IN THE COURT OF JUSTICE OF THE EUROPEAN UNION
CASE C-151/17

B E T W E E N:

SWEDISH MATCH AB

Claimant

-v-

SECRETARY OF STATE for HEALTH

Defendant

NEW NICOTINE ALLIANCE

Intervener

WRITTEN OBSERVATIONS
On behalf of the
NEW NICOTINE ALLIANCE

(Referring court: High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) – United Kingdom) (CO/3471/2016)

Submitted by: Paul Diamond, barrister: Chambers of Paul Diamond, PO Box 1205 Shelford, Cambridge CB22 5WG: chambers@pauldiamond.com

Reference to the Court of Justice of the EU for a preliminary ruling under Article 267 of the Treaty on the Functioning of the European Union:

> *Are Articles 1(c) and 17 of Directive 2014/40/EU invalid by reason of:*
> *i. Breach of the EU general principle of non-discrimination;*
> *ii. Breach of the EU general principle of proportionality;*
> *iii. Breach of Article 5(3) TEU and the EU principle of subsidiarity;*
> *iv. Breach of Article 296(2) of the Treaty of the Functioning of the European Union ("TFEU");*
> *v. Breach of Articles 34 and 35 TFEU; and*
> *vi. Breach of Articles 1, 7 and 35 of the EU Charter of Fundamental Rights.*

1. Introduction:

1. The New Nicotine Alliance (the "NNA") is a registered charity in England and Wales[1]; with the objective of promoting public health by means of 'tobacco harm reduction', a method of reducing harm from cigarette smoking without

[1] Charity Registration No. 1160481.

necessarily giving up the use of nicotine. Tobacco harm reduction is a public health strategy to reduce smoking.

2. The NNA was given permission to intervene as a Party by the High Court because the NNA presents a distinct expertise that focuses on consumer interests in access to and use of safer nicotine products as an alternative to smoking cigarettes. The NNA has no commercial interest in the case and its intervention is made solely in the interest of public and individual health.

3. The NNA is a civil society organisation and operates on a not-for-profit basis and is free from commercial bias. The NNA policies and public statements are evidence-based, with a clear focus on the health of consumers and the wider public and with specific interest to the 8.8 million smokers in the United Kingdom, ex-smokers and those affected by smoking. The NNA is non-political and no activities are to the benefit of or in support to any political party. It works closely with other European and international organisations sharing its objectives[2].

4. The NNA was founded in February 2015. It was established because none of the existing tobacco control and public health organisations reflected the interests of those who wished to switch from smoking tobacco to using safer nicotine products. Its Trustees include people from academia, social care, business, journalism and information and computer technology. It is assisted by Associates who share the NNA's commitments to tobacco harm reduction, and who have a wide range of expertise in science (including in toxicology, epidemiology and chemistry), health policy analysis, communication, business, smoking cessation and policy advocacy. Many are ex-smokers who have stopped smoking with the help of safer nicotine products, including e-cigarettes, and who report how these products have changed their lives and health for the better. The NNA is considered by Public Health England[3] ("PHE") to be a key stakeholder in tobacco harm reduction and is PHE's designated partner in representing the interests of consumers of reduced risk products.

[2] The NNA is an associate of the International Network of Nicotine Consumer Organisations (INNCO), the umbrella organisation of groups which represent the interests of those who wish to use safer nicotine products, see "Statement of Judy Gibson" Annex 1, para 1.
[3] PHE is an executive agency set up by the UK Government to protect and improve the nation's health and wellbeing, and reduce health inequalities.

5. The NNA provides evidence that snus is both a markedly safer alternative to smoking and that the experience of its use in Sweden and Norway shows that it makes a major contribution to the reduction in smoking; it helps protect against the smoking habit with consequent significant reductions in smoking-related mortality. The NNA will assert that on the basis of this evidence snus should be available to purchase across the EU.

6. The NNA will limit its observations to the questions ii) and vi) above, and asserts that the prohibition on the marketing of tobacco for oral use, as set out in Articles 1(c) and 17 of Directive 2014/40/EU[4] (the "2014 TPD") is manifestly inappropriate and contrary to the principle of proportionality and violates the EU Charter of Fundamental Rights (the "CFR"). The NNA asserts that deliberately depriving smokers of options to address their health risks by using snus is a violation of especially Articles 1, 7 and 35 of the CFR, together constituting a *Right to Health.* The Right to Health comprises the right of individuals to conduct themselves in a manner that avoids dangers to their health and a right to access less harmful products.

7. In support of its written observations in the present case, the NNA relies in particular on the following statements, and the studies and reports referred to therein:
   - the Expert report of Professor Gerry Stimson[5], Chair of the NNA, Emeritus Professor at Imperial College London and Honorary Professor at the London School of Hygiene and Tropical Medicine,
   - the Expert report of Professor Martin Jarvis[6], Emeritus Professor of Health Psychology in the Department of Epidemiology & Public Health. University College London,
   - the Expert report of Dr Karl Lund, Research Director at the Norwegian Institute of Public Health,[7]

[4] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1–38).

[5] "Report of Professor Stimson", report of Professor Emeritus Gerry Stimson for the High Court of Justice, Queen's Bench Division, Administrative Court, submitted in support of the intervention of the NNA, Annex 2.

[6] "Report of Professor Jarvis", report of Professor Martin Jarvis for the High Court of Justice, Queen's Bench Division, Administrative Court, submitted in support of the judicial review challenge brought before the High Court by Swedish Match AB, Annex 3.

- the Witness statement of Louise Ross, Service manager of Stop Smoking Service of Leicester City,[8]
- the Witness statement of Judy Gibson, Co-ordinator of the International Network of Nicotine Consumer Organisations (INNCO),[9]
- the Statement of Dr Lars Ramström, Director of the Institute for Tobacco Studies, Sweden,[10] and
- the Statement of Dr Jacques le Houezec, independent consultant.[11]

2. Breach of the principle of proportionality

8. The principle of proportionality requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see, inter alia, judgment of 9 June 2016, *Pesce and others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 48).

9. With regard to judicial review, the lawfulness of a measure of the EU legislature in an area which entails political, economic and social choices, and in which it is called upon to undertake complex assessments, is affected if it is manifestly inappropriate in relation to the objective pursued (see, inter alia, judgment of 22 June 2017, *E.ON Biofor Sverige*, C-549/15, EU:C:2017:490, paragraph 50).

10. The NNA submits that the ban on snus is manifestly inappropriate and disproportionate. It is an unsuitable means by which to achieve the aim of a high level of health protection because it removes from consumers who wish to avoid cigarettes and other combustible tobacco products, but who are unable or unwilling to give up using nicotine, the option to use a substantially safer product and it goes further than what is appropriate and necessary in order to attain the objectives of the 2014 TPD.

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[7] "Report of Dr Lund", report of Dr Karl Lund, for the High Court of Justice, Queen's Bench Division, Administrative Court, submitted in support of the intervention of the NNA before the High Court, Annex 4.
[8] "Statement of Louise Ross", submitted in support of the intervention of the NNA before the High Court, Annex 5.
[9] "Statement of Judy Gibson", submitted in support of the intervention of the NNA before the High Court, Annex 1.
[10] "Statement of Dr Ramström", Annex 6.
[11] "Statement of Dr Le Houezec", Annex 7.

Tobacco smoking in the EU

11. Across the EU, the European Commission Eurobarometer survey found that in 2017 some 26% of the population are current smokers and 24% are daily smokers[12]. In UK in the same survey some 17% of adults are current smokers and 16% are daily smokers[13]. The UK Department of Health estimates that there are 8.8 million adult smokers in the UK,[14] whose health may be compromised by this habit.

12. The annual rate of reduction of smoking in the EU is small. According to the UK Royal College of Physicians the annual rate of decline in smoking in the UK is around 0.7 percentage points each year[15]. The 2014 TPD will not have a dramatic effect on reducing the prevalence of smoking. The European Commission Impact Assessment carried out for the drafting of the 2014 TPD estimated that the package of policy options might lead to a 2% reduction in consumption within five years of transposition, equating to a 2% reduction in the number of smokers, corresponding to 2.4 million fewer smokers in the EU[16].

13. This projected annual reduction of 0.4 percentage points in smoking under the 2014 TPD legislative framework is unambitious and leaves current smokers unprotected from the effects of smoking. At a potential annual rate of decline of 0.4 percentage points per annum, it would take, other things being equal, over 50 years for smoking prevalence in the EU to reduce to 5%. *In Sweden, where snus is used, the prevalence of daily smoking has already been reduced to 5%*[17].

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[12] European Commission, Special Eurobarometer 458 Survey (2017): *Attitudes of Europeans towards tobacco and electronic cigarettes*, requested by the European Commission, Directorate-General for the Directorate-General for Health and Food safety and co-ordinated by the Directorate-General for Communication, pp. 8 and 26.

[13] A recently published UK survey by the Office for National Statistics ("ONS"), *Adult smoking habits in the UK: 2016,* 15 June 2017*,* puts the proportion of the adult population smoking at 15.8%. Difference between ONS and EuroBarometer are likely due to differences in sampling and questions, https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2016, accessed 4 July 2017.

[14] 8.8 million adult smokers is the estimate agreed with the UK Department of Health for the reference from the High Court of Justice (England & Wales) to the EU Court of Justice in March 2017.

[15] Royal College of Physicians, Tobacco Advisory Group (2016), *Nicotine without smoke: Tobacco harm reduction*, p. 6.

[16] Commission staff working document, *Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products*, Brussels, 19.12.2012, SWD(2012) 452 final, pp. 113 and 115.

[17] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, p. 26.

14. At the heart of the issue is that many smokers find it hard to stop smoking because they find it hard to go without nicotine. Over half (54%) of European smokers have tried to stop smoking[18]. Smoking cessation experts point out that many people make multiple attempts to stop smoking and that failure of a single quit attempt is normal[19]. The failure rate by one year following a quit attempt using self-directed abstinence (ie without formal help) or using Nicotine Replacement Therapy medications (such as nicotine gums and patches) is between 92% and 97%[20].

Smoking, health and nicotine

15. The scientific evidence is conclusive that the health problems associated with smoking are caused by the combustion and inhalation of the burnt vegetable matter which releases tars and toxins[21]. The smoking of tobacco is the most harmful way to consume nicotine and the cigarette is the most dangerous nicotine delivery system. The smoke from tobacco contains in excess of 4000 chemicals, many of which are carcinogenic or otherwise harmful to health.[22] It has long been recognised by smoking research experts that smokers smoke for the nicotine, but suffer ill-health by virtue of the inhalation of the toxins and carcinogens in tobacco smoke.[23] Tobacco smoke – not nicotine – causes illness and death.

16. Nicotine itself is not a carcinogen and it does not lead to illness and death, as explained by the UK Royal College of Physicians (the "RCP"):

'*Nicotine is not, however, in itself, a highly hazardous drug ... It increases heart rate and blood pressure, and has a range of local irritant effects, but is not a carcinogen. Of the three main causes of mortality from smoking, lung cancer arises primarily from direct exposure of the lungs to carcinogens in tobacco smoke, COPD from the irritant and pro inflammatory effects of smoke, and cardiovascular disease from the effects of smoke on vascular coagulation and blood vessel walls.*

[18] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, p. 92.
[19] Statement of Louise Ross, Annex 5, paras 9, 10 and 12.
[20] Report of Professor Stimson, Annex 2, para 11 and Bauld, L., Hiscock R., Dobbie F., Aveyard P., Coleman T., Leonardi-Bee J., McRobbie H. and McEwen A., International Journal of Environmental Research and Public Health, December 2016, 13(12);1175, in Section 4.
[21] Report of Professor Jarvis, Annex 3, para 38 and Report of Dr Le Houezec, Annex 7, para 6.
[22] Report of Professor Stimson, Annex 2, para 13.
[23] Russell MA., *Low-tar medium-nicotine cigarettes: a new approach to safer smoking*, British Medical Journal, 1976, 1(6023):1430-1433, p. 1431.

None is caused primarily by nicotine… Although the nature and extent of any long-term health hazard from inhaling nicotine remain uncertain, because there is no experience of such use other than from cigarettes, it is inherently unlikely that nicotine inhalation itself contributes significantly to the mortality or morbidity caused by smoking. The main culprit is smoke and, if nicotine could be delivered effectively and acceptably to smokers without smoke, most if not all of the harm of smoking could probably be avoided."[24]

Tobacco harm reduction

17. Providing smokers with safer forms of nicotine delivery is known as 'tobacco harm reduction'[25]. In recognition of both the difficulty of quitting smoking and the harms inherent in smoking, the RCP recognised harm reduction as an option in the 2007 report '*Harm Reduction in Nicotine Addiction*'[26]: '*Harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine that are acceptable and effective cigarette substitutes*'. The RCP further argued that the use of snus in Sweden provided proof of concept for tobacco harm reduction in that it showed that smokers want and are able to switch from smoking to lower risk products, with consequent gains to individual and public health[27].

18. Tobacco harm reduction is consistent with the World Health Organization (WHO) *Framework Convention on Tobacco Control* ("*FCTC*")[28], the international health treaty that aims to reduce the use of tobacco, to which all European Union Member States as well as the European Union itself, are signatories. As set out in Recital 7 of the Preamble to the 2014 TPD, the provisions of the *FCTC* are binding on the EU and the Member States and, according to Article 1 of the 2014 TPD, one of the objectives of the Directive is to meet the obligations of the EU under the *FCTC*. *Article 1(d)* of the *FCTC* specifically refers to harm reduction as one of the defining strategies of tobacco control:

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[24] Royal College of Physicians, Tobacco Advisory Group (2016), *Nicotine without smoke: Tobacco harm* reduction, p. 5.
[25] Report of Professor Stimson, Annex 2, paras 18 -20.
[26] Royal College of Physicians, 2007, *Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit*, p. 229, para 12.10. It notes that nicotine is not a particularly hazardous substance.
[27] Royal College of Physicians, Tobacco Advisory Group (2016), *Nicotine without smoke: Tobacco harm reduction*, p. 6.
[28] WHO Framework Convention on Tobacco Control, http://www.who.int/fctc/text_download/en/, accessed 4 July 2017.

'"tobacco control" means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke;'

19. "Harm reduction" is commonplace in public health responses to reducing the risks from potentially hazardous activities where for one reason or another it is difficult to prevent the activity itself. Examples are automobile seat belts and other car safety measures, and helmets and safety bindings for skiers.

Consumer interest in safer nicotine products as alternatives to smoking

20. There is an increasing range of safer nicotine products on the market. The most common are Nicotine Replacement Therapy ('NRT') products such as gums, sprays and lozenges, and e-cigarettes, which have come onto the market since the judgment of 14 December 2004, *Swedish Match*, C-210/03, EU:C:2004:802. Just as snus, NRT and e-cigarettes help many smokers to protect themselves against smoking. Professor Stimson provides evidence of the rapid rise in the popularity of e-cigarettes in the UK, which is a grass roots consumer driven phenomenon[29] that mirrors the consumer behaviour in Sweden and Norway in relation to snus. Snus, NRT and e-cigarettes are examples of products that satisfy the need for nicotine but deliver it without the hazards associated with the use of combusted tobacco.

21. The use of e-cigarettes provides evidence that autonomous personal choices are helping a switch from smoking. The most recent data for the UK show that there are 2.9m users of e-cigarettes in 2017, up from 700,000 in 2012. Of the 2.9m, 1.5m (52%) are now ex-smokers.[30] According to the European Commission EuroBarometer survey, in the EU, nearly one in ten of adults (9%) has tried them once or twice and 2% use them regularly[31]. The main reason for taking up e-cigarettes is to stop or reduce tobacco consumption. Just over six in ten (61%) of those polled say that they started using e-cigarettes for this reason.[32]

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[29] Report of Professor Stimson, Annex 2, paras 26-34.

[30] Action on Smoking and Health,, *Use of electronic cigarettes (vapourisers) among adults in Great Britain*, 16 May 2017, http://ash.org.uk/information-and-resources/fact-sheets/use-of-electronic-cigarettes-vapourisers-among-adults-in-great-britain/, accessed 4 July 2017.

[31] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, pp. 105-106.

[32] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, p. 118.

22. The NNA contends that the rapid uptake of e-cigarettes indicates that smokers are interested in trying products that are safer than smoking. However, there is also evidence that e-cigarettes do not work for all smokers. The EuroBarometer survey found that half of smokers and former smokers who use, or have used, e-cigarettes say that these devices did not help them to reduce their tobacco consumption.[33] Evidence from the UK also supports the interpretation that e-cigarettes do not work for all smokers. The Report of Professor Stimson references the ONS' survey in 2015 which shows that the number of smokers who have tried e-cigarettes (at 8.7m) is four times higher than those currently using them (at 2.2m)[34].

23. The NNA avers that the rise of e-cigarettes shows that smokers want to avoid smoking-related harms and also the potential to reduce smoking if effective alternative products are available to consumers. This is also the experience of the *International Network of Nicotine Consumer Organisations*, which reports growing interest across Europe in non-combustible nicotine products[35]. Consumer interest in snus is also evidenced in the EU public consultation on the possible revision of the 2001 Tobacco Products Directive[36] in 2010 which generated over 85,000 responses, of which 96% were submitted by ordinary citizens[37]. Some 83.5% of the 70,925 who responded to a question on the legal status of snus were in favour of removing the ban on snus.[38]

24. The NNA avers that additional lower risk nicotine products which people can choose to use instead of tobacco cigarettes need to be available. The NNA contends that such products need to be effective alternatives to tobacco cigarettes and acceptable to those wishing an alternative to smoking. The NNA

[33] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, p. 121.
[34] ONS, *Adult smoking habits in the UK: 2016*, 15 June 2017, para 28.
[35] Statement of Judy Gibson, Annex 1, paras 14 and 22.
[36] Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p.26-34).
[37] European Commission, Health and Consumers Directorate-General, *Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC),* July 2011, pp. 4 and 13, http://ec.europa.eu/health//sites/health/files/tobacco/docs/consultation_report_en.pdf accessed 4 July 2017.
[38] European Commission, Health and Consumers Directorate-General, *Report on the public consultation on the possible revision of the Tobacco Products Directive (2001/37/EC),* July 2011, pp. 5 and 25, http://ec.europa.eu/health//sites/health/files/tobacco/docs/consultation_report_en.pdf accessed 4 July 2017.

further contends that for smokers and for improving the health of the public the evidence is clear that snus fulfils the criteria for a tobacco harm reduction product and hence should be available in the EU, additional to other lower risk nicotine products. Consequently, by removing the option to use a safer product from consumers wishing to avoid cigarettes or other more harmful tobacco products, the ban on snus is a manifestly unsuitable means by which to achieve the aim of a high level of health protection.

Snus is a several times safer product than smoked tobacco

25. As stated above, snus is markedly safer than smoking cigarettes. In 2008, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks ("SCENIHR"), found that *'[r]espiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU. There is no consistent evidence that any STP [Smokeless Tobacco Product] cause any of these major respiratory diseases*'. SCENIHR concluded in the following sentence that '*[c]omplete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking*'[39].

26. Snus is not a new product. It is well researched and there is substantial evidence for its health effects. Professor Jarvis shows that using snus confers no excess morbidity or mortality from chronic obstructive pulmonary disease (COPD), or other respiratory diseases and little in the way of other adverse effects[40].

27. Concerns have been raised in the past about the risk of cancer linked to the use of snus. However, considerable scientific evidence has been amassed since the adoption of Directive 2001/37 and the evidence does not support assertions about the carcinogenicity of snus. A systematic review and meta-analysis[41] examined the evidence relating to snus and health across six major Swedish, Norwegian, Danish and Finnish studies, up to 2010, and concludes that the

[39] Opinion of Scientific Committee on Emerging and Newly Identified Health Risks, *Health Effects of Smokeless Tobacco Products*, 6 February 2008, p. 113.
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

[40] Report of Professor Jarvis, Annex 3, paras 72-87.

[41] A 'systematic review' is a method for reviewing results across different studies; a 'meta-analysis' combines data from several selected studies to develop a conclusion that has greater statistical power than a single study.

evidence provides scant support for any major adverse health effects of snus: snus is not associated with cancers of the oropharynx, oesophagus, pancreas, or heart disease or strokes. Compared with smoking, snus poses about 1% of the risk of cancer or cardiovascular disease[42].

28. A recent definitive study from the Swedish *Karolinska Institutet* confirms that snus is not associated with an elevated risk of pancreatic cancer.[43] Because snus has been used in Sweden for a long time it is possible to study samples of the population over time (so-called cohort studies) and to link survey data with registers of disease and mortality. A total of 424,152 men from nine cohort studies was followed up for risk of pancreatic cancer through links to health registers. The nine prospective cohort studies included participants of varying ages, who were recruited at different time periods from diverse geographic regions across Sweden. During a cumulative 9,276,054 person-years of observation[44], current snus use was not associated with risk of pancreatic cancer[45].

29. Snus is not completely free from adverse health effects. The Report of Professor Jarvis identifies potential adverse pregnancy outcomes, localised gingival recession and dependence. But he states that *'the public health impact of these adverse effects pales into insignificance in comparison with the public health impact of smoking'.* Adverse effects that have been observed among some women who continue to use snus during pregnancy are, Jarvis states, likely to be similar with any source of exposure to nicotine including pharmaceutical nicotine products; these products are licensed in the UK for use during pregnancy[46].

30. Furthermore, snus poses no risk to others as there is no 'second hand' smoke.

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[42] Lee PN (2011), *Summary of the epidemiological evidence relating snus to health*, Regul Toxicol Pharmacol, 59(2):197-214, doi: 10.1016/j.yrtph.2010.12.002, https://www.ncbi.nlm.nih.gov/pubmed/21163315, accessed 4 July 2017.

[43] Araghi M, Galanti R, Lundberg, M et al (2017) '*Use of moist oral snuff (snus) and pancreatic cancer: pooled analysis of nine prospective observational studies'*, International Journal of Cancer. Accepted Article doi: 10.1002/ijc.30773.

[44] 'Person-years of observation' is calculated from the number of people in the nine studies multiplied by the number of years that they were followed-up.

[45] Araghi M, Galanti R, Lundberg, M et al (2017) '*Use of moist oral snuff (snus) and pancreatic cancer: pooled analysis of nine prospective observational studies'*, International Journal of Cancer. Accepted Article doi: 10.1002/ijc.30773.

[46] Report of Professor Jarvis, Annex 3, paras 85-86.

31. Switching from cigarettes to snus appears to have much the same reduced health risk as quitting smoking altogether. It has been calculated that the life expectancy of smokers who switch from smoking to snus is little different to the life expectancy of those who quit smoking[47]. This finding is confirmed by a recent analysis of six major studies from Sweden which found that switching from smoking to snus is associated with major reductions in morbidity and that switching to snus appears to have much the same reduced health risk as quitting smoking[48].

The ban on snus is contrary to the principle of proportionality

32. It follows from the above that the ban on tobacco for oral use set out in Articles 1(c) and 17 of the 2014 TPD exceed the limits of what is appropriate and necessary in order to attain the objective of the Directive. It also follows that by imposing a total ban on the sale of snus, while at the same time allowing cigarettes, a several times more harmful tobacco product, and thereby hindering consumers from choosing a proven effective and attractive lower risk, harm reduction product, the ban is manifestly inappropriate to achieve the objective of the 2014 TPD, which is to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people. Articles 1(c) and 17 of the 2014 TPD are thus contrary to the principle of proportionality.

3. The Right to Health; Articles 1, 7 and 35 of the CFR

33. The NNA argues that because snus is both a much safer alternative to smoking tobacco, and because the evidence is that it helps protect against smoking with resultant reductions in smoking-related mortality, it is a breach of the *Right to Health* to prevent the marketing of snus in the EU (except in Sweden). Smokers in the EU (except in Sweden) are denied the opportunity to choose a safer product that would help them to protect themselves from smoking.

Considerations regarding the right to health

34. The *Right to Health* is an important Human Right, which is mentioned in a number of international human rights conventions: the preamble to the

[47] Gartner CE et al. (2007), *Assessment of Swedish Snus for Tobacco Harm Reduction: An Epidemiological Modelling Study*, Lancet 369(9578):2010–14, p. 2010.
[48] Lee PN (2013), *The Effect on Health of Switching from Cigarettes to Snus - a Review*, Regulatory Toxicology and Pharmacology: 66(1):1–5, p. 4.

Constitution of the World Health Organisation 1946, Article 25 of the *UN Declaration of Human Rights 1948,* Article 12 of the *International Covenant on Economic, Social and Cultural Rights (1966),* Article 24 of the *UN Convention on the Rights of the Child* (1989), Articles 11 and 13 of *European Social Charter* 1961, Article 3 of the *Convention on Human Rights and Biomedicine* 1996 and Article 10 of the *Protocol of San Salvador* 1988[49].

35. The EU has a high level of health protection enshrined in primary law: Articles 9, 114(3) and 168(1) TFEU as well as Article 35 CFR. The right to health can be accurately described as a *Right to Health Protection*.

36. The NNA submits that the *Right to Health* has two components: the *firs*t is a claim or a positive obligation on public authorities to prevent disease and for access to health treatment, and the *second* is freedom for individuals to make choices with a view to protect their health and freedom from State interference without justification. The right to health means that the EU should protect the health of its citizens and not impede an individual who seeks to improve his own health.

The right to health protection

37. Article 35 CFR provides that "*[a] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities*".

38. The Explanations on Article 35 CFR state that *"[t]he principles set out in this Article are based on Article 152 of the EC Treaty, now replaced by Article 168 of the Treaty on the Functioning of the European Union, and on Articles 11 and 13 of the European Social Charter".*[50]

39. The European Social Charter (the "ESC") represents a legally binding obligation in international law, to which all Member States are signatories[51]. The ESC is

[49] There are further references in *Article 12 of the Convention on the Elimination of All Forms of Discrimination against Women, Article 5 International Convention on the Elimination of All Forms of Racial Discrimination, Article 25 Convention on the Rights of Persons with Disabilities, Article 24 of the United Nations Convention on the Rights of the Child.* Further, some 18 Member States include provisions in their Constitution on the *'right to health', 'the right to health care'* or the *'right to medical aid or medical insurance'*.

[50] (OJ C 326, 26.10.2012, p. 2) referred to in the *Preamble* and *Article 52(7) CFR*. Article 6(1) *TEU* provides that the *CFR* should be interpreted with *'due regard to the explanations…'*.

[51] Either the 1961 Charter and/or the Protocol of 1998 and/or the revised ESC 1996 and specific Articles thereof.

also referred to, inter alia, in Article 151 TFEU[52], and by the EU Court of Justice (the "Court of Justice").[53] Furthermore, the European Court of Human Rights ("ECtHR") has held that the European Convention on Human Rights ("ECHR") and the ESC both inform each other on their respective applications.[54]

40. Article 11 ESC provides that:

"Part I: "Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable."
Part II: "With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in co-operation with public or private organisations, to take appropriate measures designed inter alia*:*

1. *to remove as far as possible the causes of ill-health;*
2. *…*
3. *to prevent as far as possible epidemic, endemic and other diseases, as well as accidents."*

41. The NNA submits that the right to health in Article 11 ESC imposes an obligation to "take appropriate measures" to fulfil sub-paragraphs (1) and (3) of Part II; this would include the provision of access to snus in order to help people avoid the causes of ill-health due to smoking.

The right to health is underpinned by the right to personal autonomy

42. The right to health is a combination of CFR Rights; it includes not only Article 35, but also Articles 7 (privacy) and 1 (dignity). The right to health is a facet of the fundamental right of bodily integrity and of privacy; and the right of personal autonomy to self-determine how to protect and promote one's own welfare.

43. Article 7 CFR, which set out that everyone has the right to respect for his or her private life, applies to the field of health care; and so informs the content of

[52] Article 52(3) refers solely to the decisions of the European Court of Human Rights and not the *European Committee on Social Rights;* but the European Court of Human Rights incorporates the European Social Charter and other international treaties.
[53] Judgment of 5 June 1978, *Defrenne v Sabena,* 149/77, EU:C:1978:130, para 28.
[54] *Zehnalova & Zehnal v Czech Republic* (dec.), no 38621/97, ECHR 2002-V, pp. 11-12. In *International Federation of Human Rights (FIDH) v Greece,* decision on the merits, complaint no 72/2011, §§ 50-51, Council of Europe: European Committee of Social Rights, 23 January 2013, *the European Committee of Social Rights* (the "*ECSR*") held that the ESC and ECHR complement each other; both emphasise dignity. The *ECSR* held that Article 11 ESC is informed by Article 8 ECHR in formulating the scope of Article 11 to including the right to a healthy environment.

Article 35 CFR. The Explanations state that the rights guaranteed in Article 7 CFR correspond to those guaranteed in Article 8 ECHR.

44. The privacy rights are expansive and wide ranging. In relation to Article 8 ECHR, the ECtHR has held that 'the concept of 'private life' is a broad term not susceptible to exhaustive definition'.[55] Article 8 ECHR has been held to apply to issues such as human dignity[56], quality of life,[57] self-determination,[58] protection from environmental pollution[59], the right to refuse medical treatment[60] and conversely, choices in relation to medical treatments to prolong life[61].

45. The ECHR focuses on *civil and political rights;* there is no corresponding *Article 35 CFR.* However, the ECtHR has based itself on *Article 8 ECHR* to establish the *Right to Health* in the cases *Sentges v The Netherlands*[62] and *Hristozov & Others v Bulgaria*[63]. As stated above, it follows from the jurisprudence of the ECtHR that *Article 8 ECHR* is applicable to issues of *personal autonomy, dignity* and *quality of life*. This jurisprudence should inform the substantive content of *Article 35 CFR*.

46. Further, the right to health is an issue that engages Article 1 CFR as health is central to a dignified life. In *Defence for Children International (DCI) v Belgium*[64], the ECSR confirmed that "*health care is a prerequisite for the preservation of human dignity and that human dignity is the fundamental value and indeed the core of positive European human rights law – whether under the European Social Charter or the European Convention on Human Rights*"[65].

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[55] *Pretty v United Kingdom,* no. 2346/02, ECHR 2002-III, § 61; see additionally *Niemietz v. Germany,* 16 December 1992, § 29, Series A no. 251-B.
[56] *L. v. Lithuania,* no. 27527/03, § 56, ECHR 2007-IV.
[57] *L. v. Lithuania,* no. 27527/03, ECHR 2007-IV.
[58] *Sentges v. The Netherlands* (dec.), no. 27677/02.
[59] *López Ostra v. Spain,* 9 December 1994, §§ 11 and 50-51, Series A no. 303-C. Spain breached Article 8 ECHR when it failed to protect homes and families from environmental pollution; although there was not considered to be any serious danger of health. The ECtHR ruled that "*severe environmental pollution may affect individuals' well-being and prevent them from enjoying their homes in such a way as to affect their private and family life adversely."*
[60] *Glass v. the United Kingdom,* no. 61827/00, § 70, ECHR 2004-II.
[61] *Hristozov and Others v. Bulgaria,* nos. 47039/11 and 358/12, §§ 116-120, ECHR 2012 (extracts).
[62] *Sentges v. The Netherlands* (dec.), no. 27677/02, pp. 5-6.
[63] *Hristozov and Others v. Bulgaria,* nos. 47039/11 and 358/12, ECHR 2012 (extracts).
[64] *Defence for Children International (DCI) v. Belgium*, decision on the merits, Complaint No. 69/2011, Council of Europe: European Committee of Social Rights, 23 October 2012.
[65] The ECSR referred to *International Federation of Human Rights Leagues v. France*, decision on the merits, Complaint No. 14/2003, Council of Europe: European Committee of Social Rights, 8 September 2004, § 31.

47. The Court of Justice has also recognised the '*fundamental right to human dignity*'[66] and it is enshrined in Article 2 of the EU Treaty.

48. The concept of dignity has many strands; but the concept is clearly additionally related to autonomy; the right to make decisions on lifestyle and how to live. Such choices *'[presuppose] that people are given a range of valuable options from which to choose'*[67]. In ECtHR jurisprudence, the '*notion of personal autonomy is an important principle underlying the interpretation of Convention guarantees*'.[68] It follows from Article 52(3) CFR that similar principles apply to the CFR.

49. Thus, Article 1 CFR relates to personal autonomy; as does Article 7 CFR. For example in *A, B & C v Ireland*[69]*,* the ECtHR recalled that "*the notion of "private life" within the meaning of Article 8 of the Convention is a broad concept which encompasses, inter alia, the right to personal autonomy and personal development (see Pretty v. the United Kingdom, cited above, § 61)"*, and that it concerns subjects such as "*a person's physical and psychological integrity (Tysiąc v. Poland judgment, cited above, § 107)*".[70]

50. As follows from the jurisprudence of the ECtHR, personal autonomy is an interpretative principle.[71] The right to autonomy implies that people are allowed to make decisions that others may not make (or even disapprove of).

51. The NNA submits that the *Right to Health,* resulting from Articles 1, 7 and 35 CFR, and the underlying principle of personal autonomy, imply a right to protect one's health by having access to products that are less harmful than others or products that would improve one's health when replacing other products. The NNA further submits that the evidence establishes that snus is such a product both *de jure* and *de facto*.

Evidence for the health protective effects of snus as an alternative to smoking

[66] Judgment of 9 October 2001, *Netherlands v Parliament and Council*, C-377/98, EU:C:2001:523, para 70. See also for example Case C-34/10, *Brüstle*, EU:C:2011:138, Opinion of AG Bot, para 46.
[67] Case C-303/06, Coleman, EU:C:2008:61, opinion of AG Maduro, para 9; see further paras 8-15 and 22.
[68] *Vörður Ólafsson v. Iceland,* no. 20161/06, § 46, ECHR 2010.
[69] A, B and C v. Ireland [GC], no. 25579/05, ECHR 2010.
[70] A, B and C v. Ireland [GC], no. 25579/05, § 212, ECHR 2010.
[71] See e.g. *Vörður Ólafsson v. Iceland,* no. 20161/06, § 46, ECHR 2010.

52. In Sweden and Norway (where the sale of snus is also legal) the increase in the use of snus has been accompanied by a dramatic decrease in smoking. The prevalence of smoking in Sweden and Norway is now the lowest in Europe. The Report of Dr Lund shows that in Norway in 1984-6 96% of the tobacco was consumed as cigarettes and 4% as snus; but by 2013-15 cigarettes had dropped to 61% of the tobacco market and snus has increased to 37%. The percentage of daily smokers dropped rapidly from 25% in 2005 to 13% in 2015[72]. Smoking is fast disappearing in Sweden, with the latest European Commission EuroBarometer survey showing that for 2017 only 5% of adult Swedes are daily smokers, compared with an EU28 average of 24%[73]. *Such an exceptionally low prevalence of smoking has not been achieved in any other higher income country*.

53. A comparison with the UK is pertinent. Sweden has implemented fewer tobacco control measures than the UK and laws on tobacco use and promotion are less strict than in the UK[74]. The European Cancer League shows that overall the UK ranks number 1 in implementing tobacco control measures, whilst Sweden ranks joint 9th in 2016[75]. Sweden has achieved a lower prevalence of smoking than the UK yet has less strict controls on smoking. It is clear that the difference in the prevalence of smoking between Sweden and the UK is due to snus.

54. This is also the conclusion of the Royal College of Physicians, that argued in its 2016 report that the use of snus in Sweden is proof of concept for the efficacy and effectiveness of tobacco harm reduction:

'*The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7), demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of snus as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now*

[72] Report of Dr Lund, Annex 3, paras 8-12.
[73] European Commission, Special Eurobarometer 458 Survey (2017), *Attitudes of Europeans towards tobacco and electronic cigarettes*, p. 26.
[74] Tobaccocontrollaws.org, http://www.tobaccocontrollaws.org/legislation/country/sweden/summary, accessed 4 July 2017.
[75] Association of European Cancer Leagues, http://www.europeancancerleagues.org/tobacco-control/ectoh/3-newsflashes/highlights/451-tobacco-control-ranking-scale-2016.html, accessed 4 July 2017. See also Report of Professor Jarvis, Annex 3, para 49.3 and Figure 4.

by far the lowest in Europe. The magnitude of the contribution made by the availability of snus over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of snus from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following 10 years the availability of snus reduced smoking prevalence in Sweden by an additional 3.7 percentage points. Trends in snus use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of snus is strongly associated with quitting smoking.'[76]

55. The 'natural experiment' between Sweden and the rest of the EU provides evidence not only on the impact of the availability of snus on smoking rates, but also the impact of smoking rates on tobacco related disease. Sweden has the lowest rate of tobacco related disease for the EU 28 for males aged 30 and older, at 152/100 000, compared to the EU28 average of 373/100 000[77]. Hungary has the highest at 699/100 000. Dr Ramström has calculated the human cost of the ban on snus in the EU in a single year (2004):

'…it is conceivable that 355,372 deaths, i.e. 63% of the tobacco-related deaths, could have been averted if the 1992 snus ban in the EU had not been introduced and if truthful public education about snus had been sufficient to bring about Swedish tobacco use patterns'[78].

Looking forward, Dr Ramström has also calculated the potential future premature deaths that could be avoided in the EU if the ban on the marketing of snus is revoked:

'If snus is made available by lifting of the current ban in the EU, and truthful public education encourages substitution of snus for cigarettes as in Sweden, then around 320,000 premature deaths per year can conceivably be prevented among men 30 years and older in the current EU countries.'[79]

[76] Royal College of Physicians, Tobacco Advisory Group (2016), *Nicotine without smoke: Tobacco harm reduction*, p. 6. RCP also suggests that the evidence from Sweden indicates that the use of snus could add a further 0.4 percentage points per year to the rate of decline to the current 0.7% decline in smoking prevalence, thus hastening an end to cigarette smoking.
[77] Statement of Dr Ramström, Annex 6, p. 5 fig 2.
[78] Statement of Dr Ramström", Annex 6, paras 9-10.
[79] Statement of Dr Ramström, Annex 6, para 16.

56. The NNA notes the assertion sometimes expressed that snus could be a stepping stone to the use of smoking tobacco. This assertion is not supported by the evidence. In Sweden snus has led to *less* not more smoking. The largest study is an analysis of a nationally representative sample of the Swedish population recruited between 2003 and 2011, covering 60,675 individuals. Among males born in the 1940's most of those who initiated tobacco use (87%) did so through smoking. Over time the proportion initiating any tobacco use fell from over 60% to around 40%; and over time snus came to overtake smoking as the primary initiation to tobacco use. In the 1980's most of the young men started with snus with fewer starting with smoking. Those who began daily tobacco use using snus were much less likely to subsequently take up smoking than those who had not. At an individual level, this analysis shows that the proportion of those that started daily smoking was significantly lower among primary snus users. In Sweden snus has predominantly replaced smoking and the population level data show that smoking tobacco has declined whilst snus use has increased[80].

57. Evidence from Dr Lund shows that snus is used to avoid the initiation of smoking, to quit smoking and to reduce smoking levels[81]. The decline in smoking in Sweden and Norway has come about by smokers using snus to avoid smoking, and by the fact that younger nicotine users are choosing to use snus rather than to smoke[82]. Further, overall in Sweden and Norway the total level of tobacco use has remained stable or slightly declined. Snus can therefore be considered to 'immunise' or protect populations against smoking by enabling smokers and potential smokers to be resilient against smoking.

58. The NNA has also considered the objection that is sometimes made that the use of nicotine via less harmful products is itself harmful because nicotine is a product with addiction potential. This issue is considered in the Statement of Dr

[80] Ramström L, Borland R and Wikmans T (2016), *Patterns of smoking and snus use in Sweden: implications for public health*, International Journal of Environmental Research and Public Health, 2016 Nov 9;13(11), pii: E1110.
[81] Report of Dr Lund, Annex 4, paras 7-26.
[82] Lund I and Lund KE (2014), *How Has the Availability of Snus Influenced Cigarette Smoking in Norway?*, International Journal of Environmental Research and Public Health, 2014 Nov; 11(11): 11705–11717, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4245639, accessed 4 July 2017. And also Ramström L, Borland R, and Wikmans T, *Patterns of Smoking and Snus Use in Sweden: Implications for Public Health*, International Journal of Environmental Research and Public Health, 2016 Nov 9;13(11), pii: E1110, https://www.ncbi.nlm.nih.gov/pubmed/27834883, accessed 4 July 2017.

Le Houezec[83]. The first consideration is that, to quote Dr Le Houezec, *'There is a distinction between addiction and dependence, addiction being characterised by compulsive drug use despite harmful consequences.'*[84]. The habitual use of nicotine may be considered a dependence rather than an addiction because nicotine itself does not cause significant harms to the health of the user or to others. The second consideration is that as Dr Le Houezec shows, dependence on nicotine is not a single distinct phenomenon, and that the level of dependence varies by the characteristics of the product and the way in which the nicotine is delivered. The scientific evidence points to factors that make dependence on cigarettes stronger than dependence on non-combustible products such as snus. Cigarette smoke contains a number of chemicals including monoamine oxidase inhibitors that together with nicotine make smoking more dependence inducing. Snus does not contain these chemicals. Furthermore, the 'hand to mouth' action of smoking provides a powerful secondary psychological reinforcement. This does not occur with the use of snus. Snus appear therefore to have less dependence liability than smoking tobacco[85].

Snus, autonomy and tobacco harm reduction

59. The use of snus as a harm reduction product has demonstrably had a positive individual and public health impact in Sweden. Sweden, by not banning snus, allows individuals to exercise autonomy in the choice of how to consume nicotine and allows Swedes the option to pursue personal harm reduction to avoid the dangers of smoking. In consequence Sweden confers a higher level of health protection against smoking than in the rest of the EU.

60. *'Harm Reduction'* is a component part of the *Right to Health* and informs the scope of *Article 35 CFR*. As stated above, *Article 1(d)* of the *FCTC* refers to harm reduction as one of the defining strategies of tobacco control.

61. The preamble to the *FCTC* refers to *Article 12 of the International Covenant on Economic, Social and Cultural Rights,* which sets out *"the right of everyone to the enjoyment of the highest attainable standard of physical and mental health";* as well as to the *Constitution of the World Health Organisation* and the right to the

[83] Statement of Dr Le Houezec, Annex 7.
[84] Statement of Dr Le Houezec, Annex 7, paras 7-8.
[85] Statement of Dr Le Houezec, Annex 7, paras 11-17.

enjoyment of the highest attainable standard of health. Additionally, the *Preamble* provides that the signatories are *'to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations'*.[86]

62. Harm reduction strategies have been held to be component parts of a right to health[87]. The right to health in United Nations materials is closely linked to a pragmatic approach of harm reduction. General Comment 14[88] states that the right to health encompasses the "underlying determinants of health". A report to the UN General Assembly by the United Nations High Commissioner for Human Rights[89] avers that harm reduction (for drug users) is part of the right to health. Smokers are the biggest group of people at risk of ill-health and have a *Right to Health* co-equal to drug users.

63. Harm reduction is thus part of the *Right to Health* and effective harm reduction is practiced by individuals as part of their own autonomous decision making. It is a grass roots phenomenon and not led by experts[90]. This is the case in Sweden (and Norway). The Swedish experience is based on the willing participation of consumers making informed choices to protect their health. Harm reduction also does not impose any financial burden on the State since costs are born by consumers, and will bring about health care savings for the State by reducing the number of people suffering from tobacco related diseases.

64. The denial of access to snus is to obstruct the right to health by prohibiting access to less harmful tobacco products and inhibits individuals from seeking to

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[86] WHO Framework Convention on Tobacco Control, pp. 2-3, http://www.who.int/fctc/text_download/en/, accessed 4 July 2017, see above, paragraph 18.

[87] United Nations, Committee on Economic, Social and Cultural Rights, *Concluding Observations on Tajikistan,* UN. Doc. E/C.12/TJK/CO/1 (24 November 2006), para 70 on 'harm reduction' among prisoners, sex workers and drug users; and see United Nations, Committee on Economic, Social and Cultural Rights, *Concluding Observations on Mauritius*, UN. Doc. E/C.12/MUS/CO/4 (8 June2010), para 27.

[88] Office of the High Commissioner for Human Rights, CESCR General Comment no. 14, 2000, E/C.12/2000/4, Articles 11 and 33.

[89] United Nations, A/HRC/30/65, 2015, *Study on impact of world drug problem on enjoyment of human rights*, pp. 6-20.

[90] This is consistent with the public health principles of the World Health Organization (1986), "Ottawa Charter for Health Promotion", http://www.who.int/healthpromotion/conferences/previous/ottawa/en/, accessed 4 July 2017. See Report of Professor Stimson, Annex 2, para 27.

help themselves by accessing safer nicotine products[91]. This denial of access to snus in the EU means that a number of individuals will (unnecessarily) die.

65. Furthermore, the ban on snus is inconsistent and consequently disproportionate because of the availability to purchase demonstrably substantially more dangerous combustible tobacco products. Other harmful forms of smokeless tobacco products, including chewing tobacco, are also allowed to be sold under the 2014 TPD (see *Costa & Pavan v. Italy*)[92].

66. In this context, the NNA also notes that, in *Nitecki v. Poland*[93], the ECtHR recognised that Article 2 ECHR imposed a positive obligation to 'take appropriate steps to safeguard the lives of those within its jurisdiction' and can extend to 'the acts and omissions of the authorities in the field of health care policy'. In *Pentiacova (and others) v. Moldova*[94] the ECtHR recognised that Article 2 could extend to health care provision with similar positive obligations as Article 8 ECHR.

The ban on snus infringes the right to health

67. Based on the above, the prohibition on the marketing of snus in the EU outside of Sweden and the rejection of a harm reduction approach when it comes to tobacco control violates the right to health, by condemning many smokers to suffer from smoking-related illness and premature death.

68. The prohibition is contrary to Articles 1, 7 and 35 CFR. The latter Article requires that a high level of human health protection be ensured in EU policies and activities. As recalled above, health protection includes enabling people to make choices that help them avoid ill-health. The prohibition violates that right. A binary 'quit or die' policy lacks in effectiveness and causes needless suffering and debilitating illness contrary to 'human dignity' and to the 'respect for private

[91] As noted above, in paragraph 23, consumer interest in snus is inter alia evidenced in the EU public consultation on the possible revision of the 2001 Tobacco Products Directive: some 83.5% of the 70,925 who responded to a question on the legal status of snus were in favour of removing the ban on snus.

[92] With regard to Article 8 ECHR, see *Costa and Pavan v. Italy,* no. 54270/10, §§ 60-64, 28 August 2012, where an Italian legislation was found to lack consistency and therefore to be disproportionate, since it denied the right to preimplantation genetic diagnoses, which would allow screening for a healthy child, while at the same time allowing the abortion a foetus subsequently identified to suffer from the disease concerned.

[93] *Nitecki v. Poland* (dec.), no. 65653/01, 21 March 2002; declared inadmissible.

[94] *Pentiacova and Others v. Moldova* (dec.), no. 14462/03, ECHR 2005-I.

life'. It ignores the third, complementary, option – harm reduction[95], which is to help smokers switch to a less dangerous way of using nicotine, by providing a variety of less harmful products, which are effective and sufficiently attractive to smokers, such as snus. By denying access to snus, the prohibition constitutes unwarranted interference in personal choices, and thus violates the right to personal autonomy.

4. Conclusions

69. For the reasons set out above, the NNA respectfully invites the Court to answer the questions referred as follows:

Articles 1(c) and 17 of Directive 2014/40 are invalid by reason of:

- Breach of the EU general principle of proportionality; and
- Breach of Articles 1, 7 and 35 of the EU Charter of Fundamental Rights.

Paul Diamond

Barrister

[95] Which is one of the three defining strategies of tobacco control referred to in Article 1(d) of the *FCTC*.