Challenges for evidence in law and public health

Workshop report

Multidisciplinary workshop
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Trinity Hall, Cambridge

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Introduction

This workshop sought to assess the type of evidence required to justify public health regulations, especially when they are likely to harm commercial interests, and how such evidence should be presented, both for policy purposes and with regards to the law.

This report summarises the discussion held by a multidisciplinary panel of experts from across the legal and public health sectors. The interface of disciplines was particularly relevant given the litigation that public health interventions around alcohol and tobacco have recently generated.

Attendees highlighted the tension that sometimes arises between public health aims and commercial free market interests. Participants also pinpointed and challenged the differences between the type of evidence required by the scientific, policy, and legal spheres. Varying requirements within the legal and policy spheres themselves were also examined. For example, within the legal sphere, the type of evidence required might differ depending on whether the intervention is being reviewed at the EU or at the national level.

Panellists also assessed the impact of political will, public pressure, cognitive biases and the media as variables in determining whether public health interventions are successfully implemented. Issues of epistemic unease and subjectivity were unpacked as well as other areas for further investigation, including the potential for using the precautionary principle to justify the trialling of certain public health measures.

The report is divided into the following sections:

1. Setting the scene: standardised packaging legislation
2. Standards of evidence
3. Proportionality
4. The adversarial process
5. Subjectivity and epistemic challenges
6. The precautionary principle
7. Factors outside of the scientific and legal spheres
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This document was updated in October 2017 to reflect legal developments related to plain packaging.
1. Setting the scene: standardised packaging legislation

Non communicable diseases (NCDs) are an increasing burden on public health and on the public purse. Although they are largely preventable, certain public health measures designed to tackle NCDs, particularly those concerning alcohol consumption and smoking, have been challenged in the courts by industry.

On the domestic front, the UK already has in place policies which aim to limit harm from cigarettes, including taxes, bans on most forms of advertising, a ban on selling cigarettes in vending machines, and on smoking in enclosed public spaces. The UK is the second country in the world, following Australia, to introduce plain packaging legislation, which aims to reduce the attractiveness of packaging.

Under the Human Rights Act 1998, which incorporates the European Convention on Human Rights (ECHR) into UK law, corporations are legal persons and therefore have been able to use human rights (including the peaceful enjoyment of one’s property) to challenge certain pieces of legislation. British American Tobacco, Imperial Tobacco Limited, Japan Tobacco International and Philip Morris International unsuccessfully challenged the plain packaging legislation. Two of the tobacco companies proceeded to apply for permission to appeal to the Supreme Court, which was refused in 2017.

While it can be said that the EU itself has very little power in the sphere of public health, since the Treaty of Maastricht, Article 168 of the Treaty on the Functioning of the European Union (TFEU) has held that:

“The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.”

In addition, Article 114 of the TFEU, which concerns the functioning of the internal market, has successfully been used to adopt public health measures, including banning the advertisement of tobacco products.

Historically, the EU focused on providing information for consumers on potentially harmful products, however this approach is now facing criticism from certain groups, including some behavioural scientists, for being ineffective. Recently, the EU adopted a Tobacco Products Directive (2014/40/EU) which requires minimum levels of packaging standardisation, including that 65% of the surface area of packaging be covered by health warnings. Following a legal challenge by the tobacco industry, the ECJ held in May 2016 that the Directive "did not go beyond the limits of what is appropriate and necessary" and dismissed the claim.

Most regulation of tobacco products will fall within the scope of EU legislation, often through the free movement of goods (a fundamental freedom of the internal market). Thus, while litigation around standardised packaging legislation at the national level centres on property rights, at the EU level it is focused on trade. The extent to which member states can justify interferences with the internal market will depend on several factors, including whether the EU has regulated in the area, and to what extent.

Where the EU has already legislated and adopted a maximum harmonisation approach, member states cannot adopt further measures, regardless of the state of scientific evidence. If the EU has
adopted a minimum harmonisation approach, then member states are free to adopt stricter standards but cannot force a higher standard on other member states. In the case of measures around tobacco, EU regulation is close to being fully harmonised, and therefore it can be difficult for member states to legislate.

Finally, there is also litigation concerning standardised packaging on the international stage. For example, Philip Morris took Australia to the Permanent Court of Arbitration, alleging that Australia’s standardised packaging legislation violated a bilateral trade agreement with Hong Kong. The court found in favour of Australia. Australia was also successful in regards to a case brought to the World Trade Organization.

2. Standards of evidence

There are inherent complications around providing evidence in favour of certain public health interventions. These include the multifactorial causes of NCDs and the wider policy landscape, which may make it difficult to assess the impact of one policy on an NCD, and situations where an intervention has not yet been trialled at a population level and therefore evidence simply does not exist about its efficacy. Difficulties around evidence have featured in recent litigation.

Domestically, section 94(1) of the Children and Families Act 2014 gives the Secretary of State the power to create standardised packaging regulations if they consider “that the regulations may contribute at any time to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18.” When the Government went ahead with standardised packaging legislation, four tobacco companies challenged it, which led to a six-day judicial review hearing at the High Court in London in December 2015. The Government’s legislation - which would require packaging to feature, amongst other elements, a prescribed colour, font and finish - had the goals of:

1. Discouraging young people from taking up smoking
2. Persuading them to give up smoking
3. Reducing the appeal of tobacco products
4. Altering beliefs, attitudes, intentions, and behaviours to reduce the use of tobacco products

The claimant tobacco companies argued that the regulations interfered with their property rights (i.e. intellectual property), both under the HRA and the Charter of Fundamental Rights of the EU, as well as violating case law. They claimed that the regulation in question constituted disproportionate interference with their fundamental rights and that the Government had conducted a flawed consultation process.

The tobacco companies’ evidence was used to argue that:

1. Standardised packaging would not reduce smoking and, in fact, would increase tobacco consumption because consumers would have no reason to choose more expensive brands and would pay less for cigarettes
2. The evidence from Australia did not show that standardised packaging reduced smoking
3. Reducing the appeal of tobacco products would not impact smoking behaviour
4. The regulation would have negative unintended consequences, including the growth of the counterfeit tobacco market

The Government’s evidence comprised a large volume of studies encompassing a vast array of methodologies – from neuroimaging and eye tracking technologies to surveys. It included Stirling University’s *Plain Tobacco Packaging: A Systematic Review*, and the *Standardised packaging of tobacco, Report of the independent review undertaken by Sir Cyril Chantler*, which included input from tobacco companies, and concluded that standardised packaging would lead to a modest but important
reduction in the uptake and prevalence of smoking. The Government also introduced empirical evidence from Australia, where legislation had been implemented in 2013.

The claimant tobacco companies’ case was built on challenging the validity of the evidence relied upon by the Secretary of State for Health. The Government in turn pointed out that claimants had presented research funded and commissioned by industry, which was not sufficiently independent.

At the EU level, it is unclear what standard of proof is required to justify public health measures that infringe on the internal market. For example, in the Scottish MUP case, the ECJ noted that the reasons put forward by the Scottish Government in defending their regulation must be accompanied by appropriate evidence or an analysis of the proportionality, but that the proportionality analysis must also be backed by specific evidence.

It also appears that countries can support their efforts to justify public health interventions that impact on the free market by demonstrating that their intervention is part of an overall systematic effort to address a particular public health challenge.

Discussion

The vocabulary and definitions relating to evidence vary across fields. For example, a government may use terms such as ‘concrete’ when referring to evidence, which scientists would not use in the same context. Governments may also refer to evidence without using numbers, which may make it difficult for scientists to engage with. One example provided by a participant is that when a government does not provide specific numbers, for example in the context of justifying a proposed measure, there is no clear path for scientists to challenge the evidence effectively.

One panellist asked about the level of precision in evidence required by the ECJ. For example, terms such as ‘prevalence’ have a very precise meaning in fields such as epidemiology, but don’t necessarily seem to have the same meaning in the legal or policy spheres. Another panellist clarified that in the legal context, using tobacco prevalence helps to clarify a target. For example, most studies on standardised packaging have tried to put a target on the intervention. In the European context, the key target was a reduction in the prevalence of tobacco products of between 1 and 2%. The calculations are limited by the difficulties of ascribing results to one specific policy intervention, for example because there are other interventions at play. The second panellist agreed that intellectually, the limitations of these calculations can be unsatisfactory.

Panellists also noted that the type of evidence required can vary across fields such as law, public health sciences and public health campaigning. For example, a government may not need to prove that a change in corporate tax rates (outside of the public health context), will result in specific outcomes before implementing it, whereas it can be very onerous for a government to justify measures targeting the consumption of certain products in line with public health aims.

One participant noted that, from a behavioural science perspective, reducing the appeal of packaging would seem to be the most effective strategy of reducing the appeal of the products to children, based in part on evidence around marketing. Studies show that we approach products that are appealing, and vice versa, and it was unclear whether this sort of evidence could be used in court. The participant also questioned whether it would be possible to use information about how much an industry spent lobbying against proposed interventions as a form of indirect evidence.

Several participants suggested that the level of evidence required to justify certain public health interventions – specifically where the regulation seeks to reduce consumption of profitable products – seems to have increased over time.
Participants also discussed how we, and how we could, assess the quality of evidence, and to what extent evidence can be, and is, presented in a subjective way. For example, should evidence funded by industry be treated in the same way as other evidence?

What happens, in the legal context, if new evidence emerges? There was commentary during the standardised packaging case at the High Court in London around the frustrations of accepting evidence that came in at a later date. One panellist flagged that in the Scottish MUP case, the ECJ noted that the evidence should be assessed not at the point at which the legislation was adopted but the point at which the case is heard.

In the High Court case, some of the Government’s evidence was criticised for its use of stated intentions in regards to hypothetical situations. However, as an attendee pointed out, you can’t procure certain types of evidence when a regulation has not yet been implemented. Additionally, if a government’s strategy is multi-faceted and intended to work over a long period of time, it becomes increasingly difficult to provide evidence for a specific intervention.

One panellist suggested that where evidence does not exist for a policy, one might build a logical argument in favour of the policy and for each step of the argument provide supporting evidence. Other panellists pointed out that this type of argument would still be vulnerable to the criticism that the policy itself did not have robust evidence to support it.

An attendee noted that policies are generally meant to be synergistic, for example, plain packaging operates best alongside other measures. Additionally, declines in prevalence rates can go into reverse and so it is also helpful to continually update policies. Another attendee agreed that the salience of certain measures, such as warnings on packaging, can be eroded over time. This resonates with the macro-analysis that the ECJ is undertaking, including in recognising in the Scottish MUP case that MUP was part of 40 measures all targeting alcohol consumption.

A panellist noted that the EU has limited capacity to assess public health evidence and that it tends to review more evidence on economic impact than on the potential benefits of public health interventions. Another participant noted that at the European level, the court can appoint experts to help assess the scientific evidence, but this is not done systematically. However, the participant was not aware of any evidence having been set aside as being of insufficient quality. Moreover, the panellist suggested that while the court’s scrutiny seems to have become less deferential to the scientific evidence used by governments to justify public health measures, the court’s tools for conducting scientific analysis have not been altered.

Research questions

1. To what extent has the level of evidence required to justify a public health intervention shifted over time?
2. To what extent could any changes in the requisite level of evidence be linked with certain political discourses, such as the free market?
3. At what point should evidence be evaluated in courts? Should the evidence reflect the state of evidence at the time at which a measure was adopted, or should it be more up to date?
4. Are there types of evidence that are not currently used in courts but that might be helpful in the context of assessing public health measures?
5. Should, and if so how can, courts become more sensitive to the provenance of evidence?
6. Could courts, and if so in what circumstances should they, restrict evidence based on its provenance?
7. At the EU level, could experts help assess evidence more often?
3. Proportionality

At the domestic level, the standard of review applied by the courts in cases concerned with justifying interferences with fundamental rights under the HRA is the standard of proportionality. There is a four stage test, which one speaker argued is applied more rigorously domestically than it would be in the ECtHR. The proportionality test assesses whether:

1. The objective of the measure is sufficiently important to justify the limitation of a protected right
2. The measure is rationally connected to the objective
3. A less intrusive measure could have been used without unacceptably compromising the achievement of the objective
4. Balancing the severity of the measure’s effects on the rights of the persons to whom it applies against the importance of the objective, to the extent that the measure will contribute to its achievement, the former outweighs the latter

In the High Court case, Counsel for the claimants argued that if the Government was intent on limiting the consumption of tobacco products, it would ban tobacco products. However, since the Government was unwilling to do so, one of the most effective measures was taxation, which would also have less effect on the legal commercial interest of tobacco companies.

The starting point in EU cases is to assess the impact of the measure on the free market. The paradox at the heart of EU public health policy, as it pertains to products that harm public health, is that measures adopted by the EU ostensibly promote rather than restrict the free movement of the products in question. The court tends to be quite deferential in the case of measures intended to benefit public health. Once a measure falls within the scope of EU law, member states must show that the measure is proportionate, specifically whether the measure is

1. Appropriate
   a. The measure must be shown to be appropriate to achieve the public health policy objective
      i. Is it designed to further the public health objective?
      ii. Is it part of a wider public health policy addressing the particular public health hazard?

2. Necessary
   a. Were there no less restrictive measures on the internal market to protect public health?

Although it is for domestic courts to decide whether the impact on the internal market of their public health measures can be justified, recent ECJ judgments, including on the challenge brought by the Scottish Whisky Association against the Scottish Government over minimum unit pricing (MUP), suggest that the EU is willing to ask member states to demonstrate that there were no other relevant measures which would have less of an impact on the internal market.

Discussion

Panellists highlighted the differences in the way lawyers, public health campaigners and public health scientists view proportionality. Campaigners would be aware of the political need for proportionality whereas scientists might look at issues such as impact, opportunity costs, and relative risk.

Several panellists were critical of the legal proportionality tests and concerned over how it might address the tension between the interests of public health and the economic interests of corporations. Several participants queried whether, in the case of public health interventions, we might approach
proportionality tests in another manner. One asked whether it be helpful to replace the proportionality test with a test of reasonableness in the case of public health interventions. It was pointed out that the EU proportionality test commences by examining the infringement on the internal market, which creates a structural bias. With regard to the EU, it was suggested by a participant that unless the division of power between the EU and member states is altered, this tension between economic interests and public health interests cannot be altered.

Several panellists noted that there was a tension in that the larger the success of a public health measure, the more valid the claims of an industry, such as the tobacco industry, that their rights are being infringed. Again, it was pointed out that this is an unintended issue of the structure of the law, and that newer treaties such as The Transatlantic Trade and Investment Partnership exclude tobacco products from the scope of the trade provisions.

It was pointed out that the proportionality test in regards to these public health interventions is not always consistent with other domains. For example, in the case of pharmaceuticals, companies must prove that their products are safe prior to entering the market. One panellist flagged that the proportionality test is also not applied with uniform rigour at all levels. For example, it may be more difficult to pass at the national level than the EU level.

An attendee pointed out that there are value judgements being made when proportionality tests are carried out and there is a hierarchy of fundamental rights in the European Convention. It was pointed out that balancing as a notion is criticised as being flawed in other areas of human rights law, for example in regards to certain questions around security, whereas it does not seem to have attracted as much criticism in the context of interventions to combat NCDs.

There was discussion around the strategy involved in interpreting and presenting evidence. Some participants grappled with the difficulty of assessing proportionality, particularly when targets are narrow – for example, how would you measure the impact of MUP on a ‘moderate drinker’? Multiple participants agreed that the more and the broader the objectives, the more difficult it is to fail at meeting them.

One panellist asked about the proportionality test at the EU level, and how the court compares an intervention with another that might impact the internal market less. Specifically, when MUP is compared to taxation, how do you compare a fixed MUP point with a variable tax? A fellow panellist pointed out that paragraph 44 of the Scottish MUP case the ECJ explains that they are interested in protecting the free formation of prices, as opposed to the amount of taxation.

As a participant noted, on the specific protection offered to brands, a trademark acts as a badge of origin and EU trademark regulation doesn’t specify that a brand also confers rights beyond this, which the Government has argued. Another participant added that traditionally trademarks have been a private law matter to stop others from using your trademark as opposed to becoming a public law matter.

Research questions

1. Could we usefully employ other legal standards in the context of justifying public health interventions, such as ‘reasonableness’?
2. While it is mainstream in many areas of law to recognise the flaws in the act of ‘balancing’, this discourse has not yet made it to this area of law. Might it be helpful to highlight this issue to courts and other stakeholders?
3. Is there a tension in that the more effective a public health policy is in impacting the use of a dangerous product, the more credible a claim by the companies making the product might be that their human rights have been infringed upon?
4. Would it be possible to alter the current legal structure that impacts upon the burden of proof in public health policies?

4. The adversarial process

Discussion

A panellist noted that our courts rely on an adversarial system where the government puts forward their evidence and then industry puts forward their evidence. The panellist queried whether this was an effective method for getting to the ‘truth’. The panellist suggested that the Australian concept of hot tubbing (more formally known as ‘concurrent expert evidence’), might be preferable. During this process, a judge sits down with experts, questions them at the same time, and tries to unpack areas of disagreement.

Research questions

1. How might ‘hot tubbing’ impact upon public health interventions in the legal system?

5. Subjectivity and epistemic challenges

Discussion

Panellists unpacked some of the challenges around subjectivity and epistemic unease with the legal challenges to proposed NCD interventions. For example, even purely from a policy perspective, it was pointed out that there is an element of subjectivity. For example what constitutes a ‘responsible drinker’ may be viewed differently by those interested in alcohol-related crime, as opposed to those interested in public health.

Several participants noted the epistemic unease around the approaches of courts and policymakers. Several panellists discussed the idea that legally trained individuals must evaluate one side’s evidence against the evidence of the other side. How can an individual trained in law, rather than in the sciences do this effectively? One participant pointed out that this does appear to have an impact as the ECJ case law suggests that sometimes there is confusion between the evidence on the causes with the evidence on the effectiveness of the policy interventions.

Panellists generally agreed that depending on the attitudes of a society, you might see a public health intervention as a challenge to freedom, and thus a cost, or you might view the failure to implement a public health measure as a cost. Individuals will also value and define health differently.

6. The precautionary principle

There precautionary principle has generally been used to justify acting in cases where evidence of a potential harm is not robust. However, in the case of standardised packaging, it could be used to trial a measure aimed at preventing harm where the evidence around the effectiveness of a potential solution is lacking or weak.

In a case regarding a ban of visual displays of tobacco products in Norway contested by Philip Morris, the Court of Justice of the European Free Trade Association States (EFTA) had to decide what type of evidence burden to place on Norway. There was evidence from a similar regulation implemented in Iceland, but it was not clear that the regulation would function in the same way with a different population. The court ultimately held that where states have a legitimate aim, they may invoke the precautionary principle when there is relevant scientific uncertainty in regards to the suitability and necessity of the proposed measure and that you could assume – given no convincing evidence to the
contrary – that the measure would benefit public health. This conclusion was perhaps surprising as the precautionary principle is not currently a principle of international law.

In the Scottish MUP case, the ECJ noted that the potential for the measure to be temporary might be a point in favour of trialling the measure.

Discussion

Several participants were struck by the idea that a version of the precautionary principle might benefit public health interventions by allowing governments to justify implementing interventions, even if evidence supporting the effectiveness of the policy does not yet exist. The precautionary principle might most appropriately be used to temporarily trial measures, for example, minimum unit pricing.

As one participant pointed out, there are many definitions of the precautionary approach, which has been especially prominent in the environmental movement. The traditional strong standard of precaution is to avoid doing something unless you know it’s not harmful. A traditional weaker standard of precaution is to avoid something even if you’re not sure it’s harmful. The EFTA judgment seems to be equivalent to the weaker standard – trying a policy even when you’re not sure it works in order to avoid the risk of harm that might follow by not implementing the policy.

Whilst there was much support for the precautionary principle, it was also pointed out by one panellist that trialling interventions which would carry serious ramifications for producers – for example, altering how their factories are run – should not be taken lightly.

Research questions

1. How might we further develop the use of the precautionary principle in the context of public health interventions and how might it be best used?

7. Factors outside of the scientific and legal spheres

Discussion

Panellists analysed the factors outside of the scientific and legal spheres which impact upon whether a policy is implemented. Multiple attendees highlighted the role of political narratives, and the impact that party politics can have on policy, as described in the policy streams analysis (Kingdon). There was a recognition and general agreement around the differences between the legal and political processes, and that scientific evidence was not sufficient to ensure the political will to implement a policy.

One attendee raised the example of the UK’s recent ban on psychoactive substances, which did not seem to have required a high level of evidence to support it, nor did the legislation meet with the same level of corporate opposition as policies impacting alcohol and tobacco sales.

Panellists also discussed the role played by culture in the acceptability of proposed measures. For example, several participants held that there is an entrenched narrative around guns in the United States, which seems to hinder attempts at introducing new gun legislation, whereas the UK passed legislation after Dunblane quickly. On an individual level, it was argued, the relevant mechanism might be cognitive biases, including the status quo bias.

There was general agreement that an engaged public, along with the media, can influence the policy agenda. For example, it was pointed out that several years ago the English government ruled out the possibility of a sugar tax. However, partly thanks to the advocacy of Jamie Oliver and academics, the public came to support the cause. One attendee pointed out that this reveals that while corporate
influence may have a large impact, consumers equally hold weight because they can change their buying strategies.

8. Further reading


9. List of participants

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Professor Gerard Hastings, Emeritus Professor, Institute for Social Marketing, University of Stirling

Professor David Howarth, Chair, Professor of Law and Public Policy, Department of Politics and International Studies

Dr Stephen John, Lecturer, Department of History and Philosophy of Science, University of Cambridge

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Dr Kathy Liddell, Director, Centre for Law, Medicine and Life Sciences, University of Cambridge

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Dr Eva Nanopoulos, Bob Alexander College Lecturer and Fellow in Law, Faculty of Law, University of Cambridge

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