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New nicotine products and the
innovation principle

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Summary

- The benefits of innovation are unpredictable and hard to quantify. Fear of adverse consequences can lead to excessive emphasis on risk avoidance, leading to regulation that holds back beneficial innovation. The experience in tobacco harm reduction illustrates this.
- Innovative reduced-risk nicotine products, such as e-cigarettes, snus and heated tobacco, have been associated with steep declines in smoking prevalence in several countries, including the UK, but have been banned in others on the basis of the precautionary principle.
- While some residual uncertainties remain, there is ample evidence that these products will not increase the health risk to smokers who switch to them, nor to society as a whole. This evidence would not exist if every country had preemptively banned them.
- Those who are opposed to tobacco harm reduction tend to focus on the potential risks of alternative products, rather than their risks relative to the hazards of smoking. This is a mistake. The realistic counterfactual to a scenario in which hundreds of millions of smokers switch to lower-risk nicotine products is not one in which nicotine use disappears but one in which hundreds of millions of people continue to smoke cigarettes.
- Impact assessments for regulations in this field are supposed to include full cost–benefit analysis but in the case of EU laws, this has not always been reflected in the eventual legislation, and in the UK, dynamic effects on smoking cessation have been poorly addressed.
- Framing the use of precautionary principle in the field of tobacco harm reduction to better account for the benefits of new products in bringing about smoking cessation could improve cost–benefit analysis and regulatory outcomes. The same lesson can be carried into other policy areas.

Introduction

The benefits of innovation, while widely acknowledged, are unpredictable, hard to quantify and sometimes seem to be accompanied by dangers. Fear of such adverse consequences from technological development can lead to overemphasis on the avoidance of risk.

In this context, the 'precautionary principle' looms large in UK and European regulation and lawmaking. This principle has no formal, fixed definition, even in legislation that uses the term (such as the Treaty on the Functioning of the European Union and the UK's Environment Act 2021). A widely used working definition relating specifically to environmental policy (UN 1992) is:

[W]here there are threats of serious or irreversible environmental damage, a lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

However, in practice, the principle often takes on a significant aspect of deterring innovation. According to a European Commission communication on the precautionary principle, it 'may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty' (European Commission 2000).

The effect of this can then be to prevent useful innovation simply because it raises some risk. One response would be to seek a more rigorous application of the principle that balances the dangers of action and inaction, rather than allowing it to be invoked to override conventional cost-benefit analysis (Hewson 2021). Another response would be to complement the precautionary principle with an 'innovation principle', which would seek to have the potential benefits of innovations fully accounted for in regulatory decisions.

It should be clear that the precautionary principle in and of itself need not be challenged. If it were consistently applied so as to balance the dangers of new products with the dangers of preventing innovation, there need be no problem with it. Indeed, this appears to be recognised in relation to the environment by the draft policy statement of the Department for Environment, Food and Rural Affairs, which stipulates that the precautionary principle should apply:

[W]here there is *plausible evidence* of a risk that a particular policy could cause serious or irreversible damage to the environment, alongside a lack of scientific certainty about the likelihood and severity of this damage. (Defra 2021, emphasis added)

Although focused on the environment, Defra's draft policy has obvious implications for reduced-risk nicotine products when it says:

New or innovative technologies should not be held to a higher standard of safety than existing ones where the level of risk is comparable, otherwise their potential to deliver benefits will be lost. (Defra 2021)

A further aspect of the matter is that prohibitory regulation will often have the effect of preventing the acquisition of evidence. The long-term effects of new products cannot, be determined quickly. The attitude that the prevention of possible harm should dominate policy then risks having the effect of making it impossible to discover that in fact the innovation offered benefits.

To illustrate these points, in this discussion paper, we look at a mature market for a hazardous product which seemed incapable of meaningful innovation until quite recently, but where innovative products, where allowed onto markets, have brought measurable health benefits. In this instance, many jurisdictions appear to have adopted an overly precautionary, and hence anti-innovation, approach, to the severe detriment of public health. This is the market for combustible cigarettes. Cigarettes have been the most popular nicotine-delivery device worldwide for over a century. The technology of nicotine delivery remained largely unchanged throughout the twentieth century, with the only major innovation being the introduction of filter tips, which provided little or no protection from the risks of smoking and were criticised by health campaigners for giving consumers a false sense of security.

The failure of 'low-tar' cigarettes to reduce the health burden of smoking led many governments to conclude that innovation in this market was futile at best and counterproductive at worst. Regulations were introduced to prevent innovation not just in cigarettes but in nicotine-delivery technology in general. In Australia, for example, tobacco was heavily taxed and regulated and the sale of nicotine was banned *except in tobacco products*.

Such legislation was created before the invention of e-cigarettes, but it meant that e-cigarettes were automatically banned before they could be brought to market. In other countries, such as the UK, vaping was initially allowed to flourish in a relatively laissez-faire regulatory environment. Even after the EU's Tobacco Products Directive was implemented in 2016, British policy remained relatively permissive. International differences in the way reduced-risk nicotine products are regulated has created a series of natural experiments. These show that innovation in nicotine delivery has brought large public health benefits. The benefits of allowing this innovation also provide an example illustrating the general case for permitting – and encouraging – potentially beneficial innovation. It shows that when dealing with technology that reduces known risks, caution amounts to recklessness.

Tobacco harm reduction

In the last twenty years, a range of non-combustible nicotine products have become popular alternatives to cigarettes for millions of smokers. They include e-cigarettes (vapes) and heated tobacco products. A traditional smokeless tobacco product (STP) called snus has proved successful in parts of Scandinavia where smoking rates are now among the lowest in the world. Nicotine pouches, which are products similar to snus containing no tobacco, have been launched in the UK and elsewhere in recent years.

All of these products are significantly less hazardous to health than conventional cigarettes, but some risk remains. Viewed from the perspective of public health, it could be argued that none of them would be allowed on the market if there were no existing nicotine users. It could also be argued – if viewed from the perspective of health alone and ignoring welfare economics – that evidence of some risk to health, combined with uncertainty about the scale of risk, would justify a preemptive ban under the precautionary principle in such a scenario.

However, reduced-risk nicotine products differ from other innovations that could be subject to the precautionary principle because they are substitutes for products that are unusually dangerous, yet legal and widely consumed: cigarettes. It is often said that if the risks of cigarettes were known when they became popular in the early twentieth century, they would have been banned. But they were not. Smoking has been subjected to heavy regulation to discourage it and some in public health envisage an ‘endgame’ in which cigarette sales are phased out, although there is only minority support for prohibition in the near future.¹ The health risks of smoking are so great that alternatives which carry *some*

1 <https://yougov.co.uk/topics/health/articles-reports/2021/09/10/most-britons-want-ban-cigarettes-and-half-want-ban>.

risk would likely result in large aggregate health benefits if consumers switched en masse.

What are the implications of the precautionary principle for novel nicotine products? As noted above, according to the European Commission:

[T]he precautionary principle may be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty. (European Commission 2000)

It is certainly plausible that reduced-risk nicotine products 'may have a dangerous effect'. Their advocates do not claim that they are 'safe' (indeed, no product is 100 per cent 'safe' in the sense of having no potential to cause harm). Nicotine itself does not cause cancer, but it raises blood pressure in a similar way to caffeine (Smits et al. 1993) and this could cause health problems in extreme cases. E-cigarettes require nicotine, propylene glycol and vegetable glycerin to be inhaled into the lungs which could lead to inflammation or other disorders.

The potential for harm is therefore not disputed. The question is about relative risk and, crucially, uncertainty. What are the health risks, how do they compare to smoked tobacco and what are the likely costs and benefits of allowing the sale of products such as e-cigarettes on the open market?

We already know a great deal about the toxicology of snus and e-cigarettes, in particular, and we have good evidence of their efficacy in smoking cessation. Snus has been used in Scandinavia for over two centuries and the weight of epidemiological evidence over several decades indicates that it does not cause cancer or any other serious disease (GBD 2016 Risk Factors Collaborators 2017). Cancer warnings were removed from snus products in Sweden in 2001, and there is now so much evidence that snus is low risk and helps smokers quit cigarettes that the US Food and Drug Administration (FDA) granted its first ever modified risk orders to eight Swedish snus products in 2019, allowing them to be marketed as safer than cigarettes. Being safer than cigarettes might seem a low bar, but the FDA does not give this permission easily. Manufacturers not only have to prove that their products are significantly safer than cigarettes but that they would benefit the health of the population.

Nicotine pouches have been brought to market in the last three years and have been subject to relatively little academic attention. They work in exactly the same way as snus, with the pouch put under the top lip so the gum absorbs nicotine, but contain no tobacco. With the tobacco replaced by cellulose, it can be assumed *a priori* that nicotine pouches' risk potential is even lower than that of snus. Toxicological analysis supports this assumption (Azzopardi et al. 2021).

Heated tobacco products partially resemble cigarettes but do not involve combustion. They heat the tobacco in an electronic device to produce a nicotine-containing aerosol. The UK's Committee on Toxicity (2017) found that the aerosol from heated tobacco products contains fewer 'harmful and potentially harmful compounds' than cigarette smoke, with reductions of 50 per cent for some chemicals rising to more than 90 per cent for others. One heated tobacco product – called IQOS – was licensed as a modified risk tobacco product by the FDA in 2020. Based on toxicological evidence, the FDA concluded that:

Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.²

E-cigarettes have been widely available as consumer products for over a decade in most countries and have been subject to extensive research. It is beyond the scope of this paper to assess this scientific literature; suffice to say that the benefits of e-cigarette use in smoking cessation have been shown in a series of randomised controlled trials, the gold standard of scientific evidence. Hayek et al. (2019), Walker et al. (2019) and Adriaens (2014) all showed that smokers were more likely to quit smoking if they used e-cigarettes than if they used a placebo or nicotine replacement therapy. There is strong evidence from the fields of toxicology and public health showing that vaping is far less dangerous than smoking (e.g. Hajat et al. 2021; Stephens 2018), and from the field of economics there is strong evidence that cigarettes and e-cigarettes are direct substitutes, meaning that policies which deter the purchase of the latter drive up sales of the former (Pesko and Warman 2021: 3–4).

2 <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.

The acute health effects of vaping are relatively trivial – the most common complaint is mouth and throat irritation – but the products have not existed for long enough for the long-term health effects to be established beyond doubt. Toxicological analysis has been extensive and strongly suggests that the risks of cancer, heart disease and lung disease from vaping are a tiny fraction of those from smoking, but some uncertainty remains about exactly how much safer e-cigarettes are compared to combustible tobacco. While some of the most common compounds in e-cigarette fluid, such as propylene glycol, are generally considered safe to ingest, the impact of long-term inhalation (i.e. over decades) is not known.

Most experts agree with the view of the USA's National Academies of Sciences, Engineering, and Medicine (2018) that there is 'substantial evidence that except for nicotine, under typical conditions of use, exposure to potentially toxic substances from e-cigarettes is significantly lower compared with combustible tobacco cigarettes'. Public Health England (2015: 6) concluded that vaping 'is around 95% safer than smoking'. Similarly, and perhaps more accurately, the Royal College of Physicians (2016: 84) concluded that the long-term health risks from vaping are 'unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure'. Cancer Research UK acknowledges that e-cigarettes are 'far closer to other nicotine replacement therapy (NRT) products than tobacco in terms of harm'.³

3 https://www.cancerresearchuk.org/health-professional/awareness-and-prevention/e-cigarette-hub-information-for-health-professionals/safety#E-cigs_safety0.

Risk: it's all relative

Organisations, activists and academics who are opposed to tobacco harm reduction tend to focus on the proven or hypothetical risks of alternative products, rather than their risks relative to smoking. They implicitly, and sometimes explicitly, compare a scenario in which many smokers switch to vaping (and some non-smokers take up vaping) with a scenario in which nobody uses nicotine in any form. The latter is better from a public health perspective but it is wholly unrealistic. The meaningful counterfactual is one in which hundreds of millions of people continue to smoke for many years to come. In this scenario, what matters is not absolute risk but risk relative to the risks of smoking.

EU institutions and the World Health Organisation (WHO) have increasingly made the mistake of ignoring relative risk. A 2020 report from the EU's Scientific Committee on Health, Environmental and Emerging Risks focused on small and often unproven health risks from vaping while largely ignoring the health benefits to smokers who switch (Snowdon 2020). The first draft of the European Commission's Beating Cancer Plan similarly portrayed e-cigarettes as a threat rather than an opportunity by ignoring their potential for mass smoking cessation (Snowdon 2021). Both reports gave support to the idea of banning flavourings in e-cigarette fluid on the basis that they appealed to children. Most vapers of all ages use flavoured e-cigarettes and research shows that ex-smokers cite 'the wide variety of available flavourings and superior taste of e-cigarettes as factors that aid smoking cessation' (Goldensen et al. 2019: 7).

The idea of banning flavourings to protect minors – who cannot legally buy e-cigarettes in any case – brings to mind Mark Twain's comment about censorship, that it is like 'telling a man he can't have a steak just because a baby can't chew it'. The putative threat of reduced nicotine products to children and teenagers has often been cited as a justification for heavy-

handed regulation and outright prohibition. It is of course inevitable that some minors will experiment with products that are not designed for them, although e-cigarette use by minors who have never smoked is quite unusual in the UK (Action on Smoking and Health 2020). But, again, we must ask what the most realistic counterfactual is. Some teenagers have always smoked, often in large numbers. Would the availability of reduced-risk products lead to more teenagers smoking or less? Would laws aimed at reducing underage use have the unintended consequence of deterring adult smokers from switching?

Plausible risks and tangible benefits

There is an inevitable lack of certainty about the direct health impact of new products such as e-cigarettes on individuals, but there are also legitimate questions about their impact on the whole population if they become widely used by the public. Three concerns are often raised. First, that the availability of lower-risk products could encourage the initiation of nicotine use by people who would not otherwise use nicotine. Second, it is feared that many of these would-be abstainers will move on from snus, e-cigarettes, etc. and become cigarette smokers; this is known as the gateway hypothesis. Third, that smokers who would otherwise quit smoking will use these products in conjunction with cigarettes and become 'dual users' instead.

These are testable propositions so long as the products are widely used for a period of years. The first two can be tested by looking at the behaviour of young people (the group most likely to take up nicotine products for the first time). The third can be tested by studying the behaviour of older smokers. In each case, prevalence of smoking, nicotine use and dual use can be compared to a realistic counterfactual or to the period immediately before the reduced-risk product was widely used.

The three concerns listed above combine to build a broader fear that the availability of reduced-risk nicotine products will lead to a greater burden of ill health than would be the case if they were prohibited. This could come about if more people smoked than would be the case in the prohibition counterfactual or it could come about if the substitute products were only slightly less risky than cigarettes and many more people consumed them.

This, again, can be tested by real-world evidence so long as the products are available for a period of years in at least some jurisdictions. The British experience with e-cigarettes shows a steep decline in smoking after vaping became popular in 2012. Figures from the USA show a similar trend, particularly among high school students (Jamal et al. 2017). In both cases, e-cigarettes seem to have led smokers to give up.

The Swedish experience with snus is even more compelling. Snus is banned in all EU countries except Sweden, thus offering an ideal natural experiment. Sweden now has the lowest smoking rate in Europe at 7 per cent, much lower than its neighbours Denmark (16 per cent) and Finland (15 per cent). It is almost the only country in the world where the smoking rate is lower among men than among women, likely because of snus's reputation as a masculine product. The 'Swedish experience' with snus has been documented for many years and provides proof of concept for tobacco harm reduction (Clarke et al. 2019). Snus is also legal in Norway where it has become particularly popular since the 1990s. Norway now also has a very low smoking rate and since 2017 has had more snus users than smokers (ibid.: 3).

Taken together with evidence from Japan, where the smoking rate fell sharply when heated tobacco products became popular (Cummings et al. 2020), these natural experiments strongly suggest the net effect of reduced-risk nicotine products on population health is positive and that there is little evidence of a significant 'gateway effect' leading non-smokers to take up smoking.

The danger of the precautionary principle

Clearly, an overly precautionary policy stance can be damaging. It could be said that the precautionary principle does not require absolute certainty. In the words of the European Commission, it requires 'sufficient certainty'. If judiciously applied, the precautionary principle would require that for a product to be banned or strictly controlled, there would have to be *plausible evidence* of serious risks.

The purpose of this paper is not to provide a detailed review of the thousands of studies in the scientific literature on reduced-risk products. The point is that most of these studies would not exist if governments had preemptively banned the products under the precautionary principle. This is not a hypothetical scenario. The sale of e-cigarettes is banned in 47 countries.⁴ Some of them, such as Australia, banned them from the outset as the result of pre-existing laws on the sale of nicotine. Others, such as India, have done so more recently under the influence of the WHO, which has adopted an increasingly prohibitionist stance towards all nicotine products.

A parallel can be drawn between tobacco harm reduction and responses to the Covid-19 pandemic. In theory, it would be possible to drive rates of the virus down to zero, introduce strict travel bans and reintroduce lockdowns if and when the virus re-enters the country. This 'zero Covid' policy has been tried in New Zealand and Australia, but even these countries do not see it as a long-term solution. Lockdowns create huge social and economic costs, travel bans are unpopular and complete elimination of the coronavirus is unrealistic. A better approach is to accept that the virus is endemic and use vaccines for harm reduction. COVID-19 vaccines, like

4 <https://profglantz.com/2021/11/03/47-countries-have-banned-e-cigarettes/>.

reduced-risk nicotine products, are neither perfect nor totally safe, but they lower the health risks to a level that society is prepared to accept. They are a pragmatic solution.

The WHO strongly supports the use of COVID-19 vaccines in the full knowledge that a non-trivial number of fully vaccinated people will die from COVID-19 and that the vaccines themselves will kill a (very) small number of people. When it comes to tobacco-related diseases, however, it takes an approach that is not just zero tobacco but zero nicotine. It is explicitly working towards a 'nicotine-free future'.⁵ Although there is no ethical, economic or public health justification for this goal, and a proper application of the precautionary principle would not necessarily support it, the WHO hopes to achieve it by using socially and economically costly prohibitions that, in practice, have very little chance of bringing about their intended effect.

Advocates of reduced-risk products, by contrast, support the equivalent of vaccines: alternatives to smoking that greatly reduce the amount of harm currently associated with nicotine consumption while preserving individual rights and avoiding the damage done by prohibition. This more pragmatic approach is much more likely to be appealing to tobacco users, of whom there are over a billion worldwide, even if it does not satisfy a small number of non-users who feel particularly strongly about the issue.

Despite continued opposition to tobacco harm reduction from certain quarters, the experience of the UK with e-cigarettes, Sweden with snus and Japan with heated tobacco demonstrates the potential of lower-risk nicotine products to slash smoking rates and reduce the burden of ill health caused by the use of combustible tobacco. But what would have been the consequences if the vaping revolution had been strangled at birth by the precautionary principle? What will be the consequences in the future if the precautionary principle obstructs the progress of new nicotine technology or harm reduction innovations in other fields, such as alcohol and drugs?

5 <https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/news/news/2020/12/new-who-report-reveals-that-while-smoking-continues-to-decline-among-european-adolescents,-the-use-of-electronic-cigarettes-by-young-people-is-on-the-rise>.

An innovation principle for safer nicotine products

In considering how a similar policy statement might apply to the regulation of nicotine-containing products (NCPs) and STPs, the impact assessment produced by the European Commission in support of its proposals for the 2014 revision of the Tobacco Products Directive⁶ is instructive. The Commission considered that NCPs below a certain nicotine level should be sold as consumer products, subject to labelling requirements but no additional registration or authorisation requirements. This was considered to '[encourage] R&D in smoking cessation with the aim of maximising health gains' (European Commission 2012). A full application of medicinal products legislation to all NCPs was dismissed as disproportionate, and the option that was eventually legislated was not featured in the impact assessment at all. In the event, the political processes to pass the legislation led to requirements for authorisation as a medical product for NCPs above certain nicotine concentration thresholds and lesser notification requirements for NCPs below the threshold. The Directive also included advertising restrictions, specific regulations for cross-border sales and various limits on e-cigarette devices and fluids. When this was challenged in the Court of Justice of the European Union, the Court found that the legislation adopted met the requirements of the precautionary principle and that there was no binding commitment to follow the options or recommendations in an impact assessment.⁷

6 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.

7 Cases C-358/14 Poland v. Parliament and Council; C-477/14 Pillbox 38(UK) Limited v. Secretary of State for Health; and C-547/14 Philip Morris Brands SARL and Others v. Secretary of State for Health.

While this no doubt reflects the compromises and contours of the EU system of lawmaking, it also reflects the point that regulatory frameworks, while useful and important, can only be partially effective in constraining lawmaking within the boundaries of good regulatory practice – political considerations often override even the most rigorous of impact assessments (Hewson 2021). To be more effective, due account for principles of innovation and harm reduction needs to be embedded at policy formulation stages, before desired options are subject to impact assessment, and conveyed effectively to the legislators who will debate and vote on the regulations. In the case of tobacco harm reduction, this could include the Department of Health adopting a policy statement similar to the draft put forward by Defra, as set out above, to apply in the field of tobacco harm reduction and NCPs.

Impact assessments are slightly different in the field of tobacco control compared to environmental or other product safety regulations. The objectives are not only to ensure that the products meet an acceptable standard of safety and consumers are given useful information, but also to influence behaviour away from consumption of tobacco and nicotine products at all because of the risk that they cause smoking initiation.⁸ This means that the usual thresholds for precautionary action based on plausible risks from the products alone will not determine the scope and extent of the measures. However, it also means that indications that the proposed measure might have dynamic effects in opposition to this overarching objective should be given closer scrutiny than appears to have been the case in either the Directive or the Tobacco and Related Products Regulations 2016 (TRPR), which implemented the Directive in the UK. The plausible risks that ought to have been demonstrated were both the risks to health from the use of the products themselves and the risk that the NCPs and STPs lead to more smoking initiation than quitting.

The Department of Health's impact assessment on the TRPR noted that the Directive was focused on 'initiation of tobacco consumption, in particular by young people'. Its assessment of the costs of implementation of the Directive included losses of tobacco taxes to the exchequer, transition costs for manufacturers, costs of labelling requirements and costs to the

8 The Directive was a single-market measure, to harmonise labelling, advertising and authorisation requirements and tackle illicit trade. It also aligned with health protection policies. According to the 2021 review of the TRPR, the objectives of the regulations were: discouraging people from starting to use tobacco products, encouraging people to give up using tobacco products, protect young people from the harms of tobacco and implementing elements of the WHO Framework Convention on Tobacco Control.

government for data handling. A dynamic cost in the form of reduction in the ability of tobacco companies to compete through offering products with differentiating characteristics such as flavours and pack sizes was acknowledged. The potential for losses from making NCPs less available or attractive to current smokers were brushed off and not included in the calculation of monetised costs and benefits, but it was assumed that NCPs and STPs would still contribute to smoking cessation:

Whilst the scientific evidence on the effectiveness of e-cigarettes as a cessation tool is limited, data from ASH indicates that in March 2014 there were 2.1 million users of e-cigarettes; a third of whom were both sole users and ex-smokers and data from the Smoking Toolkit Study, reports that 30% of quit attempts now involve the use of e-cigarettes making them the most popular method of stopping smoking. It is possible that an advertising ban may have health costs resulting from smokers not being informed of the availability of products that would reduce the harm of their addiction to nicotine. However, any effect is likely to be limited as awareness of e-cigarettes is already very high in the general population – over 95% amongst smokers and 90% in nonsmokers. (Department of Health 2015)

To ensure a more balanced assessment of risks (both direct and indirect) in tobacco harm reduction, a policy statement could include a bespoke iteration of the formulation proposed by Defra above in respect of new and innovative technologies:

New or innovative technologies should not be held to a higher standard of safety than existing ones where the level of risk is comparable, *other than to the extent that they can be shown plausibly to exacerbate the risks from the existing technologies*, otherwise their potential to deliver benefits will be lost.

A regulation that sought to apply the precautionary principle parameterised in this way, with restrictions based on plausibility of risks from the product itself and a reasonable benchmarking of risks as against existing products, could ensure harm reduction is better accounted for in NCPs and STPs.

It is important to stress that the UK's success with vaping was not the result of institutional commitment to innovation. David Halpern, the head of the Behavioural Insights Team (popularly known as the Nudge Unit), recalls that he first saw an e-cigarette in 2010 after a chance encounter

with his friend, the technology enthusiast and journalist Rory Sutherland. Halpern saw the harm reduction potential and urged David Cameron, the prime minister, to 'seek to make e-cigs available, and to use regulation not to ban them but to improve their quality and reliability' (Halpern 2015: 189–90). This went against the advice of the public health establishment, including the Chief Medical Officer, who were inclined to regulate e-cigarettes as medical products, effectively banning them.

No doubt public health bodies would have considered themselves to be supportive of innovations in known smoking cessation products like nicotine patches (regulated as medicines in the UK), but they did not foresee the development, popularity and success in harm reduction of NCPs. This seems to indicate that, in this as in other fields, not only is innovation vital for improvements in health and prosperity, but that government support for innovativeness among actors in the market, rather than for specific, desired innovations, is most likely to yield transformatively successful products.

Conclusion

It is frequently posited that overapplication of the precautionary principle can hold back innovations that could have positive effects far greater than the risks that precautionary regulation aims to prevent. The experience in tobacco harm reduction described in this paper illustrates how this can be the case.

Reduced-risk nicotine products, such as e-cigarettes, snus and heated tobacco, have been associated with steep declines in smoking prevalence in several countries, including the UK, but have been banned in others on the basis of the precautionary principle. These prohibitions have been harmful to health and well-being by preventing smokers from switching to less risky substitutes.

There is ample evidence that reduced-risk nicotine products has not increased the health risks of smokers who switch to them, nor to society as a whole, but this evidence would not exist if every country had preemptively banned them. Opposition to tobacco harm reduction therefore demonstrates the dangers of a rigid interpretation of the precautionary principle and illustrates the need for an innovation principle.

As mentioned above, the UK's pro-vaping stance began, in part, when David Halpern met a friend who showed him an e-cigarette. Halpern happened to be in a position to advise the prime minister to allow the market to grow. With hindsight, it is clear that this was the right decision, but it could easily have gone the other way. We should not have to rely on influential advisors having random encounters with friends to have a regulatory environment that fosters innovation. An innovation principle for tobacco harm reduction would help to maintain progress in this area and a general innovation principle would help in other areas of the economy that could learn from the case study outlined in this paper.

We argue that an innovation principle for reduced-risk nicotine products should provide a more rigorous basis for the application of the precautionary principle in the field of tobacco harm reduction. This would need to be embedded at the policy-making stage and included in formal cost–benefit analyses to ensure that the benefits of new products are accounted for in the round. An innovation principle could help ensure that policy in this area does not revert to over-regulating products, and that the UK can continue to set an example and produce useful data in tobacco harm reduction for the rest of the world.

Defra has already set out an approach in relation to environmental policy that could usefully be adapted here, while acknowledging the indirect risks of encouraging the take-up of smoking and nicotine products by young people. Such an approach does not mean that new products should not be regulated at all, rather that direct and indirect risks would be assessed in a balanced way, reducing the risk of regulation that unintentionally reduces pathways to smoking cessation.

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