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Commentary

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Leveraging stringency and lifecycle thinking to advance environmental sustainability in health technology regulation

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Abstract

Regulatory actors, particularly market authorization agencies, health technology assessment agencies, and health care procurement agencies, exert a powerful influence on the adoption and use of health technologies (eg, medicines and medical devices). With health care being responsible, directly and indirectly, for an estimated 4.6% of global greenhouse gas emissions, alongside other environmental harms, these actors have recognized the need to address the environmental impacts of health technologies. In this commentary, we utilize concepts of regulatory stringency and lifecycle thinking, considering scope, prescriptiveness, and performance requirements, to analyze recent efforts to incorporate environmental sustainability into the regulation of medicines and medical devices. While we acknowledge recent progress, we argue that there is significant, untapped potential for developing more fulsome and effective regulatory mechanisms to improve the environmental sustainability of health technologies.

Key words: health technologies; environmental sustainability; regulatory stringency; lifecycle thinking.

Introduction

Regulatory actors, particularly market authorization agencies (eg, Health Canada, the US Food and Drug Administration, and the European Medicines Agency), health technology assessment (HTA) agencies (eg, Canada's Drug Agency [CDA-AMC] and the UK's National Institute for Health and Care Excellence [NICE]), and health care procurement agencies (eg, Canada's Mohawk Medbuy and England's National Health Service [NHS] Supply Chain), exert a powerful influence on the adoption and use of health technologies (eg, medicines and medical devices). Market authorization agencies adjudicate safety, efficacy, and good manufacturing practices required for health technologies to be brought to market; HTA agencies inform coverage and appropriate-use decisions in the context of collective payment and health care procurement agencies coordinate purchasing of goods and services for use within health care delivery organizations. These actors are "regulatory" in their capacity to steer "the flow of events"[1] and drive innovation from the demand side.[2]

Health care is responsible, directly and indirectly, for an estimated 4.6% of global greenhouse gas (GHG) emissions.[3] Further, health technologies cause many other environmental harms, including pollution of air, water, and soil, along with resource depletion and biodiversity loss.[4-6] These harms arise from activities across their lifecycle, including manufacturing, transportation, clinical use, disposal, and waste processing.[7-11]

To varying degrees, all 3 types of regulatory actors have begun to address the environmental impacts of health technologies. As the most mature of these efforts, market authorization regulators in Canada, the United States, and the European Union have established requirements regarding the environmental risks of pharmaceuticals.[5,12] Health technology assessment agencies have expressed interest in environmental impacts,[13,14] although only 2 national agencies have made formal sustainability commitments (NICE in the UK[15] and CDA-AMC in Canada[16]). There is growing interest from many group purchasing organizations and associations.[17,18] On a national level, the most decisive activity is from the English NHS, whose procurement roadmap was the focus of an agreement with the US Department of Health and Human Services (HHS) at the 2022 United Nations Climate Change Conference (COP27). Further, a growing body of literature is exploring how each regulatory actor is working to incorporate evidence on environmental impacts, whether for expanding market authorization criteria,[5,19] developing HTA methods and metrics,[13,20,21] or leveraging procurement tendering processes.[22,23]

In this analysis, we use the concepts of regulatory stringency and lifecycle thinking to examine these emerging efforts to regulate the environmental sustainability of health technologies. Regulatory stringency is a multifaceted concept, including considerations of scope, prescriptiveness, and levels of performance required.[24] The perceived stringency of a regulatory action is

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often central to both positive and negative evaluations of legitimacy among stakeholders, both those a program aims to empower and those it aims to restrict.[24] While regulatory stringency does not address all aspects of the adequacy of a regulatory regime—critical issues related to evidentiary quality and implementation capacity are, for example, omitted—it nonetheless offers a crucial multidimensional approach to analyzing the effectiveness of regulatory action.

Stringency of existing regulatory actions

In the following sections, we utilize concepts of regulatory stringency and lifecycle thinking—scope, prescriptiveness, and performance requirements—to assess current regulatory efforts to address environmental impacts of health technologies.

Scope

A regulation's scope should describe comprehensively which policy problems it addresses.[24] For regulation of environmental harms, the scope should be guided by lifecycle thinking, which "[goes] beyond the traditional focus on production site and manufacturing processes so to include the environmental, social, and economic impact of a product over its entire lifecycle."[25] Accordingly, 2 key dimensions must be addressed—the types of environmental impacts considered (eg, GHG emissions, eutrophication potential) and the stages in the lifecycle of the technology for which these impacts are considered (ie, from upstream manufacturing, through use and downstream disposal and waste management).

For example, in accordance with the Canadian Environmental Protection Act (CEPA, 1999), Health Canada and Environment and Climate Change Canada conduct environmental risk assessments (ERAs) for new pharmaceutical substances. Although these processes are under review, they currently only assess 1 environmental concern—the toxicity risks of a substance—and only at 1 point in its lifecycle—when it is released into the environment. They do not consider toxicity at other points in the lifecycle (eg, in the upstream production of chemical precursors), nor do they consider other types of environmental impacts (eg, GHG emissions).

The NICE in the United Kingdom has begun to include environmental considerations in recent guidance and advice tools, such as a Patient Decision Aid on Asthma Inhalers and Climate Change published in 2022.[26] This decision aid provides information for patients regarding the climate change impact of metered dose inhalers (MDIs), along with decision-making tools for changing inhaler types and reducing the climate impact of asthma treatment. This guidance document has a broader scope, as it includes multiple types of environmental impact, GHG emissions and waste from MDIs, across 3 stages in the lifecycle (ie, prescribing, use, and disposal).

In March 2024, NICE published an Evidence Summary on the use of desflurane for anesthesia maintenance. It underpins the decision by NHS England to support the implementation of the national policy to stop routine use of desflurane in anesthetic practice by early 2024.[27] The scope of this regulatory action is narrow, being limited to GHG emissions in the use phase of anesthetics.

The UK NHS Supply Chain added requirements for GHG emissions reporting and reduction (suppliers to achieve "net zero" by 2045) to its procurement criteria in 2021.[28-30] The NHS Net Zero Supplier Roadmap requires suppliers to have a carbon-reduction plan that aligns with the NHS Net Zero ambition, while incorporating social value criteria (eg, completing a sustainable supplier assessment, meeting roadmap milestones, and addressing modern slavery). Although this regulatory action targets NHS supplier companies rather than health technologies specifically, and the scope is somewhat narrow in the types of environmental impacts (ie, primarily GHG emissions), the regulatory requirements are positioned to impact multiple upstream lifecycle activities including manufacturing and distribution.

By expanding the regulatory scope to include multiple environmental impacts across the lifecycle, regulatory actors can more effectively address the full extent of environmental harm. This broader scope is critical to achieving the regulatory stringency needed to advance sustainability in health technology regulation.

Prescriptiveness

While scope is essential in defining the breadth of a regulation, prescriptiveness ensures that the regulation translates into enforceable actions. Without clear prescriptive measures, even a broad regulatory scope would fail to produce meaningful outcomes. The 2 key dimensions of regulatory prescriptiveness—obligatoriness and substantiveness[24]—should be explicit in regulatory mechanisms. Substantiveness concerns whether regulatory requirements or guidelines are procedural, outcome-oriented, or a combination of both. Obligatoriness reflects the degree to which a regulatory action encourages or mandates achievement of intended outcomes—whether through voluntary guidelines, mandatory requirements, or a combination of both (Figure 1). It is important to distinguish between the level of performance requirements and the prescriptiveness of those requirements. Prescriptiveness concerns the degree to which a particular component (eg, procedures or outcomes) is obligatory and/or substantive; it does not discern the level of substantive outcomes required (eg, amount of GHG emissions reduction); we will address the dimension of performance requirements in the next section.

To illustrate, a requirement to reduce the GHG emissions of a health technology, or to limit its "carbon footprint" to a specific level, is not substantive (procedures: not included; outcome: included) but is obligatory (a mandatory outcome, emissions reduction, is required) and thus is somewhat prescriptive. Similarly, a requirement for a medical device manufacturer to have an environmental policy (possibly certified to international standards) can also be considered somewhat prescriptive, as it includes mandatory procedures but lacks outcome requirements. The most prescriptive regulatory mechanisms would include both procedures and outcomes and require the procedures to be followed and outcomes to be achieved.

As a more tangible example, Canadian regulatory requirements for ERAs of pharmaceutical products are very prescriptive. The application outlines specific data required, and assessments use detailed procedures to assess the toxicity of substances. These regulations represent high prescriptiveness as they are obligatory for market access and are substantive as they include both procedural and outcome requirements.

In contrast, the NICE Patient Decision Aid on Asthma Inhalers is voluntary—only providing decision-making guidance for patients. It is also not substantive, offering procedures in the form of several decision matrices supporting evidence-based decision-making processes, and only recommends outcomes (ie, reduce GHG emissions of the patient's asthma treatment plan).

Figure 1. Key dimensions of regulatory prescriptiveness. Abbreviations: GHG, greenhouse gas; NHS, National Health Service; NICE, National Institute for Health and Care Excellence.

The NICE Evidence Summary for desflurane was produced to expressly support the decision by NHS England to stop routine use of desflurane in anesthetic practice by early 2024. This NHS policy decision is somewhat prescriptive as it is mandatory and outcome-oriented, although it does not include procedural guidance to reach the required outcome.

The UK NHS Supply Chain requirements for supplier GHG emissions reporting and reduction are mandatory and substantive, including both procedural (ie, emissions reporting) and outcome (ie, emissions reduction) requirements.

While prescriptiveness determines the extent to which regulatory guidelines enforce procedures and outcomes, performance requirements define the specific levels of achievement necessary to meet environmental goals. Combined, a comprehensive scope with prescriptiveness ensures that actions are taken, while performance requirements measure the effectiveness of those actions in reducing environmental harm.

Performance requirements

The final dimension of regulatory stringency addresses the levels of substantive performance requirements.[24] Performance requirements could be expressed as either relative outcomes (eg, reduce carbon emissions by 20%) or absolute outcomes (eg, achieve "net zero" emissions).

For example, while the completion of an ERA is required for market authorization approval of a pharmaceutical product in Canada, approval cannot be denied based on ERA results alone. The absolute performance requirement of a ratio <1 for adverse effects of ecosystem exposure for a substance to be deemed "not toxic" adds stringency to the process; but the fact that being deemed "CEPA-toxic" does not prevent market authorization (ie, there is no mandatory requirement for nontoxicity) undermines this regulatory action.

The NICE Patient Decision Aid on Asthma Inhalers suggests relative performance targets (ie, reducing GHG emissions from asthma treatment). Further, the guidance states that "[changing to dry powder inhalers] …will have the *most* benefit on climate change," and suggests "…6 things that could help *reduce* the carbon footprint of your asthma treatment" [emphasis added], illustrations of relative performance requirements.

The NHS Desflurane Policy and the NHS Supply Chain Net Zero regulation provide stringent performance requirements. Desflurane is "the first medicine to be decommissioned by the NHS in England because of global warming potential."[31] The NHS Supply Chain requirements for GHG emissions reporting and reduction (ie, the net-zero target) demonstrate an absolute performance measure.

Stringent performance requirements are necessary for ensuring measurable outcomes, but they cannot achieve their full potential without being implemented within a comprehensive regulatory framework that balances scope, prescriptiveness, and performance requirements. The interplay of these dimensions highlights the need for a more holistic approach to regulatory stringency, which we will explore in the following discussion.

Discussion

Applying regulatory stringency concepts, we argue that, while current regulatory actions have begun to address environmental impacts, there is significant, untapped potential for developing more fulsome and effective regulatory mechanisms to improve the environmental sustainability of health technologies.

While more onerous performance requirements may initially be regarded as the most important dimension of regulatory stringency, performance requirements need to be considered together with the regulatory scope and prescriptiveness.[24] Scope alone does not account for variation in prescriptiveness or levels of performance requirements, and focusing on prescriptiveness to the exclusion of scope and performance requirements produces regulations void of substance. Finally, valuing performance requirements alone risks excluding key criteria and broad generalizations. Our analysis demonstrates the crucial role of each dimension in improving regulatory stringency.

Nonetheless, improving even 1 dimension of regulatory stringency—for example, by strengthening performance requirements, or by introducing some regulation in a previously unregulated area—is a positive step. It is also notable that regulatory actors in resource-constrained settings (eg, in low- and middle-income countries) face greater challenges in developing and implementing regulatory mechanisms. To address these challenges, the World Health Organization (WHO) Prequalification of Medicines Programme[32] offers a model that could be extended to cover environmental considerations alongside quality, safety, and efficacy.

Still, a narrow regulatory scope—both in terms of lifecycle stages and environmental issues—is a common theme in current environmental regulatory policy for health technologies. This focus has been critiqued as broader environmental discourse is increasingly prioritizing climate change over other environmental impacts.[33,34] This emerging issue highlights the importance of incorporating lifecycle thinking, where multiple environmental impacts (eg, water consumption, land use, toxicity, air quality) are included alongside GHG emissions[34] in health technology regulation.

We demonstrated that current regulatory actions to address the environmental impacts of health technologies are also lacking prescriptiveness and both relative and absolute outcomes. For example, while the NHS Supply Chain has established environmental performance requirements (ie, the requirement for NHS suppliers to achieve "net zero" GHG emissions by 2050), we put scare quotes around the term net zero because NHS suppliers retain considerable discretion in their GHG emissions accounting and reporting (eg, around data and methods used).

Regulatory stringency dimensions are also useful to develop benchmarks against which to evaluate future iterations. Future research should leverage these benchmarks to conduct comparative policy analysis and map progress towards regulatory stringency. Further, as regulatory instruments become more sophisticated, these concepts can be used to identify patterns within a regulatory regime and map gaps and opportunities to increase stringency. As noted in the Introduction, other key features, such as data quality, enforcement, and implementation, are also essential for effective regulatory mechanisms—although these are beyond the scope of this article.

Considering the significant environmental impact of health technologies, the need for robust regulatory stringency is urgent. Our analysis highlights important considerations and opportunities for designing effective regulatory mechanisms. By expanding regulatory scope, increasing prescriptiveness, and enforcing clear performance requirements, regulatory bodies can play a pivotal role in advancing environmental sustainability in health care.

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Conflicts of interest

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