

Legal Issues in the Design and Implementation of Public Health Measures

Issues that may have legal consequences are often overlooked when public health measures are first devised. In the early stages of planning to address a public health problem, civil society, public health experts, academics, and government officials may not have the technical capacity to apply a legal lens – or know when legal considerations should be taken into account. Lawyers are not typically involved in preliminary decisions like how research is conducted and evidence is gathered, yet these choices often play a critical role in how effectively measures are eventually implemented, and whether they can withstand legal scrutiny.

Awareness of important legal principles can help the public health community craft stronger, more effective measures.

The term “measure” is used to cover a wide range of legal instruments, such as legislation, regulations, and compulsory standards.

The Global Health Advocacy Incubator (GHA) supports civil society organizations that advocate for public health measures that reduce death and disease, drawing on decades of experience across public health issues and political systems. Working in multidisciplinary teams, we provide support for the development of strong, evidence-based measures that can stand up to legal threats.

GHA has developed a list of seven interdependent steps to help advocates and governments identify and account for legal issues from the outset of their work developing public health measures. This document can be used to assist collaboration between public health experts and lawyers to create effective and impactful measures.

7 steps

for incorporating legal considerations into the development of a public health measure

STEP 1. Define the public health problem

STEP 2. Identify the policy response and objectives

STEP 3. Review existing measures

STEP 4. Account for implementation and enforcement

STEP 5. Determine when to use legislation or secondary instruments (e.g., regulations)

STEP 6. Account for constitutions, cases, and other measures

STEP 7. You're ready to (ask a lawyer to help you) draft the measure!

Key terms

- **Measure:** a wide range of legal instruments for which compliance is mandatory, such as legislation, regulations, and compulsory standards
- **Secondary instrument:** a subsidiary measure (e.g., regulation), which typically provides details for the implementation of a primary instrument (e.g., legislation)
- **Policy response:** a government initiative that is intended to address a public health issue; types of policy responses can vary significantly, from specific measures to voluntary agreements or broad government plans

STEP 1. Define the public health problem

At the beginning of designing a measure, it is important to clearly define the exact public health problem it will address. Many public health measures are challenged based on how clearly their objectives are defined and linked to the measure's goals and supporting evidence.

Clearly defining the public health problem is also important for effective monitoring and evaluation when the measure is implemented. If it is challenged, the right evidence can help demonstrate the extent of the problem, that the problem was severe enough to warrant regulation, that a range of policy responses were considered, and that the selected measure was the most appropriate.

This step is particularly significant for defending domestic measures in international trade and investment law disputes, and potentially in domestic legal challenges.

Guiding questions

- (1) What is the public health problem the measure is attempting to address?
 - (a) Is the public health problem included in a national commitment or program (e.g., a national NCD policy)? How is it described?
 - (b) What kinds of products, industry practices, or behaviors are problematic?
 - (c) Are there global and country-specific data on the use and harms associated with this product or industry practice?
 - (d) Are vulnerable groups or sub-populations particularly affected by the product or practice?
 - (e) Are there places where use of the product or industry practice are particularly prevalent?
- (2) Are there baseline measures that assess the extent of the public health problem and can be used to track and monitor the effect of the selected policy response?
 - (a) Examples include product sales, consumer behavior, and disease prevalence.
- (3) Have there been other legal or non-legal attempts to address this problem in the country?
 - (a) Have these mandatory or voluntary attempts been successful? If not, document the reasons why they have been unsuccessful.
- (4) Collect evidence to support the public health goal and policy responses being considered.
 - (a) Use best practice examples and documented experience from other countries.
 - (b) Collect evidence relevant to your country.

STEP 2. Identify the policy response and objectives

After defining the public health problem, it is important to clearly articulate the relevant issues, populations, products, behaviors, and/or activities that need to be addressed with a public health measure. Use this information to identify what types of policy responses are most appropriate for addressing the problem. Then, articulate objectives that tie the public health problem to the evidence-based policy response that you have selected to address it.

Guiding questions

- (1) Identify a wide range of policy responses that could potentially address the problem defined in Step 1, and then consider which are most appropriate and have the strongest evidence base.
 - (a) The range of policy responses considered may include voluntary and mandatory options, responses that are targeted at consumers (e.g., education campaigns), measures targeted at products, and measures targeted at industry practices.
 - (b) Document all the responses considered, including evidence in support of each response. Clearly outline why each option was considered appropriate or not for the context. Note that some options may be complementary to the chosen policy response.
 - (c) Note that the term “measure” is used below for the selected policy response, since this document is meant to guide the development of mandatory legal instruments.
- (2) Choose the most appropriate policy response to address the problem at this stage.
 - (a) Define the target populations that need to be addressed in the measure.
 - (b) Define the target products and activities to be prohibited or restricted.
 - (c) Clearly justify any distinctions made between products.
- (3) Define the policy objectives based on the problem identified in Step 1 and the policy response identified above.
 - (a) Clearly articulate layered objectives against which the success of the measures can be assessed.
 - (b) Objectives should reflect short-term, measurable outcomes and be tailored to the particular circumstances of the country and available evidence.
 - (c) Link the objectives to any broader public health goals (e.g., a national NCD strategy) and explain how the measure fits into the government’s overall effort to address that goal.
 - (d) Consider whether to revisit Step 1 and refine the scope of the public health problem the measure will address.

STEP 3. Review existing measures

Rarely are public health issues so novel that they have never been addressed before. Oftentimes, measures or policies related to the problem or a similar public health issue already exist. These existing measures may provide useful insights into how to design effective and implementable measures.

Researching the efficacy of existing measures – including the reasons why they are working well or not – is essential before moving forward with new measures.

Guiding questions

- (1) Identify all existing measures that relate to the issue.
 - (a) This could include measures related to public health, marketing, communications, the environmental, child protection, consumers rights, administrative codes, etc.
- (2) To what extent are any existing measures suited to address the objectives identified in Step 2?
- (3) If there are existing measures that already address the issue, to what extent are they effective?
 - (a) If their efficacy is difficult to gauge, why? What information gaps exist?
 - (b) Are monitoring, evaluation, and reporting requirements set out in the measure?
- (4) To the extent that existing measures are not effective, why?
 - (a) Are the measures themselves poorly drafted? Do they contain loopholes?
 - (i) Do the measures align with best practice guidelines?
 - (ii) Are there definitions that could constrain the interpretation of the measure you are designing? For example, “marketing” could already be defined in an advertising law, yet might be much narrower than would be needed for an effective restriction on the marketing of unhealthy food.
 - (b) Have enforcement agencies or courts interpreted the existing measures unfavorably?
 - (i) If so, can this be addressed or overcome in the measure you are developing? For example, is it possible to reach out to the enforcement agency? Would bringing a legal action to correct the interpretation be possible or effective?
- (5) Are the existing measures being enforced? If not:
 - (a) Do they lack appropriate enforcement mechanisms?
 - (i) For example, do the right agencies have sufficient authority to enforce the measure? Is cooperation among agencies needed but not provided for in the measure?

- (ii) Is there a range of appropriate enforcement mechanisms? For instance, are the responsibilities to comply placed on the appropriate entities, such as the importer, manufacturer, retailer, or consumer as needed?
- (b) Do the measures contain appropriate enforcement mechanisms that are not being used adequately or correctly? If so, is this due to:
 - (i) Resource constraints,
 - (ii) Appropriate agencies lacking the right equipment or personnel,
 - (iii) Lack of inter-agency cooperation, or
 - (iv) Other factors?
- (c) Are the correct inspection and enforcement agencies being tasked under the measure? Do these government bodies have sufficient political will and resources, and are they best suited to do the job relative to other ministries and agencies?
 - (i) Should the existing measures be amended and strengthened, or replaced entirely?

STEP 4. Account for implementation and enforcement

Implementation and enforcement are often viewed as matters to be considered after a measure is passed, yet they can and should be addressed in the crafting of the measure itself. Far too often, public health measures are successfully passed but never implemented because these matters are not accounted for in the initial planning stages. In some cases, it may not be reasonable to move forward with a new measure until these issues can be resolved.

The questions addressed in Step 3 will provide a strong foundation for considering how best to structure the new measure to ensure that it is effective. The questions below expand on this analysis to guide the process of building strong implementation and enforcement schemes into the measure.

Guiding questions

- (1) Which government bodies are going to implement, monitor, and enforce the measure?
 - (a) Do the appropriate bodies exist, or will new ones need to be created?
 - (i) For example, in some instances a ministry of health may be responsible for regulating the advertising of food. However, it may not have the legal authority to enforce the measures, which may be more appropriately enforced by a ministry of communications or an advertising regulatory body.
 - (b) What are the remits of existing inspection and enforcement bodies? For instance, what kinds of places can they inspect? What is their connection with health authorities?
 - (c) If the appropriate bodies exist, how will this proposed public health measure connect with the law that governs those bodies?
 - (d) Does each designated government body have sufficient authority, resources, and political will to carry out the necessary monitoring and enforcement?
 - (e) Does the government body already enforce other measures or impose similar sanctions?
 - (f) Will the body require additional resources or expertise to enforce the measure?
 - (i) If so, where will these resources come from and how will they be appropriated? Does this require additional legislative or policy change?
- (2) What kind of legal authority is required for the relevant government bodies and what is the scope of their authority?
 - (a) Does the appropriate body have power to enact regulations or other subsidiary measures?
 - (i) If the body doesn't have the necessary authority, it is important to create, empower, and fund them to implement the measure.

- (ii) Consider whether there are several bodies that will need to coordinate or share information. Does the measure need to provide for this?
- (3) Do the agencies identified to implement the measure have the political will to do so? Are they implementing similar types of measures? Have they been consulted?
 - (a) Will they be vulnerable to industry interference and conflicts of interest? If so, how will this risk be managed?
- (4) How will compliance be monitored and evaluated?
 - (a) Are there inspectors or other mechanisms for monitoring?
 - (b) Are there existing regimes (such as health and safety inspections) that can be adapted and used to monitor this measure?
 - (c) Can civil society organizations or the public submit complaints to the monitoring mechanism?
 - (d) Is there sufficient funding for the compliance mechanism?
- (5) What are the most appropriate sanctions?
 - (a) Some possibilities include fines and administrative or criminal sanctions.
 - (i) If considering criminal sanctions, would the criminal penalty for violations be consistent with human rights principles, and criminal penalties for similar violations under other comparable measures?
 - (b) For product regulation, are product recalls and licensing revocations possible enforcement mechanisms?
 - (i) Could regulated products be subject to a recall for noncompliance?
 - (ii) Could manufacturers, importers, distributors, wholesalers, or retailers be held accountable through a licensing mechanism?
- (6) If there is no appropriate enforcement mechanism or potential to create one, does it make sense to pass a measure at this time?

STEP 5. Determine when to use legislation or secondary instruments (e.g., regulations)

When designing a public health measure, it is important to consider what types of measures are available. Typically, legislation contains broad rules; secondary instruments, such as regulations, often establish details for implementing those rules.

Sometimes, the type of measure to pursue will be purely a legal question, determined by a country's legal system. However, in some instances, various types of measures are available; therefore, political considerations can be factored into the decision. For example, legislation is typically stronger and harder to change, and must be enacted by a legislature. Regulations and other subsidiary measures are typically more susceptible to change and are issued by a government agency. The pros and cons of all available options should be considered. At times, a mix of legislation and secondary instruments may be most appropriate.

Guiding questions

- (1) Which of the measures identified in Step 2 should be written into legislation and which are more appropriate for secondary instruments, such as regulations?
 - (a) Do certain measures need to be approved by a legislature through a formal law?
 - (b) Are certain measures so politically controversial that the entire law may be threatened if they are included? If so, is it possible to provide a broad scope of authority in the law in order to address them through subsidiary measures later?
- (2) If legislation mandates addressing the issue in secondary instruments, what scope of authority does it provide?
 - (a) Is it sufficiently broad and flexible?
 - (b) If progressive implementation is adopted, are there clear timelines and targets?
 - (c) Can the legislation address what happens if secondary instruments are not passed within a certain timeframe?
- (3) If legislation is passed, will it be implementable without the passage of secondary instruments?

STEP 6. Account for constitutions, cases, and other measures

Once the exact policy responses are identified, but before the measure is further developed, it is helpful to ask a lawyer about other measures, constitutional requirements, and trade and investment treaties. These considerations could impact how the measures are designed and drafted.

Guiding questions

- (1) Consider whether the proposed measure infringes on any existing laws.
 - (a) Are there any constitutional rights or protections that may support or interfere with the measure? Is there any relevant domestic jurisprudence addressing constitutional limitations?
 - (i) Freedom of speech or freedom of commerce provisions can sometimes limit the ability of governments to pass strong measures or can be arguments used by industries to challenge measures.
 - (ii) Constitutional rights to health, food, and the environment, and the rights of the child can often be used to strengthen and provide support to public health measures.
 - (b) Are there any other limitations on power that need to be addressed? For example, divisions of power between national and sub-national entities.
- (2) Consider other relevant procedural requirements, such as formal due process requirements, regulatory impact analyses, and requirements to consult all stakeholders prior to passing the measure.
- (3) What is the relevance of international human rights law in the country?
 - (a) Have human rights monitoring bodies considered the particular health problem or suggested measures to be adopted? Have particular recommendations been made for the country?
- (4) Are trade or investment law issues likely to impact the measure?
 - (a) Does the measure raise any obvious trade concerns? For example, does it distinguish between domestic and imported products? Could it affect imported products more?
 - (b) Does the measure seek to substantially change the regulatory environment?
 - (c) Are there industries that are likely to make threats – justified or not – based on trade law or investment treaty arguments?
- (5) Are there particular legal arguments opponents have used to challenge similar measures? Is it possible to prepare counterarguments?

STEP 7. You're ready to (ask a lawyer to help you) draft the measure!

All public health measures will be unique, and though it is helpful to look at similar laws from other countries, it is important to tailor a measure to a country's particular circumstances. Broadly, when a lawyer is tasked with drafting a public health measure, they will include these key components:

- (a) Regulatory objective
- (b) Definitions of key terms
- (c) The measures themselves
- (d) Duties of compliance
- (e) Sanctions
- (f) Powers and authorities
- (g) Monitoring and evaluation

Conclusion

These steps are designed to assist public health experts and lawyers work together to ensure that all components of a public health measure are developed well before the drafting stage. The Global Health Advocacy Incubator can provide further legal resources and guidance on particular public health topics, along with technical assistance and advice on drafting a particular public health measure.

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