european public health alliance

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School of Social & Political Science

Between art and science:

Policy-making for health in the EU

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Executive summary

The health-relevant policy adopted by the European Union (EU) is shaped by a complex policy-making system that seeks to balance the diverse interests, values and needs of a broad range of societal groups. This system represents something between a science and an art, processing both scientific evidence and political narrative. Recognising that health and politics are inextricably connected, one of EPHA's strategic objectives is to improve the policy-making system and increase civil society involvement in it, by advocating for change and building capacity within the public health community. This report contributes to the above objective by introducing the key framework that structures the EU policy-making system – Better Regulation – and its relevance to (health) civil society advocacy and engagement.

The report is produced in the context of the Better Regulation for Better Health project (BRBH), funded by UK Research & Innovation (UKRI). The Better Regulation agenda is the EU's 'good governance' programme, dictating the process by which laws should be adopted and the common ends that they should serve. It is the framework which requires that, for instance, impact assessment be conducted for all new initiatives with significant expected impacts, options for simplification be explored in all evaluations of existing policy, and all new administrative burdens be offset by reduced burdens elsewhere. It is also a political agenda – a commitment to reducing 'red tape', simplifying legislation, controlling the 'stock and flow' of EU law, and reducing the EU's perceived image as a creator or bureaucracy and burden. As such, it shapes the political and technical space within which health policy is conceived, developed and adopted.

With a view to increasing awareness of and engagement with Better Regulation and the politics of the EU policy-making system among the public health community, the aim of this report is to provide a first point of reference for those seeking to understand how EU health policy-making structures work, what role the Better Regulation agenda has in shaping them, how they are relevant to health advocacy and objectives, and what tangible engagement with Better Regulation the public health community might seek.

The report first introduces the BRBH project, and EPHA's activities related to advocacy for improved policy-making processes and stronger, more meaningful involvement of (health) civil society organisations in EU health policy-making. It then presents the Better Regulation agenda and its principles.

Better Regulation comprises a toolbox and a set of guidelines to be utilised by officials within the European Commission, Council of the EU, and European Parliament, and has three objectives:

1. Ensure EU policy making is based on evidence

2. Making EU laws simpler and better, and avoiding unnecessary burdens

3. Involving citizens, businesses and stakeholders in the decision-making process, which relates therefore to civil society engagement in policy-making.

Better Regulation can be approached from two different angles, explored in this report:

- Firstly, as a regulatory tool and practical toolbox, which requires consultation of stakeholders and their involvement in policy-making;

- Secondly, an ideological agenda and narrative, supporting the delivery of EU political priorities.

Accordingly, the report explores civil society participation in the existing structures of Better Regulation, as well as opportunities to challenge its narrative and advocate for reform of those structures. As regards the latter, the report presents EPHA's work on reinforcing the civic space and civil society engagement, and on supporting civil society with sustainable funding, through a civil society strategy. Advocacy ahead of the EU elections, ensuring that health was placed high on the agenda and therefore shaping future policy-making, is explored, as well as the question of budget for health policy. The report also addresses how this advocacy for improved policy-making and good governance could evolve in a post-elections context, particularly regarding the question of a review of the treaties and EU enlargement, while continuing existing advocacy activities. Reflecting the interconnection of policy systems and politics, wider issues of representation of interests and the Commercial Determinants of Health are also developed.

The report concludes by providing a series of recommendations on the role of civil society and areas of advocacy that could help promote change and ensure that the Better Regulation agenda supports the delivery of improved public health outcomes.

The Better Regulation for Better Health project

The Better Regulation for Better Health (BRBH) project is a multi-disciplinary study of how the European Union's Better Regulation agenda affects its health policies and governance. It is funded by UK Research & Innovation (UKRI) as part of a Future Leaders Fellowship, held by the project's principal investigator, Dr Eleanor Brooks. The project runs from 2021 to 2025 and is hosted within the Global Health Policy Unit at the University of Edinburgh's School of Social and Political Science.

The academic team: University of Edinburgh and Maynooth University

The project's academic team is drawn from the University of Edinburgh, UK, and Maynooth University, Ireland.

Dr Eleanor Brooks is the project's principal investigator. She is a senior lecturer in European health policy at the University of Edinburgh's Global Health Policy Unit and holds a UKRI Future Leaders Fellowship, supporting the BRBH project. Dr Brooks' research addresses the governance of health in the EU, the historical evolution of EU health policy, and the relevance of meta-regulatory policies – including Better Regulation and the fiscal governance framework – for health.

Dr Kathrin Lauber is the project's postdoctoral research fellow. She is a research fellow at the University of Edinburgh's Global Health Policy Unit, and holds a Leverhulme Early Career Fellowship. Dr Lauber's research focuses on the intersection of corporate power, governance, and meta-regulation in the context of health and climate policy.

Dr Oliver Bartlett is an Assistant Professor of Law at Maynooth University's School of Law and Criminology, and a co-editor of the European Journal of Risk and Regulation. His research addresses public health governance, and he is particularly interested in EU health law and policy, alcohol policy, the right to health, and the ethics of public health law.

The policy team: The European Public Health Alliance

The project is designed and executed in collaboration with the European Public Health Alliance (EPHA). EPHA is a prominent non-governmental organisation and leading alliance advocating for better public health in Europe. It operates through a network of NGOs, patient and vulnerable groups, health professionals, and disease-focused organisations. EPHA's commitment is centred on improving overall health outcomes, advocating for more equitable, evidence-driven, and sustainable health policies, and empowering the public health voice throughout Europe.

Central to EPHA's mission is the reduction of health disparities across diverse socio-economic groups within Europe. The organisation delves into the root causes of these inequities, aiming to democratise access to health resources and ensure that every individual, regardless of socio-economic status, has the opportunity to achieve optimal health. Recognising the intertwined nature of environmental factors with human health, both physical and mental, EPHA is at the forefront of advocating for policies that foster healthy environments. This commitment extends to combating environmental hazards that contribute to noncommunicable diseases (NCDs) and advocating for urban planning and environmental laws that support healthy lifestyles, showcasing EPHA's commitment to tackle a broad perspective on the determinants of health, which include a range of non-medical factors pivotal to health outcomes.

While different colleagues of the EPHA team took part in the BRBH project across the years, the writing of this report was led on EPHA's side by Clémentine Richer Delforge, Policy Manager for politics & health and health systems & economy, with key inputs from Dr Alessandro Gallina, Senior Policy Manager, regarding the Commercial Determinants of Health, and reviewed by EPHA's Director General Dr Milka Sokolović, Head of Policy Raymond Gemen and Senior Advocacy Manager Frazer Goodwin.

1. Introduction

1.1. Concept

The Better Regulation agenda is a "good governance" programme designed to ensure the quality of legislative output, in the EU via a range of tools and activities, including mandatory impact assessment, stakeholder consultation and periodic review of the "fitness for purpose" of existing regulation. It shapes the policy process across all sectors, including health, and is therefore a core element of EU health governance. As such, it can be considered a political determinant of health, and a framework of direct relevance to public health objectives and advocacy (Brooks, Godziewski and Deruelle, 2024; Lauber and Brooks, 2023).

The European Public Health Alliance (EPHA) has monitored and engaged with Better Regulation for almost two decades. Former Secretary Generals were members of the Stoiber Group and, later, the Regulatory Fitness (REFIT) Platform – forums designed to review and provide suggestions for the simplification of EU legislation and the reduction of regulatory burdens. EPHA members have also focused on this issue; the Smoke Free Partnership, for instance, organised an event and produced recommendations on the topic (Smoke Free Partnership, 2010). In 2015, EPHA partnered with more than 50 organisations to be part of the Better Regulation Watchdog group (BEUC, 2015).

Under the current EPHA strategy, Better Regulation is a key component of the work carried out in its politics and health activities. With the objective of improving the way in which policy-making is conducted and increasing civil society involvement, this work responds to (1) the challenges facing civil society engagement in EU policy-making, (2) the increasing recognition of the commercial determinants of health and their impact upon health policy-making, and (3) the need to build awareness and capacity on the politics of health within the public health and civil society community.

1.2. Aim and outline of the report

In this context, EPHA joined a four-year collaborative project with a team of experts at the University of Edinburgh's Global Health Policy Unit, and the University of Maynooth's School of Law. Funded by UK Research & Innovation (UKRI), the Better Regulation for Better Health (BRBH) project assesses how Better Regulation operates in the field of health policy and builds civil society capacity for greater engagement with the agenda (Better Regulation for Better Health, 2024). As part of the project, several capacity building activities were organised between 2022 and 2024, seeking to introduce the Better Regulation agenda to health civil society organisations (CSOs). Specific workshops and resources aim to support them in interacting with the different elements of the agenda, and tailor their advocacy accordingly and efficiently, so that civil society's messages can influence Better Regulation processes, taking into account limited capacity compared to other stakeholders.

This report concludes the capacity-building element of the BRBH project. It draws on the various activities and outputs of the project to present Better Regulation as a core facet of policy-making for health in the EU. Its aim is to provide a first point of reference for those seeking to understand how EU health policy-making structures work, what role the Better Regulation agenda has in shaping them, how they are relevant to health advocacy and objectives, and what tangible engagement with Better Regulation the public health community might seek.

The report first introduces EPHA's work related to politics and health, which addresses the role of civil society within health policy-making structures, the EU's wider commitment to democracy and civic space, and the influence of the commercial determinants of health. It then presents the Better Regulation agenda, explaining its role in shaping the policy process and its relevance to the work on politics and health. Sections four and five address this relevance across two dimensions: the practical actors, instruments and processes that are created by Better Regulation, and what they mean for civil society participation in health policy-making, and the political, ideational narrative that Better Regulation embodies, and what this means for health advocacy and the reform of health policy-making processes. Section six summarises the lessons learned from the project and offers a set of recommendations for civil society advocacy and policy practice.

2. EPHA's focus on politics and health

The Politics and Health activities at EPHA focus on issues related to policy-making, and how the latter can (and should) place health high on the agenda and deliver improved health outcomes, particularly by including CSOs in regulatory processes. Therefore, the work from the BRBH project feeds into this advocacy and will support its future development. This fits into EPHA's wider strategy, including advocacy on cross-sectoral issues such as the different determinants of health.

2.1. EPHA's strategy & goals

EPHA has defined and published a strategy for 2021 to 2025 (EPHA, 2020), "'Artists and scientists': new partnerships for people's health". The strategy was published in a context of crossroads for public health policy in Europe, in the midst of the COVID-19 pandemic, when it was clear that health should be given the utmost priority on the EU agenda and that health systems needed to be prepared to face cross-border health threats. Consequently, the strategy frames EPHA's and its members' role as both scientists and artists: "as 'scientists', EPHA members provide evidence, as 'artists' they offer creative solutions to public health problems, in close partnership with policy-makers and peers" (EPHA, 2020). The strategy also places an emphasis on the role that the EU4Health budget and other elements of the Multiannual Financial Framework (MFF) could have to support further public health policies at the EU level, particularly by exploiting synergies and breaking policy silos.

In particular, the strategy sets out seven focus areas for EPHA's advocacy[1], but also leaving space to address cross-cutting issues. Important transversal themes include mental health, the necessity of evidence-driven policies, co-creation processes to achieve just and sustainable solutions, as well as tackling social and commercial determinants of health. Action on these themes enhances the effectiveness, sustainability, and equity of public health interventions.

2.2. Politics and health at EPHA: strategy and advocacy

In the EPHA strategy, the politics and health activities are given the objective "to improve the way in which policy-making is conducted and increase civil society involvement". The strategy outlines several indicative topics related to improved governance:

- Active involvement of civil society/citizens, European Democracy Action Plan
- Institutional transparency and conflicts of interest/corporate capture in policy-making
- Better Regulation and the policy process

These themes are closely linked to the commercial determinant of health, as presented below, and have wider links to questions of democracy and health, the rule of law, and the influence of rising populism. These elements – and the role of civil society in addressing them – are still highly relevant after the EU

[1]Healthy environments, healthcare delivery, health systems and economy, global public health, digital transformation, politics and health, all rooted in health equity

2024 elections. EPHA's work in this field was also foreseen in the context of the development of the European Health Policy Platform and the Better Regulation agenda.

Following the guidelines set out in the strategy, EPHA's advocacy activities on politics and health have focused on several key areas.

2.2.1 Civil society participation, democracy, and health policy-making

The politics and health work at EPHA has revolved around several key issues, developed below.

- Civil society engagement and stronger civic space: EPHA has been calling for stronger civil society engagement, civic space and civil dialogue for health civil society organisations, requiring that CSOs are given a meaningful seat at the table. EPHA has done so by cooperating with other health CSOs, but also through other networks. For instance, EPHA has taken part in the EU elections campaign Civil Society 4 EU, led by Civil Society Europe, calling for a stronger civic space and dialogue.

- Funding of civil society: closely related to the previous point, EPHA has been advocating for the sustainable funding of (health) civil society, therefore calling for an insured independence and capacity for CSOs to take part in policy making. This has mainly taken place through the EU4Health Civil Society Alliance and its campaign for the operating grants to be continued (see below), but also through other advocacy avenues, such as the work on the commercial determinants of NCDs with the World Health Organization (WHO) or through the active participation in the WHO Civil Society Commission (also as a member of its Steering Committee).

- Placing health high on the agenda: EPHA is pushing for the core priority of placing health high on the agenda, particularly by advocating for a strong EU4Health budget, but also on the future multiannual financial framework (MFF). Furthermore, EPHA takes part in the EU Health Union Initiative, calling for stronger competences and cooperation in public health at the European level.

- EU elections: EPHA has led a campaign ahead of the EU elections 2024. This work aimed to carry the messages and priorities from different health policy areas that EPHA works on, and from EPHA members, to the next European Parliament's mandate. EPHA published its manifesto in November 2023 (EPHA, 2023a), calling for health to be a priority on the EU agenda, articulating five core priorities and several sub-priorities. One of the priorities focused on the involvement of health CSOs in EU policy making processes. A second part of EPHA's election campaign consisted of analysing the manifestos of the political parties to assess how much of a priority health was in the proposed programmes, by assessing measures from 16 key topics (e.g., equity, climate, AMR, health workforce) against EU commitments such as the Sustainable Development Goals (SDGs). The analysis also looked at measures regarding a European Health Union, CSOs and their participation in EU policy making processes, and institutional developments (i.e., changes to the treaties, EU enlargement) (EPHA, 2024a).

EPHA's work on politics and health gains a wider audience and a stronger voice from its involvement in the EU4Health Civil Society Alliance. The latter gathers more than 30 health CSOs from across Europe, with the aim of ensuring that (public) health is given a priority in the EU political agenda. The Alliance was launched first as a campaign, in reaction to the Future of Europe white paper (European Commission, 2017), which included options to "do less" in some policy areas, including health. The core message of the Civil Society Alliance campaign was to ensure that EU action on health remained on the agenda, and that commitment to it was strengthened, rather than undermined.

Since then, the advocacy of the Alliance has focused on defence of the operating grants for health CSOs, as detailed later in the report. It has also advanced key advocacy messages designed to maintain health as a priority on the agenda, particularly through a strong and ambitious health budget, supporting health civil society, and creating space for civil society to take part in policy-making, including via its EU elections campaign (EPHA, 2023a). A core call is for the European Commission to establish a vice president for public health, wellbeing and social rights, to encapsulate these priorities and implement the necessary policies while breaking silos. These issues, and their relevance to Better Regulation and the policy-making system, are discussed further in section 5.

2.2.2. Politics, Better Regulation and the Commercial Determinants of Health

The commercial determinants of health (CDoH) encompass the several ways in which industry's activities and its products influence public health. This includes both positive impacts, such as the development of health-promoting products and services, and negative effects, particularly on non-communicable diseases (NCDs) and health inequities. Notably, commercial determinants such as tobacco, alcohol, processed foods, fossil fuels, and occupational practices (such as exposure to occupation-related carcinogens, asthmagens, and injuries) are linked to a significant proportion of global deaths, including those from NCDs and mental health issues. In the WHO Europe Region alone, these factors contribute to nearly 7,500 deaths per day, accounting for 25% of all deaths (World Health Organisation, 2024). Commercial actors and their practices influence both policy and personal choices through various direct and indirect channels. Industries use a well-funded playbook of strategies across different sectors, from tobacco and alcohol to ultra-processed foods and fossil fuels, aiming to shape public perceptions and policies. In addition to marketing strategies and product placement, these include political lobbying and engagement with the political process. It is here that the Better Regulation framework is of particular relevance. Better Regulation establishes the political opportunity structure within which stakeholders, including but not only commercial actors, operate. As detailed below, previous research revealed the role of transnational tobacco corporations (TTCs), among other actors, in the creation of an EU Better Regulation programme, and commercial actors continue to use the instrumentation and narratives of Better Regulation to advance their interests (Lauber and Brooks, 2023; Smith et al., 2015). Recognising these strategies – and understanding the relevance of Better Regulation within them – is crucial for countering the harmful practices of commercial actors, advancing public health goals and, particularly, reducing the incidence of NCDs.

3. The Better Regulation agenda and EU health policy-making

Better Regulation is not unique to the EU. Many national governments have similar "good governance" programmes, and the Organisation for Economic Cooperation and Development (OECD) works to advance and monitor such programmes. The EU Better Regulation agenda, however, is considered an exemplar across the EU member states (OECD, 2022) and is thus of particular relevance. This section introduces Better Regulation for a health policy audience, beginning with a brief presentation of the programme's origins, development and purpose. It then offers two conceptualisations. The first approaches Better Regulation as a practical toolbox for policy-making, focusing on the processes, instruments and actors that Better Regulation provides for, and their role in shaping the policy process. The second approaches Better Regulation as a political agenda, focusing on its narratives and its relationship to the political priorities of the Commission leadership. Finally, this section explores what these two different conceptualisations mean for civil society engagement and the nature of health policy-making, questions which are examined in more detail in section 4 and 5.

3.1. The origins, development and purpose of Better Regulation

The contemporary Better Regulation agenda, comprised of a toolbox and a set of guidelines to be utilised by officials in the three legislative institutions of the EU (European Commission, Council of the EU, and European Parliament)[2] was adopted in 2015 by the Juncker Commission, but the origins of the agenda reach much further back, long before the term "Better Regulation" appears in EU parlance. The Single European Market project and ideas about the role of regulation in the European economy, the Subsidiarity Principle and concern about the appropriate exercise of EU law-making powers, and successive efforts to modernise and reform the organisation of the Commission, have all contributed to the objectives and instruments of Better Regulation as it is now known. Underpinning many of these influences is a set of wider neoliberal pressures that prioritise economic growth, competitiveness and the market, and frame regulation in relation to these priorities.

The term Better Regulation first appeared in the early 2000s, in initiatives to institutionalise impact assessment, evaluation and stakeholder consultation. It came to the attention of the health community in the early 2010s, when research revealed that transnational tobacco corporations (TTCs), along with various other industry actors and several national governments, had been instrumental in lobbying for the use of impact assessment and the adoption of Better Regulation commitments at the EU level (Smith et al., 2010; Smith et al., 2015, Smoke Free Partnership, 2010). TTCs understood that models of regulatory impact assessment, and the requirement to consult stakeholders during the policy process, could be used to delay, weaken or preclude tobacco control regulation, as has been confirmed by subsequent research (Lie et al., 2018; Ulucanlar et al., 2014; Hatchard et al., 2014).

The Commission website (European Commission, 2024a) identifies three objectives of the Better Regulation agenda:

[2] Better Regulation is a responsibility of all three institutions, but the Commission has, to date, been the most active in developing the agenda and implementing its tools and is the focus of this report. The roles of the European Parliament and the Council of the EU are outlined in the 2016 Interinstitutional Agreement on Better Law-making.

1. Ensure EU policy making is based on evidence

2. Making EU laws simpler and better, and avoiding unnecessary burdens

3. Involving citizens, businesses and stakeholders in the decision-making process.

Less clear is the intended purpose that is served by pursuing these objectives. The term Better Regulation is poorly defined, in that there is no single explicit statement of how "better" should be understood or assessed, or what the rationale of the agenda is. Most often, the Commission defines Better Regulation as a "way of working" – one that involves legislating only where necessary, maximising benefits and minimising costs, professionalising policy-making – and emphasises what Better Regulation is not, generally citing deregulation or less regulation. The current guidelines state that Better Regulation "seeks to design and prepare EU policies and laws in such a way that they achieve their objectives in the most efficient way" (European Commission, 2021a, 5).

More concretely, recent revisions of the framework have directed it to simplify EU law and reduce unnecessary burdens, remove obstacles and red tape that hinder investment, mainstream the SDGs in EU policy-making, implement the "do no significant harm" and "digital transformation" goals, and integrate strategic foresight in the policy process (European Commission, 2024a). In this sense, Better Regulation combines a narrow focus on efficiency and burden (reflecting its earlier, deregulatory origins) with a much wider and fuzzier set of purposes (connected to contemporary political priorities) without explicitly addressing their coherence.

The vague and shifting definition of Better Regulation makes it difficult to pin down what is (and is not) part of Better Regulation, what warrants attention from the public health community, and how best it can be engaged. In an effort to clarify, the following sections employ two different, complimentary conceptualisations. The first approaches Better Regulation as a practical toolbox, presenting the key actors, processes and instruments that are associated with the agenda. The second treats Better Regulation as an idea, approaching it as a political agenda established to pursue political priorities.

Figure 1. The Better Regulation consultation process

Source: 2021 Better Regulation guidelines (European Commission, 2021a)

3.2. Better Regulation as a practical toolbox for policy-making

The current iteration of the Better Regulation agenda is presented in a 2021 Communication (European Commission, 2021b) and detailed in two core documents: the Better Regulation Guidelines, a 41 page document that sets out requirements for the key steps in the policy cycle, and the Better Regulation Toolbox, a 612 page document that provides practical, hands-on guidance and operational details (both available here; European Commission, 2024b). Both are designed as handbooks of internal guidance for Commission officials.

When explaining how Better Regulation is put into practice, the Guidelines highlight three initiatives that are of particular importance. The first is the Regulatory Fitness and Performance (REFIT) programme, which systematically reviews the "fitness for purpose" of existing EU law and searches for opportunities to simplify and reduce burden. The second is the one-in-one-out (OIOO) approach, which requires that the Commission offset administrative burdens created in new regulation by reducing equivalent burdens elsewhere. In support of the first two initiatives, a third practice – the quantification of costs and benefits wherever "feasible, relevant and proportionate" – is also highlighted.

Having established these overarching steers, the Guidelines identify five key instruments of Better Regulation:

- Forward planning and validation: Planning involves the advance arrangement of the timing and sequencing of initiatives, whilst validation is about gaining approval before substantive work begins. As regards the latter, the Better Regulation toolbox (tool #6) explains how initiatives are categorised to determine the appropriate level of political sign-off, based on their degree of political sensitivity and importance.

- Stakeholder consultation: Consultation is required for most impact assessments, and encouraged for most evaluations and fitness checks. The Better Regulation toolbox (tools #51 to #55) offers guidance on how to identify stakeholders, design a consultation strategy, conduct consultation activities, and analyse the resulting data.

- Evaluation and fitness checks: Evaluations (assessing one piece of legislation), and fitness checks (assessing groups of related legislation) are conducted ex post, to establish how existing legislation has performed. A key goal of the Better Regulation agenda is to use evaluations and fitness checks to inform the development of new initiatives, and to implement the REFIT programme by assessing the "fitness for purpose" of the existing acquis. Tools #45 to #50 explain when an evaluation is required, what criteria and questions might be used, and how to format the report.

- Impact assessment: Drawing on evidence (including that from evaluations), impact assessment is used to justify the necessity of a new initiative and establish how it can best meet its policy objectives. Impact assessment reports frame the policy problem and the possible solutions, identify the potential impacts of each solution, and describe how the eventual legislation will be monitored and evaluated. The Better Regulation toolbox offers extensive guidance on conducting an impact assessment (tools #7 to #17), identifying specific types of impacts, including health impacts (tools #18 to #37), and using different methodologies to analyse impacts (tools #56 to #69).

- Quality control: The above steps and processes are overseen by several groups of actors. Specialised Better Regulation Units exist within most DGs, to advise and support the development of initiatives. DG Secretariat General maintains a network of these Units, and acts as the central guidance point on

methodological issues and the overall implementation of Better Regulation across the Commission. It also chairs most interservice steering groups, which are an additional point of oversight and input into policy development. Finally, the Regulatory Scrutiny Board (RSB) is responsible for assessing the quality of all impact assessments and fitness checks, as well as selected evaluations (see below). The procedures for obtaining RSB approval are outlined in the toolbox (tool #3), and include the conduct of "upstream meetings" to guide the development of the impact assessment. The Board's mandate states that it does not comment on the substance of impact assessment, fitness checks or evaluations; rather, its role is to assess the quality of the analysis and adherence to the Better Regulation procedures.

3.3. Better Regulation as a political agenda

By contrast to the practical, instrument-focused presentation advanced above, Better Regulation can also be conceptualised from an ideational perspective. Here, it is understood as an agenda, and a narrative built around a particular regulatory philosophy. This approach can be more difficult to articulate but it captures an equally important role and impact of Better Regulation, by highlighting how it shapes the political environment in which policies affecting health are developed. It does this directly, when used as a tool for implementing political priorities and agendas, and indirectly, by advancing a narrative of EU regulation and policy-making that "chills" the regulatory environment.

Whilst impact assessment, consultation, and other initiatives brought together under the Better Regulation banner are all individually political, the idea of a single coherent agenda was most clearly advanced by President Juncker in 2015. The Juncker presidency set out to establish a more political Commission, and Better Regulation was a central part of this goal. Substantively, the commitment to creating an EU that is "big on the big things, and small on the small things", by focusing on a discrete set of priority projects and scaling back EU action in other areas, was translated into action using the various tools of Better Regulation. Forward planning and political validation are used to identify initiatives supporting priority projects and exclude or restrict those addressing non-priority issues or not envisaged in the Commission's work programme. The proportionality and added value of EU action are systematically examined within impact assessment processes, and the contribution to burden monitored via the Fit for Future Platform (previously the REFIT Platform) and Have Your Say: Simplify! Portal (previously the Lighten the Load initiative). In this sense, "the renewed Better Regulation initiative serves as the chief institutional backer of the Juncker Commission's political agenda" (Alemanno, 2015, p. 345). Its overarching objectives – evidence-based policy-making, burden reduction, and participation – should thus be understood in this context, as means to achieving the political goals of the Commission.

Organisationally, Better Regulation has also been used as part of a restructuring of how the Commission works and, specifically, to strengthen the core executive. The purpose of these reforms is to address policy-making "silos" and reduce fragmentation in EU action, facilitating delivery of priority projects which cross the remit of individual DGs. President Juncker's appointment of a First Vice President with responsibility for Better Regulation, and the expansion of the role of DG Secretariat General to oversee evaluation activities across all DGs, for instance, have increased the "centralisation" of EU policy-making and contributed to what the political science literature characterises as the "presidentialisation" of the Commission (Wegrich, 2015; Bürgin, 2018; Becker et al., 2016; Kassim et al., 2017). These organisational changes remain in place under President von der Leyen, who has also created a dedicated SME (small and medium enterprises) Envoy to provide guidance and oversee implementation of the "Think Small First" principle in EU policy-making. The mission letters to the new Commission for 2024-2029 make Better Regulation a responsibility of all commissioners, specifically requiring them to contribute to a 25% reduction in reporting requirements and a "stress test" of the entire EU acquis, among other objectives

(mission letters, European Commission, 2024c).

More broadly, Better Regulation is a narrative – a story about what regulation and policy is for and what it should try to achieve. Due, in large part, to its origins in the neoliberal, market-driven reforms of the 1970s and 1980s, the dominant narrative of Better Regulation is a deregulatory one. It directs attention and action to obligations and economic cost, using language about red tape, regulatory burden and complexity. Though the policy documentation often opens with a statement of the importance of regulatory protections and the achievements of the EU in this regard, the substance of the agenda is not focused on the value of regulation, but on the need to measure, control and minimise its costs. Specific reforms – such as the introduction of the SME Envoy and the one-in-one-out principle – are undertaken in pursuit of economic-driven goals, with scant reference to social, health or environmental values. More fundamentally, the instruments and processes of Better Regulation are presented as technocratic; as objective, evidence-based, and insulated from political decision-making, ostensibly justifying a lack of transparency.

These political, organisational and ideational elements of Better Regulation combine to create a context which inhibits the initiation and development of ambitious health policy. The tools and processes of Better Regulation, even when used robustly, serve to slow and delay the progress of legislative initiatives, and are commonly instrumentalised by commercial actors seeking to weaken or preclude regulation (Lauber and Brooks, 2023; 2024; Peeters and Glimore, 2013; Smith et al. 2015). Indirectly, officials observe this instrumentalisation and the resulting challenge to policy development, and interpret requirements to quantify costs and benefits, and simplify legislation, in the context of a narrative that favours reducing burden and red tape. The result is a "chilling" of regulatory ambition in areas that are not part of the Commission's priorities, including health (Brooks and Lauber, 2024).

3.4 Better Regulation, civil society and health policy-making

An advantage of adopting the two conceptualisations outlined above is that it facilitates more structured consideration of how civil society might engage the Better Regulation agenda. Thinking about Better Regulation as a practical toolbox, and disaggregating its individual actors, instruments and processes, allows us to focus on tangible points of engagement, such as the methodologies of impact assessment, the representation of interests within stakeholder consultation, or the conflict between the innovation and precautionary principles. Thinking about it as an agenda and narrative, and thus addressing the ideas that underpin Better Regulation, directs attention to the political level, and the compatibility of Better Regulation narratives and practices with the EU's wider (health, environment and social) objectives.

The rest of the report uses these two conceptualisations, in turn, to present a series of ideas about how civil society might engage with – and advocate for change to – the Better Regulation framework.

Section 4 discusses how (health) civil society engagement might best work within the structures (i.e. the existing actors, instruments and processes) of Better Regulation, how its individual instruments might work to advance or undermine health objectives and protections, and what can be done about this. Section 5 offers a complementary discussion about how (health) civil society might challenge the assumptions and narratives of the Better Regulation agenda. This involves engaging at the political level, focusing on how to make health an EU priority, raise its visibility, and advocate for an understanding of "better" regulation that better serves public health objectives.

4. Working with Better Regulation: civil society participation in policy-making

Drawing on the practical, disaggregated account outlined above, this section outlines how the key instruments and processes of Better Regulation shape the role of civil society in health policy-making, and offers some initial suggestions for how they might be utilised or challenged as part of civil society advocacy strategies.

4.1. Civil society participation via stakeholder consultation

The Better Regulation guidelines and toolbox set out how the Commission should approach and conduct stakeholder consultation. Better Regulation links these provisions to the Commission's wider priority, "A new push for European democracy", and the engagement of citizens and civil society in EU decision-making. So, what does it actually provide for?

Better Regulation establishes four key points or opportunities for stakeholders to participate in policy-making:

1. The "call for evidence", usually launched as part of the evaluation or impact assessment, and including a public consultation (OPC) that must be open to the public at large for a minimum of 12 weeks

2. Feedback on legislative proposals, once agreed and published by the Commission, which are usually open for 8 weeks

3. Feedback on draft delegated acts, implementing acts, and measures subject to regulatory procedure with scrutiny, open for 4 weeks by default

4. Feedback on any existing EU law, via the Have Your Say: Simplify! Portal, which feeds into the Fit for Future high-level expert group.

Work conducted as part of the BRBH project suggests that civil society engages to a varying degree with these different points of participation, generally favouring traditional pathways via the call for evidence and feedback on legislative proposals. In the following sections, we explore (non-exhaustively) some of the ways in which this participation might be expanded, to include consultation tools less commonly utilised by CSOs.

4.1.1. Making greater use of consultation processes

The call for evidence is perhaps the best known and most commonly engaged avenue of participation for civil society actors. The OPC, in particular, provides an important opportunity for advocacy (though it is flawed, as discussed below). Less commonly utilised is the provision to offer feedback on the consultation strategy. Consultation strategies are required and guided by the Better Regulation toolbox, and set out the Commission's plans for the OPC and various other consultation activities, such as conferences, focus groups, targeted surveys and workshops. In the call for evidence, consultation strategies must be open for feedback from stakeholders, providing a valuable opportunity to shape the later points of engagement available.

Figure 2. Consultation in Better Regulation

Source: European Commission

Feedback on legislative drafts and delegated/implementing acts is a pathway of engagement less commonly utilised by CSOs but it offers a crucial benefit over OPC input, in that it is usually unstructured. Feedback is entered into a "free text" box, rather than being based on a questionnaire or survey, giving greater freedom to convey information. For delegated and implementing acts, the Commission is required to report on how feedback is accounted for via the comitology register; for legislative proposals, it is required to forward a summary of the feedback received to the European Parliament and the Council of the EU.

Finally, the Have Your Say: Simplify! portal is perhaps the least well-known and well-utilised avenue of participation for civil society actors. Its purpose is to allow citizens to identify existing EU laws that are burdensome or problematic, making its relevance to civil society unclear, and framing it as a tool that advantages economic and commercial actors. However, the remit of the Fit for Future Platform – the high-level expert group which receives submissions from the portal and delivers opinions to the Commission – is broader than burden reduction. Have Your Say: Simplify! assists in "making EU laws more efficient and fit for future, while achieving the policy objectives" (HYS:S! website). Carefully used, there exists here an opportunity to use the portal as a tool for focusing attention on legislation that fails to achieve its (social/health) objectives, imposes too great a burden upon specific groups, or is in need of future-proofing in order to reach its goals.

4.1.2. Strengthening civil society participation beyond consultation

Beyond these specific points of consultation, there is a need to strengthen civil society participation in policy-making and priority-setting more broadly. Much of this is taken up in section 5 and the discussion about civic space but the specific instruments that the Commission and other institutions use to engage stakeholders link closely to the formal procedures for consultation. Here, we highlight the EU Health Policy Platform, and the potential for a civil dialogue mechanism.

The EU Health Policy Platform (EUHPP) is an online tool gathering representatives from the European Commission, health civil society and health-related stakeholders in general to exchange regarding EU health policy. It is a central part of the Commission's effort to engage health stakeholders and enables users to gather in networks, attend and organise webinars, and share/receive updates on their activities and the activities of the platform. Over the years, EPHA has taken part in numerous different activities

available on the Platform. In particular, EPHA has been managing one thematic network on the EUHPP since 2023, the DisQo Network, focusing on anti-discrimination and health equity (EPHA, 2023b). The network gathers over 80 organisations, produced a joint statement (DisQo Network, 2023), a manifesto for the elections (DisQo Network, 2024) and several webinars, hosted on the EUHPP (EPHA, 2023b). Two conferences were also organised, in November 2023 and June 2024. The events created a much-needed platform for discussion of racism, discrimination and health. Furthermore, the findings and input of the second conference will feed directly into the upcoming EU Anti-racism Action Plan for 2026 to 2030. The DisQo network is a successful example of stakeholder participation in the EUHPP, and of using its opportunities to connect, share common grounds, exchange expertise and knowledge to strengthen capacity, and build advocacy together, directly feeding into health policy-making processes.

However, possibilities for engagement in the Platform are generally limited to online inputs through the networks and workshops, or other online events it organises. This increases the value and importance of other, alternative, avenues of engagement. The EU Treaties foresee the participation of civil society actors in policy-making. Article 11.2 of the Treaty on European Union (European Union, 2012), for instance, requires an "open, transparent and regular" civil dialogue between institutions and "representative associations and civil society". Similarly, Article 11.3 of the Treaty on European Union requires the European Commission to "carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent", while Article 11.1 stresses that "the institutions shall, by appropriate means, give citizens and representative associations the opportunity to make known and publicly exchange their views in all areas of Union action". It also asks for more advanced participation structures, by requiring that institutions maintain "an open, transparent and regular dialogue with representative associations and civil society". The European Civic Forum explain that civil dialogue is a key tool of democratic legitimacy and trust, especially in a context where traditional participative mechanisms are in decline. However, current civil dialogue settings do not necessarily "guarantee the adequate level of openness, transparency and structure" (European Civic Forum, 2021) and lack an integrated framework to ensure open, inclusive participation. The Civic Forum argues that no sufficient investments have been made to support the development of an EU culture of civil dialogue and participation. Other issues include the lack of definition of what is civil dialogue, and the lack of coordination and support structures (European Civic Forum, 2021).

As a way of engaging in a more structured manner with CSOs, Civil Society Europe and the Civil Society 4 EU elections campaign have called for mechanisms similar to those of social dialogue to be established as a civil dialogue. Social dialogue supports actors in reaching agreement to work together on policy. The European Trade Union Confederation (ETUC) mentions bipartite dialogues between workers and employers, and tripartite dialogues, which also include government and EU representatives (ETUC,

2024). A more established civil dialogue might therefore include dedicated structures, processes and framework organising the dialogue with civil society, where organisations could discuss and provide feedback on policy-making processes.

4.1.3 Consultation as a tool of commercial influence

As noted in the introduction, Better Regulation is inherently linked to the CDoH, and consultation is a core instrument of commercial lobbying activities. To give just one example, the alcohol industry has successfully lobbied to maintain its exemption from providing ingredient and nutritional information on product labels, unlike other food and drink producers in the EU. Although the Commission committed in 2021 to mandate such labelling as part of its Beating Cancer Plan, intense lobbying from alcohol producers has delayed these efforts. The industry's primary push is for "digital labels" accessed via QR codes rather than on-pack labelling, which consumer advocates argue is inconvenient and limits access to important information in real-time shopping contexts. Official documents reveal that industry meetings with the Commission far outnumbered those with civil society, influencing the Commission's stance over time, and eventually resulting in the shutdown of the measure.

This example is illustrative of a broader trend in which commercial stakeholders are overrepresented in consultation activities. Within the research on consultation in EU policy-making, the existence of participation bias is well established. The dominance of business actors is recorded across policy areas and types, as well as across consultation instruments (Binderkrantz et al., 2021; Quittkat, 2011, 2013; Quittkat & Finke, 2008; Quittkat & Kotzian, 2011; Rasmussen & Carroll, 2014; Rasmussen & Gross, 2015). Examining variation by policy type, Binderkrantz et al. (2021, p. 481) find that "[b]usiness groups and trade unions are consulted more frequently in […] policy types that deal with business regulation [addressing specific sectors], whereas NGOs are consulted more frequently in proposals dealing with general regulation [addressing all businesses More broadly, a critical point of concern is the reported number of approximately 25,000 lobbyists in Brussels (Freund, 2016), with a notable imbalance between corporate lobbyists and those from civil society. The former dramatically outspend civil society groups in their lobbying efforts. It is estimated that industries spent over EUR 1.6 billion on lobbying activities in the EU for a wide array of profit-driven interests in 2023 (Transparency International, 2024). Specifically, the pharmaceutical sector alone accounted for almost EUR 40 million in lobbying expenditures in 2012, compared to just EUR 3.4 million allocated to support the work of public health civil society organisations (Pharma Times, 2012).

4.1.4 Improving consultation processes

How then can the consultation process in EU health policy-making be improved? Within its wider activities, the BRBH project conducted a survey of CSOs to identify barriers and enablers of civil society participation, and recommendations for improvement. Focusing on the main consultation activities (i.e., surveys, workshops, events, feedback processes), the survey addressed elements such as organisational capacity, access to funding and the setting and design of the avenues and/or platforms for participation, all of which can be enablers as much as barriers to participation. The early findings of the survey informed a session at the 2024 European Health Forum Gastein, where input from a wider audience, as well as a panel of policy-makers and civil society practitioners, was gathered. A formal set of recommendations is under development but the key take-aways of the survey are as follows:

- More meaningful participation of citizens and civil society in consultation and policy-making should be foreseen, and in particular, consultation activities should avoid tick-box approaches.

- Stakeholders asked for clearer communication on how the feedback and inputs were used and how they influences the policy-making process. Overall, transparency should be improved on the use of feedback.

- The design of the consultation exercises should be improved. For written inputs and consultations, the questionnaires should be more user-friendly and seek more in-depth feedback. As for input-gathering events, smaller group discussions should be preferred as they allow for more interaction and information-sharing. More time for interaction should be foreseen.

- The planning of stakeholder consultations should also be improved, by adapting timelines according to the needs of respondents and providing them with enough time to provide valuable inputs, therefore securing the legitimacy of the processes.

- Participation should be more inclusive, diverse and balanced, including in the representation between private and public interest stakeholders. Participation should overall be encouraged, by strengthening the visibility and accessibility of the process, making it more user-friendly, particularly for marginalised, vulnerable groups and smaller organisations, therefore participating in improved governance practices.

Overall, a key lesson of the consultation was for the institutions to foster trust in the consultation processes.

4.2. Impact assessment, fitness checks and evaluation:opportunities for civil society

The Better Regulation toolbox guides policy-makers in their conduct of impact assessments, fitness checks and evaluations. Importantly, it sets out when impact assessments are required and when an initiative can progress without an impact assessment (for instance if it is an emergency measure, or if the policy alternatives are restricted, such as by international trade rules). The “evaluate first” principle requires that evaluation is used to inform the development of new initiatives, either before or in tandem with the impact assessment, and there is a set of criteria used to determine when a fitness check is appropriate.

Impact assessments, fitness checks and evaluations have in common a reliance on stakeholder input – usually gathered via the call for evidence – providing civil society an opportunity to participate, as described above.

4.2.1. Impact assessment and evaluation methodologies

A first avenue of engagement concerns the methodologies of impact assessment and evaluation. The Better Regulation toolbox outlines in detail the various methods and models that policy-makers should use when conducting assessments. A central tool is the EU Standard Cost Model (SCM), which calculates the net cost of administrative obligations relating to labelling, reporting, registration, provision of data, and monitoring. The toolbox also explains how simulation models, multi-criteria decision-analysis, life cycle assessment, and various other methodologies might be applied, and when they may be appropriate.

For health, a tool for assessing health impacts (tool #32) states that these can be defined as either gains or losses. It provides a number of questions to help identify "significant health-related" impacts within an initiative, which should be subject to assessment. It goes on to identify qualitative methodologies as useful for establishing causality, and quantitative methodologies as useful for establishing scale and extent. Among the latter, the toolbox introduces the Quality Adjusted Life Years (QALY), Disability Adjusted Life Years (DALY), Value of Statistical Life (VOSL), Cost of Illness (COI), and other methods that might be used to help quantify gains, losses, costs and benefits.

The BRBH project did not address the specific operation and merits of different impact assessment and evaluation methodologies, but it highlighted the importance of developing expertise in this area. One role for civil society is to offer a critique of assessment methodologies. This will involve building capacity and expertise, likely by collaborating with or recruiting expert partners, to scrutinise impact assessments and evaluations, promote understanding of how different methodologies function and what they can be appropriately used for, and highlight their limitations. Where resources permit, another option is to compile shadow assessments. This is an approach commonly employed by commercial actors, where an impact assessment – often focusing on a single provision or aspect of the wider assessment being undertaken by the Commission – is conducted and published ahead of the official assessment, in an effort to shape the latter. It mirrors strategies that health CSOs have used in the past at later stages of the legislative process, such as the blueprint directive on protecting children from unhealthy food marketing (EPHA, 2021a).

4.2.2. Data for impact assessment and evaluation

Another avenue for civil engagement is in providing the data and evidence needed to support an impact assessment or evaluation. "Evidence" is defined broadly by the Commission as encompassing opinions, stakeholder views, statistics and expert advice. The criteria for evaluation include efficiency and effectiveness but also coherence, relevance, and EU added value. Consultation submissions need not address every criterion or expected impact – and providing narrower, specialised data might be an advantage – but a limitation commonly cited in assessment reports is a lack of available data.

Where resource constraints preclude the submission of relevant evidence, a core role for civil society is to scrutinise the evidence base used in assessments. Impacts which have not been considered, or where evidence is lacking, might be highlighted, as might efforts to quantify impacts inappropriately.

Linking to advocacy on the CDoH, this might also involve offering informed critique of evidence submitted or commissioned by commercial interests. An important example here is the Revision of the Food Information to Consumer Regulation (FIC 1169/2011). As part of the BRBH project, a workshop on the FIC addressed the relevance of Better Regulation to the (lack of) progress of the initiative (EPHA, 2023c). Foreseen as part of the Commission agenda under the Farm to Fork Strategy and the Green Deal, the premature revision of the FIC, compulsory only from 2016, was meant to address two main pressing

issues in public health: the rising prevalence of obesity and overweight rates in the EU due to unhealthy dietary habits, and the lack of awareness of the harmful outcomes of alcohol consumption. In order to tackle the first, the Commission planned on harmonised and compulsory front-of-package nutritional labelling (FOPNL) across the member states. The most known scheme and the one implemented already in several member states is NutriScore (i.e., France, Germany, the Netherlands, Spain, and UK). The proposal for a harmonised mandatory FOPNL was expected in quarter 4 of 2022. However, the intrusion of commercial interests together with a misinformation campaign has led to a high polarisation of the policy, and the delay of the completion of the impact assessment, resulting in the blockage of the proposal. The European Ombudsman inquired on the European Commission's refusal to give public access to documents concerning an impact assessment on the revision of the FIC, and concluded a case of maladministration as the access to the documents was not granted further (European Ombudsman, 2024a). This case demonstrates how commercial actors might utilise the tools of the Better Regulation agenda to influence policy-making.

4.3. Engaging the Regulatory Scrutiny Board

4.3.1. The role and mandate of the RSB

The RSB - formerly the Impact Assessment Board (IAB) - is a relatively unknown but important actor within the EU policy-making process. It is responsible for reviewing all impact assessments, as well as major fitness checks and evaluations, and passing judgement on their quality, before the file is able to progress. Draft reports (of impact assessments, evaluations and fitness checks) are submitted by the responsible Commission officials to the RSB, which scrutinises their methodology, their adherence to the Better Regulation guidelines, and their overall quality. The Board may then offer one of three opinions: positive, positive with reservations, or negative. A negative opinion requires re-submission of the report; a second negative opinion prevents the file from being progressed to interservice consultation (the next stage in the policy process), unless the Vice President for Interinstitutional Relations and Foresight intervenes. This amounts to a veto role for the RSB, in that whilst it does not itself terminate proposals, its negative opinion empowers the Vice President to do so.

When reviewing assessments, the RSB focuses on the quality of the report, rather than the substance of the policy options discussed. However, it should also pay "special attention to the application of the "one-in, one-out" principle, integration of the foresight dimension and impacts on competitiveness", and "whether the reports sufficiently explore the potential to simplify legislation and to reduce unnecessary burdens for businesses and citizens" (European Commission, 2020, Article 2(3)). It is here, in particular, that the RSB's influence inevitably speaks to the content of impact assessment and evaluations reports, and not just their methodology.

Beyond reviewing impact assessments and evaluations, the RSB is responsible for advising on the implementation of the Better Regulation agenda, and for conducting "outreach activities" with the institutions and other stakeholders (European Commission, 2022). The latter are defined as "exchanges of views on horizontal, sectoral or methodological issues in the context of better regulation, with other institutions of the Union and of the Member States, think-tanks and international organisations, relevant institutions in third countries and other stakeholders involved in regulatory impact analysis and evaluation" (European Commission, 2020, Article 2(4)). Whilst they are not permitted to discuss specific files with interest stakeholders, or to meet with any organisation not listed in the Transparency Register (on which see below), RSB members can and do meet with external stakeholders to discuss broader issues, and to explain its role in the policy process.

The independence and expertise of the Board has been criticised by both civil society and industry stakeholders, and subject to review and recommendation from the EU Ombudsman. The Board's members generally have backgrounds in either the Commission services or in national governments, industries and regulatory oversight bodies; few have experience in the health, social or environmental fields, though the RSB's mandate requires a balance of expertise. This raises valid questions – such as those submitted by Corporate Europe Observatory (CEO) to the EU Ombudsman in 2023 – about whether they are qualified to assess the full spectrum of impacts that EU regulation creates, or to challenge orthodox approaches to cost-benefit analysis (which tend to better account for economic costs than social benefits) (Corporate Europe Observatory, 2023). As regards independence, the nine-person Board is recruited from within the Commission (four members) and outside of the institutions (four members), is chaired by a Commission Director General, and is hosted within DG Secretariat General. Though the degree and value of its independence from the Commission continues to be debated (Pircher, 2023), the investigation by the Ombudsman focused on the Board's independence from external interests and concluded that its current governance structures are insufficient. Responding to examples highlighted by CEO, in which RSB members met with BusinessEurope and with a French confederation of small business employers on the "competitiveness check" and the "SME test" respectively, the Ombudsman called for a full ban on RSB meetings with external stakeholders (European Ombudsman, 2024b).

4.3.2. Opportunities for engaging the RSB

In the course of the BRBH project, it has been apparent that relatively few civil society actors are aware of the role and purpose of the RSB, and a review of the meetings published on the RSB website indicates that civil society does not engage with the Board to the same degree as other stakeholders. We suggest here two potential opportunities for engaging the RSB as part of civil society advocacy.

1. Scrutinising RSB opinions: By contrast to the reports, proposals and opinions of other EU institutions, the opinions of the RSB are less commonly scrutinised as part of civil society advocacy campaigns. Yet, they play a crucial role in shaping the content of assessment and evaluation reports, and therefore the legislative proposals which follow. More fundamentally, the role and influence of the RSB is relatively little-known within EU policy circles, and its capacity to assess the full spectrum of impacts is uncertain. As such, scrutiny of the opinions – which are issues alongside the final impact assessment report and the legislative proposal – should be a routine element of advocacy.

2. Inviting the RSB to discuss its role: As described above, the current rules of procedure include within the RSB's mandate the task of "outreach". This means that RSB members can be invited to meet with external stakeholders that are interested in, for instance, impact assessment methodologies, the implementation of horizontal principles such as one-in-one-out, and sector-wide concerns. CSOs might utilise this provision to better understand and engage with the RSB.

4.4. Utilising other tools and principles of Better Regulation

Space constraints preclude detailed discussion of every aspect of the Better Regulation agenda but the below offers some initial thoughts on the relevance of a brief introduction to a wider set of tools and principles – most of which were introduced by Ursula von der Leyen in 2021 – which may be of relevance to (health) civil society actors and their objectives.

- Mainstreaming the SDGs: a further objective of Better Regulation is now to ensure that the SDGs are mainstreamed within the policy process. This involves specifically considering the impacts

of policies upon relevant SDGs, via impact assessment and evaluation, and the Commission has created a KnowSDGs (knowledge base for the sustainable development goals) platform to assist policy-makers in this process (see tool #19). For each impact assessment, a dedicated table – "annex 3" - must be created, identifying the relevant SDGs and, for the preferred policy option, assessing progress towards the identified SDG targets.

- The one-in-one-out (OIOO) approach: OIOO was piloted in 2021 and involves "offsetting new burdens resulting from the Commission's proposals by reducing existing burdens in the same policy area" (see tool #59). OIOO focuses on offsetting administrative costs – those created by administrative requirements, such as reporting, labelling, and certification – and requires that such costs are quantified. The outcomes of the process are reported in the Annual Burden Survey, where an overall cost/saving measurement is given. For 2022, the Commission reported that the 52 legislative initiatives falling within the scope of the OIOO approach contributed to reducing administrative burden by EUR 7.3 billion (European Commission, 2023, p. 14).

- Strategic foresight: the strategic foresight agenda encourages impact assessments and evaluations to account for "megatrends" and long-term scenarios when assessing the impact of (proposed) policies. Among the megatrends of relevance to EU policy-making, the Commission identifies shifting health challenges – specifically referencing unhealthy lifestyles, pollution, and infectious diseases – as well as climate change, demographic imbalances, governance and inequalities (see tool #20).

- The competitiveness and SME checks: since 2021, all impact assessments must systematically screen for specific impacts upon competitiveness and SMEs. This involves considering, to the extent relevant for a given initiative, impact upon cost/price, capacity to innovate, and international competitiveness, as well as conducting an "SME test" to identify and minimise negative impacts falling on SMEs (see tool #23).

5. Challenging the Better Regulation agenda: protecting the civic space and advocating for change

Looking beyond the individual actors, instruments and processes, Better Regulation as a whole is a political tool for implementing the European institutions' priorities, and a vision of what policy should achieve. It is thus crucial to EPHA's work on politics and health, and civil society's wider engagement with the political system. This section explores ways in which the (health) civil society community might work together to challenge the specific narratives and priorities of Better Regulation, promote a stronger civic space and policy-making process, and advocate for health as a political priority - and thus a concern of Better Regulation.

5.1. Challenging the Better Regulation narrative

The Better Regulation narrative is built around ideas of burden, red tape, the need to simplify and improve efficiency, and the cost of regulation. Increasingly, it also references future proofing, fitness for purpose, and competitiveness. It rests, fundamentally, on a poorly defined conception of what "better" regulation is. Consequently, Better Regulation has been described as a "chameleonic" concept, because it is sufficiently vague and malleable to be used in different contexts, mean different things, and advance different interests (Smith et al., 2015). Two avenues for challenging the Better Regulation narrative are thus presented: (1) engaging and refuting the emphasis on burden, red tape, simplification etc., and (2) promoting an alternative definition of "better".

5.1.1. Engaging Better Regulation terminology and narratives

Understanding Better Regulation as a horizontal programme that shapes and affects every aspect of policy-making, across all policy sectors, implies that it should be a fixed element of CSO advocacy strategies. This might start with attention to arguments framed in terms of burden, red tape, simplification, and competitiveness, to identify and highlight specific examples of decisions taken in service of these objectives and their impact upon health. Similarly, where explanations of particular decisions or delays, for instance, point to some aspect of Better Regulation (the impact assessment, RSB, need for more evidence etc.), these explanations should be scrutinised. More broadly, efforts to defend and promote regulations – as protections, rules of the game, and safeguards for vulnerable groups and society at large – can help to challenge narratives about burden, red tape and cost (Unchecked UK, 2024).

Another possible approach is to utilise the existing terminology and challenge how it is understood. "Fitness for purpose", for instance, might be used to assess whether a regulation is achieving its (health) objectives, doing so as quickly as it might (efficiency), and in coherence with other EU (health-relevant) policies. Similarly, "future proofing" and the wider integration of strategic foresight within Better Regulation are relatively new terms which might be used to support arguments about, for instance, long term health trends, health investments, preparedness and resilience, changing technologies and risk. The mainstreaming of the SDGs, noted above, offers a similar opportunity to argue on Better Regulation terms. Moreover, where the harmonisation of a health law or the removal of complex derogations and exceptions would make it easier to implement and enforce, then an argument about simplification might be offered. Research under the BRBH project has shown that, whilst commercial actors commonly utilise the language of Better Regulation, civil society actors are less likely to frame arguments in these terms.

An important strand of engaging the agenda should thus be to (re)claim some of its terminology and challenge how it is used.

5.1.2. Promoting an alternative definition of 'better'

Challenging the terminology of Better Regulation can start with the term itself. There is space to use the vague, "chameleonic" nature of the concept of "better regulation" (Smith et al., 2015) to advance health priorities and values. Advocacy might centre around elaborating an alternative definition of "better" – better for health, better for vulnerable groups, better for equity – and promoting this as a way of influencing Better Regulation and how it operates. For example, to challenge the understanding of "better" regulation as that which reduces regulatory burden, it might instead be defined as,

> *"regulation that helps address challenges to humankind, that is timely, effective, efficient, fair and proportionate, that is participatory and transparent, that is duly evidence-based and reflects the complexity of reality and the multiplicity of stakeholders affected, while also being future-oriented" (ten Brink, 2022).*

Within this, and linked closely to advocacy on the CDoH, "better" regulation might be understood as that which genuinely benefits public health and is not unduly influenced by commercial interests, or conflict of interest.

The persistence of Better Regulation as a programme and of its understanding as a tool of deregulation and burden reduction is, in part, a result of the failure of its critics to develop a compelling alternative conceptualisation.

> *"To say that EU better regulation is flawed does not shed much light on what the 'true' better regulation looks like [and] the actors that argue against EU better regulation have not produced an alternative morphology of concepts, since their initiatives have been limited to unveiling the negative features of better regulation" (Radaelli, 2023)*

The role for civil society here is to collectively adopt a single, coherent, and positive alternative vision, and to work together to promote it. Radaelli (2023) goes on to note that "In Europe, the best days of a possible alternative advocacy coalition were in the mid-2010s", referring specifically to the Better Regulation Watchdog, an alliance created in 2015 to scrutinise the evolving agenda. Whether this precise alliance is the appropriate platform, or some other, new grouping would be more beneficial, collective advocacy has the power to shift the narrative.

5.2. Advocacy focus so far: reinforcing the European civic space

Several aspects of EPHA's wider work on politics and health (have potential to) contribute to efforts to advocate on Better Regulation. These include actions to tackle a shrinking civic space, ensure access to sustainable funding, push for improved participation of civil society in (health) policy-making, call for health to be a priority, influence the elections campaign and the budget issues, and address the commercial and political determinants of health, to name a few. Building on existing work and considering the need for an improved regulatory process, this section explores what the next advocacy steps of the politics and health activities at EPHA are.

5.2.1. A growing threat to civil society participation in policy-making

According to the report on the shrinking space for civil society by the European Parliament, "civic space refers to the legal and political framework in which people and groups can meaningfully participate in the political, economic, social and cultural life of their societies, exercising the right to express views, the right to information, and the right to assemble, associate and engage in dialogue with one another and with authorities". The report adds that "for CSOs to thrive, civic space must be an enabling and safe environment free from undue interference, intimidation, harassment and chilling effects by both state and non-state actors (…)" (European Parliament, 2022; EU4Health Civil Society Alliance, 2022a).

In addition to threats, attacks and obstacles, CSOs are facing difficulties in securing sustainable means of funding, allowing them to develop their policy and advocacy work. They are impacted by a "rapid deterioration of democratic processes, civic freedoms and adherence to the rule of law in several EU member states" (European Civic Forum, 2023). They are also facing increasing barriers in the implementation of their activities at all levels of governance (Civil Society 4 EU, 2023). This has been stressed in the Commission's 2022 rule of law report and various European Civic Forum reports, highlighting gaps in European measures to support CSOs that are facing such challenges (EU4Health Civil Society Alliance, 2022a). While some progress has been made in several EU Member States, the Commission's latest rule of law report notes a continuation of "the trend noted in previous reports" where civil society and human rights defenders have faced increasing challenges, including "new legal restrictions, lack of funding or physical and verbal attacks", while issues were labelled as systemic in some cases (European Commission, 2024d).

The result is a shrinking civic space, meaning that CSOs are facing difficulties in accessing mechanisms to take part in policy-making, as well as having capacity to create and take part in meaningful dialogue. This includes threats to the existence of organisations, in some cases, and obstacles to their activities. This is the case in many Member States of the EU, especially regarding access to funding and maintaining sustainable finances (EU4Health Civil Society Alliance, 2023a; EPHA, 2024b). Furthermore, civil dialogue, i.e., exchanges between civil society and policy-makers, lacks transparency, structure and regularity, leading to a democratic deficit (Civil Society 4 EU, 2023). All these elements hinder the development of capacity CSOs to dedicate the time needed to take part in consultation exercises, scrutinise impact assessments, and engage critically with the broader Better Regulation narrative. This creates in turn an imbalance in terms of participation compared to other actors of policy-making. For these reasons, CSOs have been calling for a Civil Society Strategy that would protect them against threats and support their participation in policy-making.

Developments at the European level have shown encouraging signs, however limited. Following a push from French President Emmanuel Macron in 2017, and the organisation of European Citizens Consultations (ECCs) in 2018 (which were not followed by concrete changes), Commission President candidate Von der Leyen brought the suggestion to the European Parliament in 2019 to organise the Conference on the Future of Europe (CoFoE). It was to be a two-year participatory democracy exercise providing recommendations on the future of Europe by citizens. While CSOs were initially not part of the process, a number of organisations set the Civil Society Convention, providing inputs in the process through representatives. On 9 May 2022, the conference closed and adopted a set of 49 recommendations (Oleart, 2023). Among them was a recommendation calling for a strengthened role for CSOs and a stronger civic space, strengthening links with citizens, and improved transparency (EU4Health Civil Society Alliance, 2023a; EU4Health Civil Society Alliance, 2022a). Key conclusions for civil society include:

- “Provide enhanced structural support, financial and otherwise, for civil society, especially for youth civil society and support local authorities in setting up local youth councils; this could be achieved through a specific pillar in the European Democracy Action Plan for involvement of civil society and social partners, and a dedicated civil society strategy.

- Strengthening cooperation between EU legislators and civil society organisations to utilise the link between decision-makers and citizens which civil society organisations constitute.

- Ensure proper civil and social dialogue mechanisms and processes at every step of the EU decision-making process, from impact assessment to policy design and implementation.

- Reform the way the European Union works by better involving social partners and organised civil society. (…)” (EU4Health Civil Society Alliance, 2022a).

The CoFoE was an essential step in strengthening the calls for an improved civil society engagement. The recommendations, if implemented, would foster more meaningful participation of civil society to policy-making, while levelling the playing field (EU4Health Civil Society Alliance, 2022a).

Concerningly, recent policy developments seem to cast additional scrutiny on civil society in the EU, rather than strengthening the civic space. These policy developments add more scrutiny mainly on the activities of CSOs, which are already required to follow clear, defined reporting rules, and show transparency on their activities and on the spending of public grants. In early 2024, a report was adopted by the European Parliament on the transparency and accountability of non-governmental organisations (NGOs) funded from the EU budget (A9-0446/2023). Civil Society Europe highlighted concerns regarding the implications of this report in terms of civic space (Civil Society Europe, 2024). The report advises transparency requirements for NGOs, while hinting towards an increased risk. This fails to recognise that CSOs are already subject to the same financial rules as other stakeholder groups. While more transparency could be valuable, it should apply to all stakeholders that are beneficiaries of EU funding. The narrative of the report was highlighted as potentially weakening the work of NGOs (Civil Society Europe, 2024; EPHA, 2024b), therefore impacting civic space.

The European Economic and Social Committee (EESC) Civil Society Week 2024 saw discussions on the Defence of Democracy Package. The aim of the Package is to tackle foreign influence, promote free and fair elections, and foster civic engagement and citizens’ participation in European democracies. Whilst the initiative’s aim of fostering “an enabling civic space” and the promotion of civil society and citizens engagement is to be welcomed, the package does not go far enough in recognising that CSOs comply with

high standards of transparency and accountability, fulfil requirements at EU level, hold transparency as a core value, and have a key role in ensuring a vibrant and thriving European democracy (EPHA, 2023d). Furthermore, during the EESC event, civil society actors and policy-makers highlighted that the Package contains provisions aimed at addressing foreign interference which might negatively impact civic space. Another element of concern was the scope of the legislation, which focused on foreign interference but overlooked influence and important challenges to democracy that come from within the EU, with the example of Hungary's diminishing civic space and infringements on the rule of law (EPHA, 2024b).

As outlined above, this difficult context for CSOs may prevent their participation in policy-making, therefore undermining the democratic legitimacy of EU processes. The recent developments of the Defence of Democracy Package and particularly the Report from the European Parliament could also lead to more burden for CSOs, which may lack capacity to fulfil new requirements while carrying out their work.

5.2.2. Sustainable core funding and the representation of interests

Sustainable core funding is an essential element and enabler of civil society participation in policy-making, alongside other actors that have stronger means to do so. It provides financial certainty and sustainability for CSOs, supports the planning and forecasting of activities, and therefore the planning of capacity to take part in policy-making developments, and ensures stronger impact from their activities (European Civic Forum, 2023; European Civic Forum, 2024). Sustainable sources of public funding for CSOs also allows them to play their part independently, and have capacity to advocate in and on the policy-making processes. As part of a shrinking civic space, civil society's access to funding and resources has been constrained in a number of Member States (European Civic Forum, 2023). As an illustration, the 2023 Fundamental Rights Agency civic space survey found that 75.4% of respondents felt that funding concerns threatened some, much, or all of their activities in the last year, while 90.4% said that their financial reserves covered less than a year of activity (European Civic Forum, 2024). Specific to the health sector, the operating grants, the key funding mechanisms from the Commission, have faced difficulties in the past years. This has presented uncertainty for health CSOs that need such funding, threatening their independent and strong participation in policy-making.

Operating grants allow CSOs to take part in policy-making processes in an efficient, sustainable and independent manner. Such funding mechanisms enable CSOs to advocate for the public interest, bring their critical expertise to policy-making, support the Commission in delivering on its priorities, and be a voice for citizens, particularly vulnerable groups. In addition, they are supported in adapting and reacting to emergency situations, as it was the case for CSOs during the COVID-19 pandemic, and Russia's war in Ukraine, for instance. Operating grants also give CSOs capacity to play their role as watchdogs, therefore safeguarding democracy and the rule of law at different levels of governance. Finally, operating grants allow a level playing fields with the representation of private interests and ensures the democratic legitimacy of EU policy-making by including civil society and citizens' representations in the processes (EPHA, 2021b; EU4Health Civil Society Alliance, 2021; EU4Health Civil Society Alliance, 2022b; EPHA, 2023e; EU4Health Civil Society Alliance, 2023a).

Crucially, operating grants need to be foreseen in long-term, financial frameworks including the MFF and the EU4Health programme (rather than, for instance, in ring-fenced, project/action grants; EPHA, 2021b). This enables long-term vision and financial certainty, as well as allowing civil society the capacity and means to continuously adapt to changing realities and adjust to potential emergencies (EPHA, 2021b; EPHA, 2023e). Responding to the announcement, in 2021 EU4Health Work Programme, that the operating grants for the health sector would be discontinued, the EU4Health Civil Society Alliance

campaigned successfully for the grants to be reinstated on a year-by-year basis (see Annex 1). However, there were no certainty for 2023 and no possibility to have a multiannual financial framework. Only in December 2023 did the Commission announce that the EU4Health programme will continue the operating grants mechanism in 2024, and that a call for the framework partnership agreements (FPAs) for 2025-2026 will be published (EPHA, 2023e). This seems to answer the long-lasting call for multiannual funding framework opportunities, even though there are still discrepancies with other policy sectors.

Indeed, funding opportunities for CSOs vary greatly in the EU, depending on the funding programme and the policy areas worked on. The situation of the health civil society organisations shows a discrepancy with other funding programmes, such as Citizens, Equality, Rights and Values Programme (CERV), Environment and climate action programme (LIFE) or the Employment and social innovation (EaSi)/ European Social Fund (ESF+) programmes. These include different lengths of multiannual financial frameworks, when they are made available, but also different co-funding rates. For instance, in the EU4Health grants, health CSOs need to find 40% of their funding outside of Commission funding, while in other programmes, this rate is lower. Finally, the CERV programme offers the possibility for CSOs to re-grant some of the funding to other small organisations. This would be a relevant tool to streamline to other funding programmes, as it would support the funding of smaller organisations in different policy areas and governance levels (i.e., if re-grants are provided to member organisations of European-level civil society organisations, for instance) and therefore their participation in policy-making (EU4Health Civil Society Alliance, 2023a). However, all programmes, including the CERV, have limitations in terms of co-funding requirements, co-creation opportunities, and can be administratively burdensome for CSOs (European Civic Forum, 2023; European Civic Forum, 2024).

5.2.3. Addressing the threats: the need for a Civil Society Strategy

Following the CoFoE, and in the context of a shrinking civic space, CSOs have been calling for a Civil Society Strategy. In 2022, a letter coordinated by Civil Society Europe and the European Civic Forum called for the inclusion of a proposal for a Civil Society Strategy in the Commission's 2023 work programme (Civil Society Europe, 2022). The letter was supported by more than 300 CSOs, including EPHA and the EU4Health Civil Society Alliance (EU4Health Civil Society Alliance, 2022c), from the European, national and local level, across the EU. The letter stressed the key role that CSOs play, particularly their part as a watchdog and as "democratic antibodies when rights, democracy and the rule of law are under attack", but also in "build[ing] public spaces, upscal[ing] participatory democracy and channel[ling] citizens' participation". The letter adds that this role is threatened by a shrinking civic space, attacks, obstacles and threats. Therefore, going further than limited support action, the signatories asked for a comprehensive Strategy, building on the European Parliament resolution on the shrinking space for civil society in Europe (2021/2103(INI)) and the conclusions and recommendations (particularly 36.8) of the CoFoE.

Ahead of the European elections in 2024, this call was renewed in the Civil Society 4 EU campaign, led by Civil Society Europe and in which EPHA and the EU4Health Civil Society Alliance took part (Civil Society 4 EU, 2023). The campaign outlined concrete measures to be taken, including:

- The Civil Society Strategy should aim at strengthening civil society and protect it from attacks and smear campaigns, and any form of discrimination, harassment, violence and ill-treatment; this protection should also be for the communities that CSOs represent;

- The key role of civil society should be recognised, as well as its role, value and specificity;

- Policies impacting civil society should be in line with EU fundamental rights;

- Full transnational cooperation between CSOs should be enabled, therefore, existing obstacles to cross-border activities should be removed (i.e., legal and fiscal uncertainties);

- Access to core, multi-annual, consistent, and flexible structural funding should be guaranteed, and accessibility should be improved by simplifying administrative procedures;

- CSOs should be involved from the first step in the design of funding policies and programmes, including regarding the definition of accessibility criteria. This should be done through a structured mechanism ensuring adequate and regular dialogue and information flow between CSOs and public donors regarding the implementation of funding programmes;

- Civil dialogue should be organised on an equal footing to social dialogue. The manifesto therefore calls for a civil dialogue agreement, to recognise civil dialogue as an essential element of European participatory democracy and harmonise standards across institutions and Member States.

Such a Strategy could also contain re-granting mechanisms, on the model of the CERV programme. This would allow smaller CSOs to take part in policy-making processes and benefit from sustainable funding opportunities to do so, and to dedicate capacity to it. This funding could also support capacity building within these organisations to take part in policy-making (EU4Health Civil Society Alliance, 2023a).

The Strategy should be developed in cooperation with CSOs, to provide a framework for meaningful civil society participation in policy-making processes beyond consultations and tick-box exercises. This could include participation in programme development, agenda-setting, and the definition, implementation, evaluation and monitoring of policies for EU strategic priorities (EPHA, 2023f). Taking the example of the health sector, the EU institutions could develop similar initiatives to, for instance, the WHO Framework of Engagement with Non-State Actors. This framework recognises the role of non-state actors in the advancement and promotion of public health. It requires demonstrating that the engagement has a clear benefit to public health, supports and enhances the scientific and evidence-based approach of the WHO's work, and avoids conflict of interests. A similar framework at EU level would enable civil society to be involved in key public health debates and policy-making processes and would provide more balance with the other represented interests (EPHA, 2023f).

Addressing the shrinking civic space and the issue of funding would tackle key political determinants of health, in that it would support improved (health) civil society participation in policy-making processes. As such, this is an essential advocacy point ahead of the next EU mandate.

5.2.4. Key advocacy messages ahead of the EU 2024 elections

The 2024 EU elections were an important opportunity for civil society to set the agenda for the future of EU policy-making, and the implementation of the Better Regulation agenda. Health CSOs called, ahead of the EU elections, for health to be a priority on the EU agenda for the next political mandate. COVID-19 has shown the need for health systems to be prepared to face health crises, and that therefore, health should be given the priority it deserves. Making health a priority of the Commission would be a strong step towards ensuring that the Better Regulation agenda is used to pursue health, rather than undermine it.

This message was conveyed by EPHA's and the EU4Health Civil Society Alliance's manifestos. Specifically, the EPHA manifesto called for a comprehensive European Health Strategy to be developed and implemented with the involvement of civil society, focusing on immediate health concerns and the long-term health resilience and the health of future generations. The manifesto further recommends setting

robust mechanisms to manage and mitigate potential conflicts of interest between policy decisions and industry stakeholders, particularly when it comes to health. Both the EPHA and the EU4Health Civil Society Alliance manifestos call for a European Commission Vice President on public health, social rights and wellbeing to be appointed, in order to prioritise health within the institutions. This role would focus on health determinants and gather the portfolios of DG SANTE, DG JUST (non-discrimination policies) and DG EMPL (social rights, disability) (EPHA, 2023a; EU4Health Civil Society Alliance, 2023b). However, in the resulting strategic agenda for 2024 to 2029, health is only mentioned three times, the focus being rather on defence, security and migration (EPHA, 2024e). The mentions of health are limited to facing health emergencies, and strengthening cooperation on health (European Council, 2024). While the Mission letter of the Commissioner for Health and Animal Welfare calls for the completion of the Health Union, it fails to mention the EU4Health programme, which raises further questions about the place of health as a priority (European Commission, 2024e).

Going hand in hand with prioritising health is the need to have an ambitious EU budget that enables the EU to deliver on its health objectives, which was also stressed in the EPHA and EU4Health Civil Society Alliance's manifestos, with the key idea that health is an investment and not a cost (EPHA, 2023a).It has been estimated that every euro invested in health generates on average an economic return of 14 euros (Masters, et. al., 2017; EU4Health Civil Society Alliance, 2024a). Specifically, health promotion, prevention and environmental exposure should be given a strong focus and should be reflected in the MFF, to provide stability and predictability for long-term health initiatives (EPHA, 2023a; EU4Health Civil Society Alliance, 2023b). The manifestos also suggested civil society involvement in the drafting of the EU4Health budget and programmes, ensuring that they align with the most pressing health needs and priorities (EPHA, 2023a).

However, in contrast to these recommendations, recent developments on the EU4Health budget have created uncertainty the place that health would be given in the future of the EU. Early 2024, the EU4Health Civil Society Alliance shared its concerns over the midterm review of the EU MFF which saw the EU4Health Programme affected by a EUR 1 billion cut of its total budget in February 2024, therefore reversing the significant. Budget increase that was agreed at the launch of the programme. EU4Health is in its early stages and the budget cuts further threaten its ability to deliver on its objectives (EU4Health Civil Society Alliance, 2024a). In addition, this cut could impact the development of EU health policy and health CSOs (EPHA, 2024b). The future of the programme beyond 2027 could also be impacted.

In addition to political commitment and a secure budget, a third pillar of current advocacy is to break policy silos, making sure that health is considered across other policy areas during the policy-making processes. This follows the health in all policies approach, which was also envisaged as an advantage of a potential dedicated Vice President for health, wellbeing and social rights in the EPHA and EU4Health manifestos. This approach was a core part of both documents.

Indeed, coordinating between policy areas would be key in connecting health with policies that impact it, such as environmental elements impacting the health of citizens; employment and education policies impacting prevention and health and care workforce; food policies directly impacting health and agriculture, to name a few. In that regard, the Commission Vice President for public health, wellbeing and social rights would ensure an overarching vision, considering health as an investment and not a cost, ensuring that they are taken into account in the necessary policy areas. The EU4Health Civil Society Alliance addressed a letter to President von der Leyen asking for this role to be created, following the European elections. The letter stresses that this role could ensure that health is maintained a political priority; that the EU Health Union is deepened and further implemented especially when planning for the next MFF; and should allow a strong and coordinated EU health policy to counter current pressing

challenges and ensure the sustainability of health systems (EU4Health Civil Society Alliance, 2024b).

While the upcoming Commission does not seem to include such a role, it is essential for civil society to keep pushing this message and vision. Breaking policy silos would positively challenge current policy-making processes to deliver improved health outcomes and change the perspective on health (i.e., seeing it as an investment and an element to be considered systematically). It would in turn reinforce the Better Regulation agenda in strengthening the health criteria in the consultation processes and the impact assessment methods. Finally, the link to SDGs, also part of the assessments in the Better Regulation toolbox for assessments, would be even stronger and reinforce policy-making on the issue.

5.3. Advocating for improved policy-making: what next after the 2024 elections?

The aftermath of the European elections held in 2024 will be key in defining the priorities of the EU for the next five years and paving the way for longer-term decisions. Drawing on the lessons from the European elections, this section explores the future of health civil society advocacy on policy-making processes.

5.3.1. The post-election context: what to expect in the next mandate

Ahead of the European elections, EPHA carried out an analysis of the political parties' elections manifestos, focusing on the priorities having a direct or indirect impact on health, and comparing them with EU priorities and commitments. This analysis sought to support citizens to make an informed choice at the elections. The project provided an analysis of each of the five main parties' manifestos – European People's Party (EPP), the Party of European Socialists (PES), the Alliance of Liberals and Democrats for Europe (ALDE), the European Green Party (EGP) and the European Left (EL) – as well as an overarching analysis which also included inputs from other European parties' manifestos (European Free Alliance (EFA), Volt, European Democratic Party (EDP), European Christian Political Movement (ECPM), European Conservative and Reformists Party (ECR))[3].

The analysis found that health was given different degrees of importance. Whilst the ALDE manifesto barely mentions health, for instance, the Greens and Socialists hint at health in all policies. The EPP, Greens and the Socialists also call for a stronger European Health Union. Specifically, the EPP makes references to the achievements of the past mandate and commits to building a "true European Health Union to be prepared and equipped to deal with cross-border threats, improve the resilience of our health systems (…)" (European People's Party, 2024; EPHA, 2024c). The Socialists make a significant call for the European Health Union, in particular for pandemic response, cross-border cooperation, and national healthcare provisions (Party of European Socialists, 2024; EPHA, 2024d). Furthermore, the reflection of a stronger EU role in health within the institutions is hinted at. The Socialists have called in their programme for a stronger role of EU institutions, while EPP calls for a Vice-President of the European Commission with an overarching role in addressing demographic change and its challenges, including in healthcare (EPHA, 2024e).

However, while the manifestos include provisions on budgetary policy, none call for a stronger budget for health. In terms of participation, all manifestos include elements relating to the role of civil society in democratic processes and policy-making. For instance, the Greens have called for adequate funding for CSOs, while the EPP mentions accelerating funding procedures, and the Socialists make a call to support

[3]The campaign is available here: https://epha.org/eu-parties-manifestos-a-critical-analysis/

the crucial role of civil society in democracy (EPHA, 2024e; EPHA, 2024f; Party of European Socialists, 2024). The Greens also call for a stronger role for the Parliament and for civil society in monitoring EU spending. Recognising the shrinking civic space, the document calls for protection mechanisms for CSOs, and for support for a civil dialogue –modelled on the social dialogue – through, for instance, a statute of European cross-border associations and non-profit organisations (European Green Party, 2024; EPHA, 2024g).

Based on this analysis, it can be expected that some elements of public health will advance within the new Parliament, but also that other aspects of health may not be given the priority that they deserve. Key crises are not addressed, such as the health workforce (which is largely absent from the documents), preparedness of health systems, NCDs and anti-microbial resistance. Taking this into consideration, and considering the recent EU4Health budget cuts, it is likely that some key health topics and issues are at risk of disappearing from the agenda, or not being given the necessary priority and ambition (EPHA, 2024f).

This mandate will be a turning point, following a mandate where health was placed high on the agenda by the COVID-19 pandemic, and taking place in a context where health systems are in crisis, and societies facing polycrises (including climate change and the burden of NCDs). The last mandate saw key achievements such as the launch of the Health Union, and stronger coordination between Member States on the COVID-response, as well as the creation of the Health Emergency Preparedness and Response Authority (DG HERA). There was, before the elections, a demand from citizens to be a central focus point. A Eurobarometer survey listed the fight against poverty and social exclusion (33%), and supporting public health (32%) as top issues that citizens wanted to see discussed in the elections debates (Eurobarometer, 2024; EPHA, 2024f). Taking these elements into account, it could be expected that the legacies from the Spanish and Belgian Presidencies of the Council are followed in the next mandate. While the Spanish Presidency committed to the European Health Union, the Belgian one provided a strong focus on health policy and on addressing the healthcare workforce challenges (EPHA, 2024f). However, in terms of elections results, while the previous coalition in the European Parliament has maintained a majority (Le Monde, 2024), the rise of populist and far-right parties and elected MEPs will challenge the completion of the planned priorities, the deepening of integration of policy areas, and could impact the development and implementation of health and health-related policies.

5.3.2. Enlargement and treaties updates

The wider geopolitical context present some potential avenues, on the longer-term horizon, for change to the EU's policy-making processes and priorities. With the potential enlargement to Ukraine, Moldova and Georgia, the possibility for treaty revision is presented. This could involve a review and strengthening of EU competences, which could be positive for health policy-making at the European level. Indeed, the EPHA manifesto analysis found that all of the manifestos stress the need to reform the treaties, following an expected EU enlargement. Some of the parties have, in that context, evoked a stronger role from the institutions. The European Left for instance, explicitly referred to health in institutional changes, while the Greens mentioned the need for the EU to adopt necessary tools to face current challenges (EPHA, 2024f; European Green Party, 2024; EPHA, 2024g). The Socialists called for the institutions to be given the "tools to safeguard our democracy, strengthen our economy, protect our environment and our social model", which could also imply health (Party of European Socialists, 2024; EPHA, 2024d).

Regulation itself was also touched upon, with the ALDE manifesto calling for the implementation of the OIOO principle, and pushing for citizens' engagement in open consultation (Alliance of Liberals and Democrats for Europe, 2024; EPHA, 2024h). More generally, the EPP proposed a European Convention

to discuss the treaties (European People's Party, 2024; EPHA, 2024c). This could be a very interesting development in terms of participation in policy-making, where civil society should be able to provide inputs and expertise, and support the shaping of the future of European policy-making and priorities.

Beyond the political programmes and manifestos, various discussions and reflections have been taking place, including a FEPS report, "EU Treaties – Why they need targeted changes" (FEPS, 2023b). and its launch event (FEPS, 2023c). The latter brings forward the context of war, geopolitical tensions, but also of polycrises between climate, cost of living, pandemic experience, migration, and misinformation, as arguments for treaty renewal that would bring stronger European capacity to act. It builds on earlier publications discussing the question of the treaties, such as the EU leaders' Granada Summit declaration (European Council, 2023); an EU Parliament report on proposals for the amendment of the treaties (European Parliament, 2023); the Franco-German report on reforming and enlarging the EU for the 21st Century (Franco-German working group on EU institutional reform, 2023); and the manifesto "The European Union at the time of a New Cold War" (CEPR, 2023).

The report consists of a proposed treaty review, including health in the policy fields that would require an upgrade of EU competencies. The report also proposes a list of European public goods (i.e., civil protection mechanism, rare diseases insurance, to name a few) which could only be delivered through a change of the treaties, including a reform on budgetary means to support the EU in co-financing these public goods. Specifically, regarding health, the report calls for a strong Health Union, that would allow the EU to tackle common challenges that cannot be addressed by individual Member States on their own. This involves having the necessary means allocated. Currently, EU health policy has also been delivered through other policy fields, as the treaties provisions are limited (see Greer et al., 2024). This has resulted in a broad but fragmented range of instruments across several areas. The revision would therefore entail replacing in the areas of shared competence the "common public health security issues" by the implementation of the Health Union (FEPS, 2023a; FEPS, 2023b).

To support its call for stronger EU competence, the report relies on the conclusions of the Conference on the Future of Europe, which include:

- Amending Article 4 TFEU to include health and healthcare among shared competencies;
- Promoting better health by acting at the intersections between health and environment;
- Reinforcing health care systems and access to affordable healthcare for all;
- Increasing funding for health policies and measures to mitigate pandemic impact in the MFF 2021-2027;
- Adapting financial mechanisms in the new MFF to support pandemic response and ensure sufficient economic recovery. (FEPS, 2023a; FEPS, 2023b).

These proposals are highly relevant in terms of prioritising health on the EU agenda, advocating for improved governance practices, and increasing participation in policy-making. In the aftermath of the European elections, health CSOs should have a role to play in potential treaty revision discussions. In particular, the role of civil society in pushing for health to have a stronger place in the treaties and competences is instrumental, supporting the prioritisation of health in policy-making itself. This would, in turn, impact the Better Regulation agenda's priorities, leading to a better consideration of impacts on health in policy-making processes.

5.3.3. CDoH and the Better Regulation agenda: from existing advocacy to balancing interest in policy-making

As discussed in section 4.1.3, commercial practices shape policies and personal choices through marketing, lobbying, and political and social engagement, utilising the tools and narratives of Better Regulation within these strategies. In this context, EPHA has been instrumental in advocating for action to address the CDoH. In 2024 the WHO Europe released a groundbreaking report on the Commercial Determinants of NCDs (World Health Organisation, 2024), which showcases successful case studies at the national and supranational levels, underscoring the effectiveness of collective action and strategic alliances in influencing policy. EPHA led the authorship of Chapter 13, which includes case studies focusing on the EU framework, underscoring the effectiveness of collective action and strategic alliances in influencing policy across Europe. These case studies detail EPHA's involvement in efforts to improving the policy-making process, for instance by drafting amendments for the Parliamentary Subcommittee on Public Health (SANT)'s Own-Initiative Report on NCDs (EPHA, 2023g), and advocating for a European framework to regulate marketing of unhealthy products targeting youth (EPHA, 2021c).

The pervasive influence of commercial actors often extends beyond the regulatory reach of any single legislative framework, even an international or EU framework, making it difficult to secure comprehensive public health protections. This issue is compounded by the inconsistent implementation and enforcement of policies across nations and regions, leading to uneven health outcomes. The global nature of CDoH means that actions confined to the EU framework, or that relating toa particular sector, may be insufficient to address the broader, systemic issues that contribute to NCDs. It is for this reason that civil society must build alliances and capacities horizontally, engaging in the development and implementation of "meta-regulatory" frameworks like Better Regulation, at the global, EU and national levels (Lauber and Brooks, 2023).

In the next mandate, CSO advocacy should be mindful of the link between the CDoH and Better Regulation. There are several policy files where the CDoH will play a prominent role. These include the FIC directive and an alcohol strategy (including health warning labels, ingredients and nutritional info, calories, taxation, marketing), and the implementation of the elements from the ECBP, including those that have been removed from the implementation roadmap. Policy developments in the digital field could also be an area where CSOs develop advocacy around the CDoH, particularly focusing on the risks for health of social media profiling and advertising (Winter et al., 2021). Beyond the advertising of pharmaceutical products, civil society could advocate for the regulation of other health-related products in the coming years. In that regard, regulations in France and Spain on influencers' advertising of products that have effects on health could be a leading example. Another area could also be advocacy on regulation for health-related apps and data protection, where commercial interests will also play a role.

As discussed in section 4, CDoH have played a part in shaping, slowing and, potentially, blocking regulatory measures, such as the FIC Regulation or alcohol labelling. In the post-elections context, it is paramount that civil society actors include this lens to their advocacy on prioritising health in the EU agenda. Chapter 13 of the WHO Europe Report on the Commercial Determinants of NCDs highlights the critical need for effective CSO engagement, as key actors in advancing health and counterbalancing profit-driven interests in health policy. This requires a clear separation between civil and commercial interests, enhanced transparency, and the prevention of conflicts of interest, all of which depend upon change to the Better Regulation agenda and its instruments.

6. Conclusions

6.1. Lessons learned

The Better Regulation agenda is a central tool of EU policy-making processes, and aims to promote good governance across the EU institutions. This report makes the case that, to support the development of policies beneficial to public health, CSOs need to consider the Better Regulation agenda as part of their advocacy activities on policy-making and civic space. It advances two complimentary conceptualisations of Better Regulation to support the development of understanding and advocacy by CSOs:

- Better Regulation as a practical toolbox, focusing on its individual instruments, actors and processes. This conceptualisation supports advocacy on how to improve tangible features of the policy-making system, such as the consultation process, impact assessment exercises, and RSB oversight.

- Better Regulation as a political agenda, focusing on the narrative, purpose and framing of the policy-making system and the regulation which it produces. This conceptualisation supports advocacy on the wider context of health policy-making, such as how to improve the participation and capacity of civil society, and how to challenge the Better Regulation agenda so that it might work better for improved health outcomes.

- In addition to presenting the components and complexity of Better Regulation, the report situates Better Regulation in the wider landscape of health and politics, highlighting its relevance to advocacy on the civic space, CSO participation in policy-making, the CDoH, and developments in the institutional (and constitutional) structure of the EU.

It demonstrates, fundamentally, that CSOs need to approach Better Regulation with a “wide-angled lens”, and that they require support to do so. This refers to internal capacity building within the CSO community, but also to access to sustainable funding opportunities, protection from threats, and active inclusion in policy processes. The latter are key advocacy avenues that civil society has been active on for many years, but that are of increasing importance. The former requires more capacity and tailored resources to interact with the Better Regulation tools: to participate in the consultation activities, and to advocate on an improvement of the agenda to better include health in its priorities. It is here that EPHA and the BRBH project are currently focusing attention.

6.2 Next steps: the civil society toolkit

It is important for civil society to engage in the structures of policy-making and of the Better Regulation agenda – to take ownership it, use it, advocate on how to improve it, and make health a priority of the agenda. To support such advocacy, and as part of the BRBH project, a civil society toolkit will shortly be developed.

The toolkit will contain information to support CSOs in building capacity to engage with the Better Regulation agenda, and other aspects of policy-making impacted or related to the agenda, to advocate for improved health policy-making. The aim of the toolkit it to facilitate health civil society in maximising their impact in policy-making with the existing framework, by providing tools and resources to improve understanding of the Better Regulation agenda, and engage more effectively with the various pathways for participation in policy-making. The resources will range from introductions to the Better Regulation agenda and health policy-making in the EU, as well as the BRBH project outputs and other research on these issues. Reflecting the conceptualisations presented in this report, they will balance two objectives, facilitating engagement with the existing Better Regulation processes, on the one hand, and supporting advocacy to change or raise awareness of the agenda, on the other. The toolkit will contain videos and podcasts related to the topic, briefs on key issues, and links to useful sources. It will be hosted on the EPHA website and is due for completion at the end of 2024.

6.3. Recommendations

As the report has demonstrated, Better Regulation is a vast and complex agenda, and one which (because of its horizontal nature) may not instinctively feel like part of "health policy" or the mandates of (health) civil society. For these reasons, the adoption of recommendations for action is undertaken with caution, and premised with a call for collective action. CSOs must pool resources and expertise to build effective and sustainable engagement with the agenda. The recommendations below are presented as a starting point. They draw on specific, tangible actions, often linked with existing areas of advocacy, that are identified within the report.

- Ownership: Better Regulation needs to become a systematic and automatic part of CSO advocacy strategies and activities, requiring the building of understanding and capacity. This fundamental goal is the driving rationale of this report.

- Practical tools and processes: As a first step to learning how Better Regulation works in practice, CSOs should engage directly with the RSB, making use of the Board's "outreach" mandate to establish a dialogue with this important actor. CSO could ask for more transparency of the regulatory scrutiny board decisions and its methods in general, and the representativeness of its composition more particularly, which needs to be assured to ensure that regulations are genuinely being made "better".

- Shifting the narrative: An important strand of engaging the broader agenda is to (re)claim some of its terminology and challenge how it is used. Civil society must mirror commercial actors' utilisation of Better Regulation language when responding to consultations, arguing for health protections and advocating for EU action.

- Defining "better": A tangible project might be to rethink what is understood as "better", and collectively adopt a single, coherent, and positive alternative vision that can support wider advocacy.

- The policy process: CSOs should continue calling for more transparency and the development of guidelines on conflict of interest to tackle CDoH in policy-making, to ensure that public health priorities are safeguarded and not compromised by undue influence.

- The constitutional structure: CSOs should prepare to engage in advocacy, should the European treaties be reviewed. This would be an important opportunity to push for health to be given a stronger place in EU policy-making, and thus re-framing it as a priority within the Better Regulation agenda.

- The civic space: CSOs should continue to advocate, collectively, for an enabling environment for civil society participation to be fostered through a Civil Society Strategy that also addresses funding considerations, and a stronger civil dialogue built on the model of social dialogue at the EU level. This would provide structural engagement with the EU institutions and a framework for organising dialogue with civil society.

- Coalition-building: Crucially, in its advocacy on the Better Regulation agenda, civil society must work together, utilising networks such as the Better Regulation Watchdog and partnerships with wider academic and research institutions.

Annex

Annex 1 – EU4Health Civil Society Alliance campaign on sustainable financing

Box 1. EU4Health Civil Society Alliance advocacy on sustainable funding

EPHA and EU4Health publications related to sustainable funding for civil society organisations in health policy, chronology, building momentum on the issue of sustainable funding for civil society:

2021: As the funding mechanism was discontinued in the EU4Health Work Programme, the EU4Health Civil Society Alliance coordinated a letter to Commissioner Stella Kyriakides by 57 MEPs, highlighting the importance of operating grants for civil society organisations and calling the Commissioner to revise its position on operating grants.

2021: The letter was followed by a statement presenting the critical importance of operating grants for the functioning of civil society organisations, for developing their core work and activities.

September 2021: the letter was supported by a letter from then Slovenian Presidency to Commissioner Kyriakides calling for DG SANTE to recognise and support the critical role of civil society.

September 2022: Following the reinstalment of the operating grants for 2022, but with no guarantees for 2023, the Civil Society Alliance published a statement calling for the operating grants to be put on the 2023 programme.

December 2022: The EU4Health Civil Society Alliance published a position paper sharing recommendations for more meaningful engagement of civil society, including the provision of transparent, multiannual funding mechanisms, aligned across the different DGs to avoid discrepancies between sectors.

June 2023: In the build up to the European elections, the EU4Health Civil Society Alliance published a manifesto with 10 key priorities. The manifesto calls, among others, for the EU to ensure increased participation of CSOs in policy-making across health and other sectors through dedicated funding mechanisms.

June 2023: The Civil Society Alliance organised an event at the European Parliament hosted by MEP István Ujhelyi, to discuss the issue of sustainable funding for civil society across sectors.

June 2023: EPHA and the EU4Health Civil Society Alliance endorsed the Civil Society 4 EU manifesto, calling in particular for a Civil Society Strategy and adequate funding.

September 2023: a joint statement of the EU4Health Civil Society Alliance called for sustainable funding for civil society, and clearer and more coherent support from the European Commission.

November 2023: EPHA published its manifesto, including prioritising effective civil society participation in health policy-making through a Civil Society Strategy and sustainable funding opportunities.

(EPHA, 2023e)

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