the hypothesis that electronic cigarettes are much less harmful than smoked tobacco, and are primarily used by current or former smokers to help quit smoking or prevent relapse, we wish them to be widely available to consumers in the UK, provided that they are appropriately regulated and not marketed to never-smokers and young people. Therefore we would permit cross border sales of such devices provided that those imported to the UK comply with both national and EU regulations.

34. It is very difficult to put in place effective age checks for cross-border (or domestic) distance sales of products to consumers, for example through websites, since self-certification is clearly an inadequate check. Article 2 of the TPD2 on definitions, paragraph 36, states that "'age verification system' means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements;" It is therefore essential that any 'age verification system' should be fail safe.

Question 15: Should novel tobacco products be subject to a notification scheme? If "No", please explain why you think an authorisation scheme would be preferable.

Question 16: Under a notification scheme the Government is minded to include provision to require manufacturers or importers of novel tobacco products to provide, with any notification, information on:

a) the toxicity of the product, its ingredients and emissions;
b) the addictiveness of the products, its ingredients and emissions;
c) the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
d) the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

The Government believes that this information should and will be available to manufacturers and importers prior to launching all new products. Do you agree with this approach?

35. ASH agrees with this approach and strongly recommends that the Government proceeds with a notification scheme rather than an authorisation scheme. If the Government were to authorise such products and allow them to go on sale there would be an implicit implication that they are

[17] ASH fact sheet. Use of electronic cigarettes (vapourisers) among adults in Great Britain. ASH, May 2015.

'safe'. We recommend that novel tobacco products are treated the same as existing tobacco products, which are not authorised. If tobacco companies believe their products are a significantly safer alternative to smoking, and wish to be able to promote them as such, they can apply for licences from the UK's medicines regulator, the MHRA.

36. Public Health England is responsible for the protection of the public's health from hazards to health, and has significant toxicology capacity to undertake this work. We would therefore recommend that PHE take over responsibility from DH for ensuring the effective reporting of ingredients, emissions and additives, both for existing tobacco products (Articles 3 to 7) and novel tobacco products. The categories of information set out in Q16 (a) to (d) are a minimum acceptable list for novel tobacco products. The information has to be provided to Member States in electronic form and should also be made publicly available electronically.

Question 17: The Government is minded to use the TPD2 definitions of an 'electronic cigarette' and 'refill container'. Do you foresee any problems with inconsistency with the definitions in the draft The Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations?

37. Although there are differences in the wording of definitions between the TPD2 and the Regulations, we consider them sufficiently close to be compatible. However, we would have no objection to the Government making any changes to the Regulations it considers necessary to ensure that the TPD2 is fully transposed into UK law.

Question 18: The Government intends to handle notifications of e-cigarettes and refill containers electronically and make all information contained in notifications automatically available to the public unless this information can be considered truly commercially confidential. What information contained in the notifications should be considered commercially confidential?

38. ASH considers electronic notification of electronic cigarettes and nicotine containers to be an acceptable approach. In regard to matters of commercial confidentiality, we would recommend an approach based on placing the burden of proof on the party making the notification to show that requested information should properly be considered confidential. This could be supplemented by appropriate online guidance. In general we consider the most open approach to be the one most likely to lead to the rapid development of such products and their subsequent use by smokers and former smokers, with the public health gains that would result. However, we can conceive of narrow circumstances in which the invention of major novel features in a product might need time-limited protection, so that innovators can gain a reasonable rate of return from their innovation.

Question 19: The Government is minded to put the obligation on "producers" (which included manufacturers, importers into the UK and those that rename a product) in the transposing regulations which will ensure that there will always be a person in the UK who collects information about suspected adverse effects in relation to e-cigarettes and refill containers. Do you agree?

39. Although the current evidence strongly supports the hypothesis that electronic cigarettes and associated products such as refill containers are far less harmful than tobacco, the market is still at a relatively early stage of development, and the possibility must be conceded that particular products or the product type as whole could in future be shown to cause health damage or significant risks to some or all users. Therefore it is important that any information about suspected adverse health effects is collected and appropriately communicated. To ensure that manufacturers and producers do this, ASH would support a legal requirement on them to designate a person in the UK as having individual responsibility in this area.

Question 20: The Government is minded to give the Secretary of State for Health the power to prohibit the supply of an e-cigarette or refill container or to require producers and suppliers to recall a product if he/she considers them a serious risk to public health. Do you think there are other options that should be provided to the SoS, for example the power to require modification of a product or to require enhanced monitoring and/or reporting of company data?

40. ASH considers that it would be appropriate to give the Secretary of State wider powers than simply the prohibition of supply or the issue of product recalls. We note, for example, that the UK product recall system in relation to goods shown to be dangerously defective has been criticised as inadequate, and is currently the subject of a review headed by Ms Lynne Faulds-Wood and reporting to DBIS. [18] We would therefore favour a wider set of powers, including powers to require modification of products, disclosure of relevant information on product safety if this is believed to exist and has not been provided, disclosure of sales and marketing information when relevant to potentially dangerous products, and a general power to require appropriate remedial action by companies engaged in the sale, distribution or marketing of such products if they are shown to pose a serious risk to public health. We would expect such powers to be used only rarely.

Question 21: The Government is minded to require that e-cigarettes be labelled with the warning "This product contains nicotine, which is a highly addictive substance. It is not recommended for use by non-smokers". Do you agree?

41. ASH prefers this warning to the alternative which does not include the words 'It is not recommended for use by non-smokers'. Given the likely major public health gains from smokers switching to electronic cigarettes, the Government will wish to exercise care to ensure that warnings on electronic cigarettes do not deter smokers from starting to use them as an alternative to tobacco products.

42. It is crucial that monitoring and surveillance be carried out to determine whether the health warning deters smokers from using these products within the first year of the warning coming into effect. If the health warning is found to deter smokers from using these products the European Commission should be required to use delegated acts to revise the health warning, and to carry out research to ensure that any replacement health warning does not deter smokers while discouraging use of electronic cigarettes by never smokers.

43. The DH consultation does not include any questions about domestic advertising of electronic cigarettes, which is not harmonised under the TPD2, and recital 48 states that, 'Member States are free to regulate such matters within the remit of their own jurisdiction and are encouraged to do so'. ASH is responding on this issue under Q.21 as advertising of electronic cigarettes is an issue of concern.

44. For the purpose of this response, the assumption is made that the provisions of the TPD2 still permit, subject to domestic law:

    - Bill boards
    - Leafleting
    - Free distribution

[18] Consumer champion Lynn Faulds Wood to lead product safety review: DBIS media release, March 15 2015. For example, ASH has been advised by experts from Fire and Rescue Services that the rate of return of potentially dangerous electrical products is routinely low – a proportion of 20% or less is apparently common. Recalled products frequently continue to be sold online and through discount and secondhand sales outlets.

- Nominal pricing
- Point of sale advertising, and events sponsorship, if such events have only a domestic reach.

45. In general, the following principles should be applied to regulation of electronic cigarette advertising:

    - Regulation of un-licenced electronic cigarettes and other nicotine containing products should be consistent with that for licensed products.
    - Electronic cigarettes and other nicotine containing products should not be advertised or promoted in ways that could reasonably be expected to promote smoking of tobacco products.
    - As far as possible, electronic cigarettes and other nicotine containing products should be advertised as an alternative to smoking cigarettes or other tobacco products.
    - Electronic cigarettes and other nicotine containing products should not be advertised in ways or through channels that could reasonably be expected to make them appealing to non-tobacco users.
    - Electronic cigarettes and other nicotine containing products should not be advertised in ways or through channels that could reasonably be expected to make them appealing to children and young people
    - Advertising of nicotine containing products that are licensed for medicinal use should be permitted to include appropriate and well-supported health claims.

46. The existing CAP code is broadly consistent with these principles, although it does not prohibit either celebrity endorsement or free samples, both of which are prohibited under rules for over the counter medicinal products such as licenced nicotine products. When the current code was published in October 2014 a commitment was made to 'monitor the effect of the rules and conduct a formal review after 12 months'.[19] This review needs to ensure the CAP code is amended to reflect the reduced scope and other changes in regulation put in place by the TPD2. In addition there are growing concerns about the impact on youth uptake of celebrity endorsement and free samples, and we urge the ASA to review these issues in particular.

Question 22: Should the Government charge the industry proportionate fees to recover costs associated with the following activities as provided for in the TPD2:

a) The verification of the levels of tar, nicotine and carbon monoxide (TNCO) in cigarettes (Article 4)
b) The receiving, storage, handling, analysis and publishing information on ingredients and emissions of tobacco products including novel tobacco products (Article 5)
c) The peer review of scientific studies and additives undertaken by the tobacco industry (Article 6)
d) Assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect of the carcinogenic, mutagenic or reprotoxic (CMR) properties of the tobacco product concerned (Article 7)
e) If the UK chooses to implement an authorisation system for novel tobacco products then a fee can be charged for that authorisation (Article 19); and
f) The receiving, storage, handling and analysing information submitted to them on e-cigarettes (Article 20).

If not, please explain why.

[19] CAP. New UK Advertising rules for electronic cigarettes. 9 October 2014.

47. Given the health damage caused by tobacco consumption, and that the tobacco companies are responsible for promoting and selling the products that cause this damage, it is entirely right that they should bear the cost of appropriate fees. The major tobacco companies remain some of the most profitable businesses in the world and are estimated to make over £1 billion profits in the UK each year.[20]

Question 23: Should retailers and importers be given a transition period until May 2017 to sell through old stock?

48. ASH can see no good reason for permitting retailers a 12 month transition period to sell through old stock. Such a long transitional period threatens to create public confusion about the new regulations, and to undermine the public health gains that might be expected from their introduction. Australian standardised packaging legislation contained transitional provisions that allowed an extra six weeks beyond the implementation date of 1st December 2012 for distributors to clear old stock and a further six weeks for retailers. ASH considers this timescale reasonable and appropriate.

Question 24: Do you have any comments on the draft regulations, including anything you want to draw to our attention on the practicalities of implementing the regulations, as drafted?

Question 25: To better understand the likely costs and benefits of implementing the TPD2, and to develop the consultation-stage impact assessment, we are seeking further evidence on the following questions:

a) What is the likely cost of reassigning or retiring capital and adjusting manufacturing processes in response to the restrictions on certain product lines and requirements for additional health warnings?
b) What are the likely marginal impacts of implementing the TPD2 on e-cigarette manufacturers?
c) We are aware that tobacco products that benefit from transitional arrangements (menthol), or are exempt from the ban on characterising flavours, will no longer be able to provide a reference to the flavour on the packet. We would be interested to receive views on the impact of this provision.
d) Do you have any further information that may inform the calculations in this IA, specifically in those areas outlined in Annex E?
e) Do you have any further comments on the approach taken in this IA? A full list of areas in which additional information is being sought is provided at annex E of the Impact Assessment

Consumer Choice

49. ASH is concerned that the Impact Assessment assumes that the decision whether to smoke or not is a matter of 'consumer choice' (see Impact Assessment point 15 bullet one). Smoking is an addiction and the evidence suggests that most cigarette smokers continue to smoke in order to avoid unpleasant withdrawal symptoms rather than to obtain pleasure from consumption. Data from 2012 indicate that 82% of heavy smokers in England would find it difficult to go without

[20] Branston, J. R. and Gilmore, A. (2015) The extreme profitability of the UK tobacco market and the rationale for a new tobacco levy. University of Bath. 2015

smoking for a day.[21] Nearly 6 in 10 smokers in England say they want to quit, and nearly 4 in 10 make a quit attempt in any given year.[22]

50. Growing evidence from neuroscience and neuro-economics suggests that demand for addictive goods is a cue-triggered 'mistake' rather than a rational decision.[23] [24] Decisions to smoke made by a "cued" individual are the result of particular changes to neurological decision-making systems, which are regretted later by the same individual when in a "cool" state. The new, larger health warnings in the TPD2 play an important role not just by increasing awareness of the risks of smoking, but also by increasing motivation to quit, and by providing information about how to avoid the threat highlighted by the 'fear appeal'.[6]

One In Two Out

51. Point 81 of the Impact Assessment states, *"Only direct impacts on business should be counted for OITO purposes. Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of tobacco are contingent on the changed behaviour of smokers and so were excluded from OITO calculations in previous tobacco IAs. The Regulatory Policy Committee have now advised that policies which ban or severely restrict a particular activity, that explicitly prohibit a form of promotional activity, and have a primary objective to reduce sales (even if by promoting behaviour change) should be considered as having a direct impact on businesses. Whilst the primary reason for the TPD2 is to harmonise rules across the EU, this legislation is explicitly attempting to maintain a high level of health protection. In this IA we therefore treat profit losses resulting from the expected reduction in tobacco consumption as a direct impact for OITO purposes. We note that the Better Regulation Executive's Framework review is considering the question of the definition of "Direct" for OITO purposes."*

52. To quote the explanation for the one in two out (OITO) policy on the BIS website[25] *"To reduce the number of new regulations for businesses, the government operates a 'one-in, two-out' rule. This prevents government policymakers from creating new regulations that increase costs for business and voluntary organisations. When policymakers do need to introduce a new regulation, and where there is a cost to complying with that regulation, they have to remove or modify an existing regulation with double the cost to business."*

53. The burden of meeting the OITO standard falls on individual Government Departments which have to find regulations to get rid of worth double the cost to business for any new regulation they wish to introduce, with no account taken of the wider benefit to society of such regulations. As set out in the BRE Ninth statement of regulation, published in December 2014, *"Departments will be held to account for their overall performance under the OITO rule in the six-monthly Statement of New Regulation, and at the end of this Parliament (assessed from January 2013). Departments who were in One-in, One-out deficit at the end of 2012 will also need to ensure they achieve One-in, One-out when considered over the entire Parliament."* [26]

54. The effect is to discourage Government departments from bringing forward new regulations and to make it very difficult to get any that are brought forward implemented. Any regulatory measures, with limited exceptions for tax, civil emergencies, some EU legislation and regulations that have no impact on business, have to conform to this rule. It is particularly

21 Statistics on Smoking: England, 2012. NHS Health and Social Care Information Centre (HSCIC)
22 Healthy Lives, Healthy People: A Tobacco Control Plan for England. HM Government, March 2011
23 Bernheim, B. and Rangel, A. From neuroscience to public policy: A new economic view of addiction. Swedish Economic Policy Review, 2005.
24 Loewenstein, G. Out of Control: Visceral Influences on Behavior. Organizational Behavior and Human Decision Processes. 1996; 65 (3): 272–292.
25 Collection. One-in, two-out: statement of new regulation. DBIS, July 2014.
26 Better Regulation Executive. The Ninth Statement of New Regulation. DBIS, December 2014.

difficult for departments whose overall purpose does not include business regulation, to conform to the OITO rule, as it is particularly difficult for them to find regulatory 'Outs'.

55. Worse, the advice by the Regulatory Policy Committee that lost sales are a *'direct impact for OITO purposes'* has made the standard even tougher since the final Impact Assessment on tobacco displays was signed off [27], and the standardised packaging regulations were assessed at consultation stage, by including lost profits to tobacco businesses as a direct cost to business. The primary purpose of tobacco regulation is to reduce the number of adult smokers and the number of young people taking up smoking. If reductions in tobacco industry sales and profits can be counted against any public health benefits from regulations designed to cut smoking rates, then virtually any tobacco control regulations would count as an 'in' for the purposes of OITO.

56. In addition, the Government has committed to achieve at least £10 billion of savings to business by reducing regulation over the next five years[28], and it has acted to widen the remit of the RPC, which now has a statutory role[29], by confirming that actions of independent regulators will be brought within the scope of the business impact target, through the first-session Enterprise Bill in this parliament.[28]

57. We cannot understand why this should be the case, as according to the DBIS Better Regulation Framework Manual, dated July 2013 and most recently updated in March 2015 with the same wording, only direct impacts to business should be scored for OITO and any *"subsequent effects that occur as a result of the direct impacts, including behaviour change, are indirect. These are not scored for OITO*". [30]

58. At the time the display legislation Impact Assessment was signed off DBIS guidance was very clear that lost sales are not counted as a direct impact as set out in the Impact Assessment, "*To reach a figure for One In One Out (OIOO) policy, it is necessary to estimate the direct costs on business. The July 2011 OIOO guidance states that "OIOO is based on direct costs and benefits on business and civil society organisations only. Direct impacts are those that can be identified as resulting directly from the implementation or removal/simplification of the regulation (paragraph 36). A first order cost/benefit occurs as a direct effect of the regulation. If the effect happens after something else happening first (as a result of the regulation) it is considered a second order effect." In the case of display prohibition, although the full economic costs upon business are as estimated above, the direct costs are only those incurred in order to comply with the regulation. For further clarification on what this involves, we have referred to the August 2011 'Frequently Asked Questions' document (FAQs) (BIS (2011). The 'one-in, one-out' (OIOO) rule: frequently asked questions. London: Department for Business, Innovation and Skills.). There it is stated (page 10) that "The impact of any regulatory changes on the potential demand for the goods or services of business are counted as second order, or indirect effects and therefore would not be counted". Thus, in the present case, the impact of the regulation on demand for cigarettes is out of scope, as is a second order effect; though serving customers, maintaining the price list and assessing stock are in scope as direct administrative burdens imposed on businesses. This interpretation is confirmed in this guidance specifically by the tobacco-related examples (smoking ban and display of tobacco products) provided on page 11. The direct impacts, which are those relevant for OIOO (page 7 'How will OIOO operate?'), are*

[27] Department of Health Impact assessment on the prohibition of Display of tobacco products at the point of sale in England. IA number 3076. October 2011.
[28] Regulatory Policy Committee. RPC advice on deregulation and implementation of the SBEE Act 2015 – summary of evidence. June 2015
[29] RPC press release. Regulatory Policy Committee appointed as the independent body verifying the costs and savings of changes in law. RPC 21 July 2015.
[30] DBIS. Better Regulation Framework Manual. Practical Guidance for UK Government Officials. 1.9.35. March 2015.

defined as those 'necessarily incurred by business' (smoking ban) and the 'necessary cost incurred by retailers' (display of tobacco products)." [31]

59. Lost sales were also counted as an indirect impact by the DH for the consultation stage Impact Assessment for the draft standardised packaging regulations which stated that *"Losses of profits to tobacco companies and others in the supply chain due to reduced consumption of cigarettes or downtrading are an indirect effect (as agreed for legislation to end the display of tobacco in shops) and out of scope for OITO."* [32] As a result there was a zero net cost to business at consultation stage. However, at the final stage, because the RPC changed its advice, the IA was revised to include as direct costs lost sales due to behaviour changes which reduce smoking prevalence. To be specific this includes as a cost the anticipated drop in the number of smokers, and downtrading among those who remain smokers, and the impact of these behaviour changes on the profits to retailers, wholesalers and tobacco manufacturers, while no countervailing benefit was included for consequential spending by consumers on products other than tobacco. [33] [34]

60. Despite this it has been agreed that standardised packaging will be implemented, and as the Tobacco Products Directive is an EU measure, it will not be prevented by the OITO process. However, there is now a precedent which could be used to stop further public health regulations, for fear they would result in lost sales to business.

61. And while we are pleased that legislation was passed to introduce standardised 'plain' packaging of tobacco products, we are deeply concerned that the Department of Health is being forced to remove regulations with costs to business of twice the value of lost profits to tobacco companies as a result. The primary purpose of the DH is to *"help people stay in good health and live independent lives"*[35], not to regulate business. It is therefore very difficult for the DH to find regulations to remove, particularly since it has been removing regulations since 2010, first under *'One In One Out'*, then, since December 2012, under the even tougher, *'One In Two Out'* standard.

62. Even after the £10 billion in additional NHS funding committed by the Government there will be an annual funding shortfall of £22 billion by 2020. [36] The NHS Five Year Forward View, in explaining how this shortfall will be met, is very clear that *"The future health of millions of children, the sustainability of the NHS and the economic prosperity of Britain all now depend on a radical upgrade in prevention and public health."*[37]

63. Despite this, the Chancellor recently announced £200 million in-year cuts to DH funding for local authority controlled health budgets, amounting to a reduction of 6.2%[38] in what is supposed to be a 'ring-fenced' budget. Further cuts are threatened in the current Spending Review, which is designed to deliver a further £20 billion cuts in departmental budgets over the next four years. This is a particular concern for public health budgets, given that spending on the NHS is prioritised.

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[31] Department of Health Impact assessment on the prohibition of Display of tobacco products at the point of sale in England. IA number 3076. October 2011.
[32] DH. Impact Assessment 3080 Standardised packaging of tobacco products. Consultation stage. 17 June 2014
[33] DH. Impact Assessment 3080 Standardised packaging of tobacco products. Final. 10 February 2015.
[34] Regulatory Policy Committee. Opinion: Standardised packaging of tobacco products. IA number 3080. 9 February 2015.
[35] DH. One pager landscape. Downloaded 20th July 2015.
[36] HM Treasury. Summer Budget 2015. HC24 8 July2015.
[37] NHS Five Year Forward View. NHS England. 23 October 2014.
[38] Public Health Policy Strategy Unit (PHPSU). Local authority public health allocations 2015/16: in-year savings. A consultation. DH, 31 July 2015.

64. With such serious cuts to public health budgets, it is even more essential that policies which encourage behaviour change at population level are implemented, as these are the most effective, and indeed cost-effective, way of achieving the necessary *'radical upgrade in prevention and public health'*. Such policies are often best introduced by regulation rather than on a voluntary basis, as this ensures consistency in approach and a level playing field for all businesses. A good example is smokefree laws, which the Better Regulation Executive itself cited as a case study of effective regulation.[39]

65. Driving down smoking prevalence remains a priority for government. Two thirds of current smokers started before their 18th birthday. One in two lifetime smokers will die from smoking-related disease. Smoking is a deadly addiction, very difficult to escape, not a free choice by smokers and young people. It cannot be right for lost profits to tobacco manufacturers and retailers to be used as a reason not to proceed with measures which have as their main purpose the intention of reducing tobacco consumption. The current Government, its coalition predecessor and the previous Labour Government all agreed that reducing tobacco consumption to nil is a long term objective. Indeed when the standardised packaging regulations were passed the Secretary of State for Health and the Labour Shadow Health Secretary enjoyed what the Secretary of State for Health called *'a rare moment of consensus'*, when he tweeted, *'Let's hope both our children can grow up in a smokefree generation'.*

66. The Government's OITO process sets an unreasonably high bar for any new regulations. The OITO system is not fit for purpose and the DH needs to raise the problems it is causing for better regulation with the Better Regulation Executive Framework Review as a matter of urgency.

67. We recommend that the OITO system should be revised to include not just costs and benefits to business, but costs and benefits to wider society as well. Alternatively there should be an exemption for public health measures, in the same way as regulations on civil emergencies and financial systemic risk are exempted. It is appropriate that costs to business of regulation should be considered in determining whether a regulatory measure is effective, and cost-effective, but not that this should be the deciding factor. This problem has a wider impact than simply the regulation of consumer products such as tobacco. For example, following scandals about the treatment of the vulnerable and elderly in care homes the benefits of increased regulation to the public were not included in the impact assessment of revised regulations, while the costs to business were included, so that in order to bring in regulations to improve market oversight the DH had to commit to removing regulations worth twice the amount to business.[40]

[39] Better Regulation Executive. Better Regulation, Better Benefits: Getting the Balance Right. DBIS May 2009.
[40] DH. IA no. 9532 FINAL. Market Oversight in Adult Social Care. 26 March 2013.