World Health Organization

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A practical tool

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Foreword

Courtesy of Jérôme Salomon, Assistant Director-General

Noncommunicable diseases (NCDs) continue to place substantial demands on our societies and health systems. Effective and sustainable responses will require not only innovation but also collaborative approaches. When we delve into the complexities of NCDs and their many interconnected risk factors, it becomes evident that the public health sector alone cannot achieve Target 3.4 of the Sustainable Development Goals by 2030, which aims to reduce premature mortality from NCDs by one third and promote mental health and well-being.

Achieving this target requires closer and more effective collaboration with both government counterparts and non-State actors. The World Health Organization (WHO) recognizes the crucial role that multisectoral and multistakeholder engagements play in preventing and controlling NCDs, emphasized in the WHO's Global Action Plan for the Prevention and Control of NCDs, which has been extended to 2030. Civil society, academia, development partners, the private sector, communities, young people and those with lived experience all have a role to play. By leveraging their resources, expertise and networks, we can develop and implement comprehensive strategies and innovative solutions.

Unfortunately, many countries still find it challenging to build and sustain policy coherence across government sectors and to develop meaningful collaboration across many diverse stakeholders, including the private sector, to achieve public health goals. WHO hopes to contribute by developing robust tools and guidance to support governments in making informed decisions, including the Decision-making tool described in this document, which specifically addresses engagement with private sector entities.

How can we best harness the private sector's resources, expertise and networks without compromising our public health goals? For one, it is essential to implement transparent and informed decision-making processes aligned with core public health principles and NCD priorities, to conduct proper due diligence and to identify and manage risks. By doing so, Member States can enhance their decision-making capacity and unlock untapped opportunities while safeguarding public health from risks, including undue influence and conflicts of interest.

I extend my sincere appreciation to all those who contributed to the development of this practical tool and to those working tirelessly to meet the NCD goals and targets. It is through your dedication and collaborative spirit that we can envision a world free of the avoidable burden of NCDs, and attaining the highest standard of mental health and well-being for all.

Jérôme Salomon
Assistant Director-General

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Abbreviations and acronyms

COVID-19	Coronavirus disease 2019 (SARS-CoV-2)
DALY	Disability-adjusted life year
FCTC	Framework Convention on Tobacco Control
GCM	Global Coordination Mechanism
ICWG	Informal Consultative Working Group on the Prevention and Control of NCDs
LMIC	Low- and middle-income country
NCD	Noncommunicable disease
NGO	Nongovernmental organization
NSA	Non-State actor
SDG	Sustainable Development Goal
UN	United Nations
WHO	World Health Organization

Glossary

The following terms were developed and/or adapted for the purpose of this Decision-making tool.

Academic institutions are entities engaged in the pursuit and dissemination of knowledge through research, education and training [1]. In the context of this tool, academic institutions, their departments, institutes or academic staff serving in their institutional capacity, that are not independent (i.e. not "at arm's length") from the private sector, are considered to act as private sector entities; therefore, the guidance provided in this decision-making tool should also apply to them.

Conflict of interest arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of government's work in a given area) to unduly influence, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (protection of population health). The existence of conflict of interest does not mean that improper action has occurred, but rather that there is a risk of such improper action occurring. Conflicts of interest are not only financial, but can also take other forms.

Due diligence is an information-gathering process initiated and supervised by an appropriate public sector entity combining a review of information – provided by the private sector entity and taken from independent and reliable sources on the private sector entity – to find and verify relevant evidence on the private sector entity's nature and business conduct in order to reach a clear understanding of its profile. Due diligence should include screening of different sources of information guided by relevant rules and policies with explicit exclusionary criteria as a process of determining eligible and relevant partner attributes in order to identify potential opportunities for collaboration.

Health authorities are public health officials and/or government entities that are part of national or subnational governments and are responsible for developing, implementing and monitoring health policies and strategies and supporting and advising the government on health-related matters. The term may refer to ministries of health, secretaries of health, departments of health or equivalent, as well as to their respective subordinated agencies.

Industry interference refers to industry behaviours or practices that intentionally or unintentionally stop, delay or weaken the progress towards the achievement of national NCD goals and SDG target 3.4.[1] These behaviours or practices may include: undermining science and evidence; manipulating and unduly influencing public opinion, including through engagement of media (including social media, sponsorships and support of social, cultural, sports or charitable events or causes), often under the cover of "corporate social responsibility"; using new technologies, marketing methods and strategies and other means to circumvent NCD policies and regulations (e.g. by framing to promote individual responsibility at the expense of regulation of health-harming products); mobilizing political and public opinion against NCD policies and regulations, including through lobbying and creating front groups or artificially created grassroots organizations or movements; and intimidating governments and advocates, including through actual or threatened legal challenges, political pressure or attempts to corrupt public officials [2].

Meaningful and effective engagement is the desired end-result of a principles-based engagement with the private sector towards the achievement of evidence-informed national NCD goals and strategies set and led by the government in which the decision on engagement was informed by a systematic assessment and analysis, free from commercial influence, of the potential benefits and risks.

1 By 2030, reduce by one third premature mortality relative to 2015 from NCDs through prevention and treatment and promote mental health and well-being.

Nongovernmental organizations (NGOs) are non-profit entities that operate independently of governments and are free from concerns which are primarily of a private, commercial or profit-making nature. They are usually membership-based, with non-profit entities or individuals as members exercising voting rights in relation to the policies of the NGO, or are otherwise constituted with non-profit, public-interest goals. They could include, for instance, grassroots community organizations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups and patient groups [1]. In the context of this tool, NGOs that are not independent (i.e. not "at arm's length") from their private sector sponsors or parent entities are considered to act as private sector entities and therefore the guidance provided in this decision-making tool should also apply to them.

Non-State actors include NGOs, private sector entities, philanthropic foundations and academic institutions [1].

Policy coherence is a government-led approach that recognizes that alignment across all areas of public policy is important for the realization of health equity and well-being for all. This is done through systematic promotion of mutually reinforcing policies across government departments to create synergies towards achieving agreed objectives and to avoid or minimize negative spillovers in other policy areas. Policy coherence for health equity can mean increasing transparency and participation, introducing mandatory health assessments, changing the membership of key committees to represent health-focused interests, or staffing key bureaucracies with people engaged in the topic [3].

Philanthropic foundations are non-profit entities whose assets are provided by donors and whose income is spent on socially useful purposes. They shall be independent from any private sector entity in their governance, purpose and mission, decision-making [1] and investment interests. In the context of this tool, philanthropic foundations that do not satisfy the above-mentioned elements are not independent (i.e. not "at arm's length")[2] from their private sector sponsors. They are, therefore, considered to act as private sector entities and the guidance provided in this decision-making tool may also apply to them.

Private sector engagement is a results-oriented and principles-based approach that aims to engage the private sector in national NCD responses towards the attainment of SDG target 3.4 and the nine voluntary targets defined by the WHO Global Action Plan for the Prevention and Control of NCDs. It refers to the participation of the private sector, as appropriate, through different modes of interaction, involvement and collaboration, ranging from dialogues and consultations to more complex forms of engagement such as public–private partnerships.[3] In this sense, private sector engagement is considered a means to an end and the decision to engage and the type of engagement with the private sector should be rooted in a careful assessment and analysis, and a theory of change that establishes how the private sector is best placed to complement the actions of the public sector towards the achievement of national NCD goals. Private sector entities may also be engaged by governments in the course of a policy process, including for example in policy impact assessments and consultation processes. In such cases the engagement may be a procedural requirement rather than a decision, collaboration may not be appropriate, the same degree of assessment or analysis may not be possible, and the engagement may need to follow a prescribed process.

2 An entity is "at arm's length" from another entity if it is independent from the other entity, does not take instructions from the other entity and is clearly not influenced by, or is clearly not reasonably perceived to be influenced in its decisions and work by, the other entity [1].

3 This definition is deliberately broad in order to capture all modalities for engaging the private sector in development cooperation – from informal collaborations to more formalized partnerships.

Private sector entities refer in this document to all entities engaged in commercial activities and/or motivated by commercial interests – either their own or on behalf of others. The term also refers to entities that represent, or are governed or controlled by, private sector entities. This group includes (but is not limited to) business associations representing commercial enterprises, entities not "at arm's length" from their commercial sponsors, and partially or fully State-owned commercial enterprises acting like private sector entities. For the purpose of this tool, private sector entities include entities and organizations (of any form or structure) that are engaged in, and/or that have a financial interest in, a commercial enterprise at global, national, subnational or local level. These entities may be referred to as corporations, corporate actors, business sector, companies or enterprises – terms which are used interchangeably throughout this document. Such entities may include: multinational and transnational companies or corporate groups; domestic companies; micro, small and medium enterprises; business intermediaries and interlocutors (e.g. chambers of commerce, trade or business associations, alliances, business roundtables, stock exchanges, law firms, lobbying consultancy firms, public relations and communication companies); social enterprises (e.g. research and education institutions, health-care providers [4]); mutual organizations (e.g. asset management companies, cooperative banks, mutual saving banks, credit unions, mutual insurance/assurance and health insurance cooperatives) [5] and investors.

Risk assessment is a process whereby the appropriate public sector entity, when contemplating engagement with a prospective private sector entity, analyses the different engagement risks (and their likelihoods and impacts) associated with a specific opportunity for collaboration. A risk assessment on a proposed engagement is conducted simultaneously with and in addition to due diligence [1]. The effort and depth of the risk assessment depends on factors such as the profile of the prospective private sector entity, as determined during the due diligence process, as well as on the circumstances, timing and specific type and mode of engagement. Risk assessments should always be completed prior to the decision on engagement and before negotiations for collaboration are advanced. A risk assessment should also be considered where private sector stakeholders are engaged or consulted in the routine course of a policy process or to comply with procedural requirements. In such cases, collaboration may not be appropriate (e.g. with manufacturers of health-harming products that contribute to the risks of NCDs). However, conducting a risk assessment would prove beneficial in identifying potential risks and developing strategies to avoid and/or manage such risks through mitigation measures.

Risk management refers to a monitoring process that supports organizational decision-making at either the policy level or the implementation level, whereby the public sector analyses and monitors the risks and the effectiveness of mitigation measures put in place to address them.

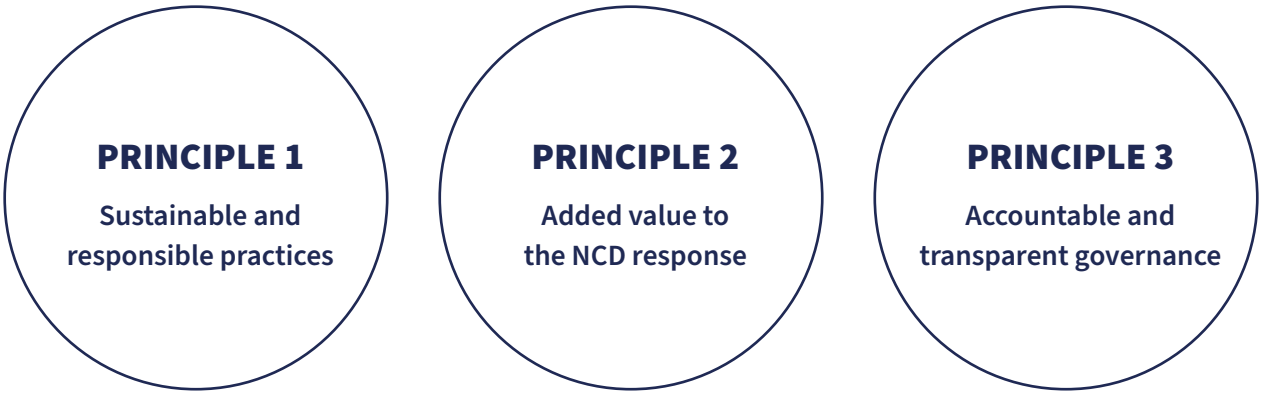
Executive summary

In 2015, Member States and the global health community committed to reduce premature mortality from noncommunicable diseases (NCDs) by one third by 2030 (SDG target 3.4). Despite growing efforts, the pace of change in most countries, and the policies and regulations required to achieve this goal, are too slow, inadequate or insufficient. Recognizing that public sector efforts alone are insufficient to address the prevention and control of NCDs, the Global NCD Action Plan emphasizes the need for coordinated multisectoral and multistakeholder engagement, acknowledging the role of nongovernmental organizations – including civil society groups, individuals with lived experience, academic institutions and private sector entities. However, WHO notes that some Member States still have limited or no capacity to establish or manage the implementation of engagement with private sector entities for the prevention and control of noncommunicable diseases.

Governments are advised to strengthen their capacity for engaging and collaborating with different stakeholders at national and subnational levels. This involves identifying opportunities where non-State actors, including the private sector entities, can contribute to strengthening national and subnational NCD responses.

WHO developed the Decision-making tool for the consideration of Member States in order to guide them through making informed decisions before engaging with private sector entities for the prevention and control of NCDs. This tool offers a systematic methodology for assessing, analysing and reaching a decision on whether or not to engage with private sector entities to complement or enhance efforts of the public sector in addressing the prevention and control of NCDs. The guidance provided in this document is expected to support Member States in analysing critical elements for decision-making when considering collaboration with private sector entities or where governments are required to engage with industry in the policy process for measures designed to prevent and control NCDs.

The Decision-making tool promotes a principles-based approach in engagements with private sector entities so that credibility, integrity and sound government processes are ensured and protected. This is intended to safeguard public health and their beneficiaries from any unintended adverse social, economic and environmental impacts arising from business practices, products or services. Health authorities are recommended to consider the following three core principles that guide engagements with private sector entities:



These three principles are interrelated, mutually reinforcing and indivisible and should establish the foundation of the relationship between the public and private sectors. The principles are operationalized in the various steps of the Decision-making tool.

The tool was designed to be practical and applicable across diverse contexts and scenarios, and throughout the various phases of an engagement cycle (i.e. planning, implementation, monitoring and evaluation). The process consists of three phases, comprising a total of 10 steps that aim to guide users to reach informed decisions on engagement with private sector entities. Each step contains a set of questions presented in a sequential and comprehensive manner.

Although reaching a decision is rarely a linear process, this tool outlines three phases and 10 steps that take a sequential approach. This structure is designed to facilitate reaching a decision centred on public health goals and good governance principles, taking into consideration the identification of gaps, strengths, risks and opportunities for meaningful engagements. Such structure supports health authorities in building understanding of the potential benefits and risks associated with the engagement and the required capacities for engaging with private sector entities. This understanding will enable health authorities to reach informed decisions by stating the expected benefits and anticipating the associated risks of the engagement.

PHASE I

Assess

It means how users assess the need to consider engagement with private sector entities as a potential viable course of action to support national NCD responses. This phase includes:

- **Step 1**: Defining the NCD challenges and context-specific pressing factors
- **Step 2**: Identifying the purpose of the engagement
- **Step 3**: Mapping potential private sector entities

PHASE II

Analyse

It describes the phase during which users analyse a specific engagement opportunity with an identified private sector entity. This phase includes:

- **Step 4**: Selecting the most appropriate type of engagement
- **Step 5**: Assessing the local environment for engagement.

PHASE III

Decide

It is the phase where users utilize the information gathered and analysed in phases 1 and 2 to reach a conscious and explicit decision on whether to proceed, or not, with the engagement opportunity. This phase includes:

- **Step 6**: Conducting due diligence and risk assessment on the prospective private sector entity
- **Step 7**: Assessing potential risks related to the engagement
- **Step 8**: Developing risk mitigation strategies.
- **Step 9**: Developing a risk management plan
- **Step 10**: Deciding on proceeding or declining the engagement.

For potential new engagements, the tool should help generate, after applying the 10 steps, one of two possible decision scenarios:

- **Engagement with a private sector entity**. This includes situations in which the expected contributions from the private sector entity to national NCD responses outweigh the risks, the risk mitigation actions are in place, and the engagement generates an estimated net benefit that warrants government consideration. It also applies when the engagement is transactional in nature (e.g. consultation or policy implementation) and/or a procedural requirement by the government. It requires a well-resourced risk management plan to ensure adequate monitoring throughout the duration of the engagement, including adjusting the terms and conditions of the engagement to manage identified risks.

- **No engagement with a private sector entity**. This includes situations in which the risks of engagement outweigh the potential benefits and the risks have a negative impact on public health, even with a risk management plan in place. In such circumstances, it is not advisable to proceed with the engagement. In this case, the reasons for not engaging should be documented and actionable recommendations should be provided to strengthen national capacity to mitigate risks associated with similar engagements in the future.

If the tool is used to monitor or evaluate existing engagements with private sector entities, decision-makers may have two possible options:

- **Continue engagement with a private sector entity**. This includes situations in which the private sector actor respects the terms and conditions of the engagement, including the three core principles, and the engagement makes definite contributions towards achieving the NCD goals set by the government. The decision to continue an engagement should be supported by effective risk mitigation and monitoring, including assessment of any new critical or high risks that may have arisen since the engagement began.

- **Disengagement from the private sector entity**. This includes situations in which the private sector actor fails to deliver on its commitments and/or compromises the public health objectives, or when the three core principles of engagement are not upheld. Terminating an ongoing engagement may also be necessary in cases when the initial risk assessment did not accurately reflect the level of risk exposure, or the mitigation strategies have proved to be ineffective in reducing the government's exposure to risks. The reasons for disengaging should be documented and actionable recommendations should be provided to strengthen national capacity to mitigate risks associated with similar engagements in the future.

The decisions derived from the application of this tool will depend on the quality (e.g. relevance, specificity, comprehensiveness and accuracy) of the information collected and analysed. It is not advisable that a single individual in the Ministry of Health applies the tool in isolation. Rather, health authorities may consider this tool as a catalytic approach to inducing interdepartmental dialogue and collaboration across government sectors. A government may also opt to engage NGOs and academic institutions as complementary players to assist in the implementation of the decision-making tool.

In light of limited domestic budgets for combating NCDs, insufficient or over-utilized public-sector infrastructure and competing global health priorities, governments, particularly in LMICs, are under pressure to address their growing NCD burden effectively. Collaboration with non-State actors, including private sector entities, in support of NCD responses cannot be overlooked. Countries must prioritize informed decision-making processes that focus on population health and equity over private and commercial interests. This tool guides governments in strengthening and scaling up their internal processes and reaching informed decisions on engagement opportunities with private sector entities.

Introduction

Noncommunicable diseases (NCDs) are the world's biggest killers. In 2019 alone, NCDs caused over 41 million deaths, accounting for 74% of all deaths globally. In the same year, 17 million people aged between 30 and 69 years died from an NCD, with 86% of those "premature" deaths occurring in low- and middle-income countries (LMICs) [6, 7]. However, resources to support the prevention and control of NCDs in LMICs remain disproportionally low with an estimated need of an additional US$18 billion every year in new spending to meet global targets and only 2% of total global development assistance for health currently being directed to NCD country programmes [8, 9, 10].

The WHO Global Action Plan for the Prevention and Control of NCDs 2013–2030 [11, 12] provides a framework for Member States to take immediate action to reduce premature mortality from NCDs by one third and to achieve the sustainable development goal (SDG) target 3.4[4] by 2030. However, WHO's latest World health statistics and NCD progress monitor reports confirms that the pace of change in most countries is too slow to attain this goal [7] with insufficient implementation of WHO "best buys",[5] including those that focus on government regulation of advertisement, taxation and restricting access to unhealthy products [13]. Reinvigorating approaches and guidance on coordinated responses need to be put in place urgently to influence public policies in sectors beyond health and to equip health systems to respond more effectively and equitably for the prevention, treatment and care of NCDs.

The Global NCD Action Plan emphasizes that an effective response to the prevention and control of NCDs requires coordinated multisectoral and multistakeholder engagement across sectors and with relevant non-State actors, including civil society, people with lived experience, academia and the private sector. This has been consistently recognized and highlighted by Member States in their high-level political declarations on NCDs, whereby the private sector has been requested to strengthen its commitment and contribution to the implementation of national responses on NCDs [14, 15, 16]. The specific requested commitments and contributions include promotion and creation of safe and healthy working environments, reduction of the harmful use of alcohol, elimination of marketing, advertising and sale of alcohol products to minors, producing and promoting food products consistent with a healthy diet, reduction of the exposure of children to the marketing of food and beverages high in fats (particularly saturated fats and trans-fats), sugars or salt, and improvement of access to and affordability of safe, effective and quality medicines and technologies.

Public sector efforts alone will be insufficient to reduce premature mortality by one third by 2030. Governments are recommended to strengthen their capacity for multisectoral and multistakeholder collaboration at national and subnational levels by identifying opportunities where non-State actors, including the private sector, can contribute to strengthening the national NCD response.

Despite ongoing efforts to establish greater collaboration across whole-of-government (multisectoral) and whole-of-society (multistakeholder) approaches, WHO notes that some Member States have limited or no capacity to establish or manage engagements with non-State actors, including in multistakeholder initiatives [17]. This includes the capacity to find common ground between policy-makers and private sector entities, which may hinder the implementation of WHO "best buys" and other recommended interventions.

4 SDG target 3.4: Reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being.

5 Effective interventions with cost-effectiveness analysis (CEA) ≤ I$ 100 per DALY averted in LMICs. Examples include: increase excise taxes on health-harming products such as tobacco and alcoholic beverages; enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising; and reduce salt intake through the implementation of front-of-pack labelling. The full list of WHO "Best Buys" is included under Appendix 3 of the WHO Action Plan for the Prevention and Control of NCDs 2013–2020.

Collaboration between governments and private sector entities for the prevention and control of NCDs remains challenging in practice, generally due to conflicts of interest, the commercial determinants of health and the fact that no engagement is risk-free.

It is important to acknowledge and address the challenges regarding engagement with private sector entities in NCDs (Box 1). These challenges can emerge in different circumstances such as when the contribution of private sector entities whose goods and services negatively affect human health and the burden of NCDs (e.g. tobacco, alcohol and/or processed foods and beverages that are often high in unhealthy fats, added sugars and/or salt). It can also result from the negative impact of industry practices and processes on the social determinants of health – be it in relation to employment practices, environmental degradation [18], tax avoidance or other factors.

On the other hand, private sector entities can make important contributions by filling important gaps (e.g. expertise, infrastructure, efficiency, data and analytics, innovations such as bringing to market essential and innovative medicines and other health technologies for the secondary prevention, treatment and care of NCDs [19].

BOX 1

Impact of corporations on health: the commercial determinants of health

The commercial determinants of health are key social determinants, and refer to the conditions, actions and omissions that affect health. Commercial determinants arise in the context of the provision of goods or services for payment and include commercial activities as well as the environment in which commerce takes place. Commercial determinants can have beneficial and/or detrimental impacts on health [20]. Commercial determinants are, therefore, considered to be the commercial dimension of the social determinants of health and comprise behaviours of and actions taken by commercial actors that cut across industries and health impacts, as well as the pathways and structures that incentivize and regulate these behaviours and actions [21].

The guidance provided in this document aims to assist Member States in analysing critical elements of engagement with private sector entities to enable them to reach informed decisions when considering collaboration with private sector entities for the prevention and control of NCDs, or where governments are required to engage with industry in the policy process for measures designed to prevent and control NCDs. The tool builds on and complements related WHO guidance on this topic [22, 23, 24, 25, 26, 27, 28, 29]. It also responds to the Member States' decision at the 74th session of the World Health Assembly in 2021 that requested the GCM/NCDs *"to provide updated guidance to Member States on engagement with non-State actors, including on the prevention and management of potential risks"* [30]. In addition, the tool addresses a specific recommendation outlined in the final report of WHO's High-level Commission on NCDs "It's Time to Walk the Talk" [31], whereby WHO was asked to provide technical support to Member States to increase the capacity needed for engagements with private sector entities to support national NCD responses.

Governments may adopt different approaches to the use of this tool. It is envisioned that the NCD-related departments in ministries of health will initiate and lead the assessment and analysis of critical elements related to private sector engagement in order to inform decision-making. One possible approach involves establishing a working group or task team comprising relevant departments across the Ministry of Health and other government sectors. The working group or task team could collaboratively undertake the assessment and analysis process or serve in a consultative capacity, providing recommendations on the basis of their collective insights. Additionally, governments may wish to seek the views of nongovernmental organizations (NGOs), people with lived experience and academic institutions.

Purpose

This tool aims primarily to assist WHO Member States in reaching informed decisions about whether to engage with the private sector for the prevention and control of NCDs.

Specifically, the tool proposes a systematic methodology to:

- **assess** the need and local capacity for considering engagement with private sector entities to address NCD challenges;
- **analyse** specific opportunities of engagement and conduct rigorous due diligence and risk assessment processes to support this approach, including the development of risk mitigation strategies;
- **decide** on the direction of the engagement based on estimated benefits and assessed risks.

When used appropriately, the decision-making tool aims to support the strengthening of public sector capacity for making informed decisions regarding engagements with private sector entities and advancing the implementation of NCD prevention and control measures, while taking steps to protect public health policies from any undue influence.

WHO also has its own framework to ensure that its engagement with private sector entities and others is in line with the Organization's policies and principles (Box 2).

BOX 2

WHO's Framework for Engagement with non-State actors

WHO's engagement with private sector entities is governed by the Framework for Engagement with non-State actors (FENSA) [1]. The Framework is an enabling policy that provides a set of key principles and guidance to strengthen and enhance WHO's engagement with non-State actors while reinforcing WHO's management of the potential risks related to these engagements. It guides the Organization in balancing the risks against the expected benefits, ensuring that a level playing field applies when engaging with non-State actors while at the same time protecting and preserving WHO's integrity, reputation, public health mandate and work.

User guide

The intended users of the tool are health authorities particularly those responsible for developing and implementing national and/or subnational NCD strategies, plans or programmes. Other government agencies from other sectors – such as economics, finance, trade, agriculture and education – that play an important role in the prevention and control of NCDs are strongly encouraged to consider the guidance provided in this document as governments seek policy coherence in applying multisectoral or multistakeholder approaches to sustainable development.

The creation of the Decision-making tool followed a co-design and co-development approach. This consisted of a literature review, a working group involving WHO headquarters and regional and country offices, in-country workshops, and broad engagement of external stakeholders, including NGOs and experts serving in their institutional capacity representing academic and research institutions. See Web Annex A for more details on the methodology.

The tool was designed to be applicable in different contexts across WHO Member States and throughout the various phases of an engagement cycle (i.e. planning, implementation, monitoring and evaluation). It proposes a three-phased approach, comprising 10 steps that guide users towards making informed decisions on private sector engagement. Each step contains a set of questions presented in a sequential manner. To address the diversity and specificity of these questions effectively, it is advisable to engage different interlocutors or departments within the health sector. See Web Annex B for a non-exhaustive list of guiding questions.

Ideally, this tool should be utilized by a group or committee composed of individuals from different areas of expertise and domains (e.g. NCD-related areas, policy and planning, procurement, legal, regulatory, partnerships etc). In cases where information is not readily available, users may wish to conduct focus groups or key informant interviews to obtain relevant information. Health authorities may also consider seeking the views of relevant NGOs, persons with lived experience and academic institutions with appropriate expertise to support the advancement of implementation of the tool.

Policy-making is rarely a linear process [32], and neither is decision-making. However, the steps outlined in this tool follow a linear approach to facilitate reaching a decision centred on public health goals and good governance principles, taking into consideration the identification of gaps, limitations, strengths, risks and opportunities for meaningful engagements.

If used in the planning phase of the engagement cycle, the tool proposes a methodology to support a decision-making process regarding a potential engagement with a private sector entity. However, it can also be used to review existing or ongoing engagements with private sector entities. In cases where engagements with the private sector might be compulsory or necessary as part of the policy implementation process (e.g. public consultation on a draft regulation), some of the steps outlined in this tool may need to be adjusted and a separate prescribed process may need to be followed. Nevertheless, the tool may assist health authorities in identifying risks and developing appropriate mitigation measures for such type of engagement.

Principles guiding private sector engagement

Planned engagements for mutual benefit between public and private actors involve common understanding, agreement and genuine commitment to achieving public health goals while recognizing that the interests of both parties must be met in order for there to be effective and sustainable engagement [33]. It is important also to recognize that some private sector entities may be able to contribute to public health objectives by providing resources (financial and non-financial) and by supporting innovation and efficiency to address societal needs. For this to happen, collaboration with the business sector in government-led activities needs to respect the mandate, duties and leadership role of the public sector and should be anchored in core principles that support health equity and public health. A principles-based approach and its operationalization is therefore necessary to ensure and protect the credibility, integrity, soundness and sustainability of the government process. This is intended to safeguard engagements and their end-beneficiaries from any unintended adverse social, economic and environmental impacts of business practices, products or services.

This tool proposes three core principles to guide engagements with private sector entities: 1) sustainable and responsible practices; 2) added value to the NCD response; and 3) accountable and transparent governance. These principles are interrelated, mutually reinforcing and indivisible in nature and should establish the foundation of the relationship between the public and private sectors.

In this tool, the three principles are operationalized across various steps, including in the selection of the private sector entity and when conducting due diligence and risk assessment. Adherence to these steps should be monitored throughout the entire life cycle of engagements.

Principle 1: Sustainable and responsible practices

Private sector entities ought to operate according to a value system whereby economic returns are achieved through the development of sustainable products and services backed by responsible business practices. This should avoid negative social, health, economic and environmental impacts, should address those that may occur, and should cooperate in remedying them through legitimate processes.

Main elements of the principle:

- To be suitable for engagement, a private sector entity is expected to comply with a set of mandatory requirements which are to be defined in advance by the government and communicated to potential partners. These mandatory attributes should reflect, at the minimum, demonstration of corporate behaviours that respect, as recognized in international treaties and standards: 1) human rights, including labour rights and the right of all people to the highest standard of health; 2) the environment; and 3) economic rights, good corporate governance and anti-corruption compliance.[6]

6 These are formulated in core international human rights treaties, relevant conventions and universally accepted standards. Examples include: the Universal Declaration of Human Rights (1948) and the core international human rights treaties, the WHO Framework Convention on Tobacco Control (2003), the International Labour Organization's Declaration on Fundamental Principles and Rights at Work (1998), the Rio Declaration on Environment and Development (1992), and the United Nations Convention against Corruption (2004).

- The government's engagements with private sector entities that are focused on the prevention and control of NCDs must be protected from any form of undue influence by corporate actors – such as misleading information, marketing strategies and activities under the cover of "corporate social responsibility",[7] and other strategies that undermine science and the evidence-based approach, subvert public-sector health policies, and harm public health objectives and outcomes [2].

- The government may need to establish exclusionary criteria in advance of engaging with entities. These criteria should require adherence to the above elements in order to screen out ineligible private sector entities. The exclusionary criteria should focus on identified areas that would disqualify entities from any engagement with the government.

Application of the principles by each party:

- **Public sector (whole-of government)**

    - Governments have the duty to protect individuals in their jurisdiction from the negative social, health, economic and environmental impacts that third parties, including private sector entities, can cause in accordance with their national constitutions and applicable international law. Governments are, therefore, expected to:

        – ensure policy coherence across government sectors to avoid or minimize negative spillovers in other areas;

        – conduct due diligence of the private sector entity and risk assessment on the prospective engagement throughout the life cycle of the engagement; and

        – decline or terminate any type of engagement with a private sector entity operating in ways that do not honour the basic responsibilities, as set out in the applicable laws and/or mandatory requirements under the terms of the engagement.

- **Private sector entities**

    - Private sector entities have the responsibility, as set out in relevant and applicable national laws and/or mandatory requirements for engagement, to respect a set of rules and principles that may include human rights, including labour rights, environmental standards, and compliance with good corporate governance and anti-corruption practices. Private sector entities are expected to avoid infringing those fundamental responsibilities and should prevent, mitigate and address negative impacts if they occur, whether directly or indirectly through their supply chains. Private sector entities are also expected to respect relevant national and international standards (e.g. the UN Guiding Principles on Business and Human Rights [42] and others [43, 44]).

    - Private sector entities should treat the above responsibilities as minimum standards. They are also required not to undermine but to strengthen their commitments and contributions to public health – as encouraged in the WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020 [11], which has been extended to 2030, and successive political declarations of the high-level meetings of the UN General Assembly on the prevention and control of NCDs [14, 16] – to develop and implement corporate practices that are consistent with relevant national and international strategies and guidelines.

7 For example, guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) recommend denormalization of activities described as "socially responsible" by the tobacco industry. In addition, the Guidelines for implementation of Article 13 of the WHO FCTC recommend banning contributions from tobacco companies to any other entity for "socially responsible causes", as this is a form of sponsorship.

Principle 2: Added value to the NCD response

Engagements with private sector entities must be principles-based, results-oriented and informed by national and international evidence, as relevant to the NCD agenda. Such engagements should be driven by shared common goals towards achieving SDG target 3.4 and the nine voluntary targets of the Global Action Plan [11], ensuring a collaborative environment for the advancement of national NCD goals, policies and strategies.[8] As far as possible, the engagement should seek to support responses that promote health equity, recognizing that certain populations are at greater risk of NCDs and certain populations are less likely to have access to affordable NCD prevention, treatment and care.

Main elements of the principle:

- The engagement should be based on recognition of the mandate, duties and leadership role of the public health authorities and the need to respect and protect their integrity, impartiality and independence in exercising their functions of developing, monitoring and evaluating NCD goals, policies and strategies in accordance with scientific and evidence-based approaches.

- The principle builds on a rationale whereby there is convergence of aims, synergies of expertise and complementarity of roles by both parties, translated into an expected public health benefit from the engagement.

- The engagement must be established on a non-exclusive and non-endorsement basis. The engagement should not provide, under any circumstances, unfair advantages and/or competitive advantage to private sector entities that undermine public health, NCD goals, policies and strategies, or that disrupt fair competition or conflict with local public procurement rules and regulations.

- The engagement entails expressed commitments by health authorities and the prospective private sector entities to deliver on their set targets through appropriate means, competencies, skills and capacity.

Application of the principles by each party:

- **Public sector (whole-of-government)**

    - Governments have the duty to protect the health of their populations. Governments are also expected – as appropriate and subject to national laws and international treaties to which they are party – to ensure policy coherence across different government sectors and to guarantee that engagements with different stakeholders, including private sector entities, do not conflict with or compromise public health, NCD goals, policies and strategies over the short, medium or long term.

- **Public sector (health authorities)**

    - Health authorities are expected to exercise and protect their mandate, duties and leadership role in:

        – developing, implementing, monitoring and reviewing NCD goals, policies and strategies in accordance with a scientific and evidence-based approach;

8 Such as adopting evidence-based "best buys" and other recommended interventions for the prevention and control of NCDs included under Appendix 3 of the WHO Action Plan for the Prevention and Control of NCDs 2013–2020.

- estimating the expected public health net benefit from the engagement in preventing and managing NCDs;
- monitoring the effects of the engagement in the attainment of NCD goals and implementation of NCD policies and strategies;
- informing and, as appropriate, guiding other government sectors in incorporating public health considerations when engaging with the private sector; and
- taking measures to identify, avoid and manage or mitigate conflicts of interest and prevent the interference of private sector entities in public health policy development.

- **Private sector entities**
  - Private sector entities are expected to act according to the terms of engagement with governments and health authorities in order to meet the targeted NCD results. They must not interfere with the health authorities' integrity, impartiality and independence in exercising their functions of developing, monitoring and evaluating NCD goals, norms, policies and strategies. Private sector entities should contribute to achieving and implementing these goals, norms, policies and strategies, as appropriate.
  - Private sector entities are encouraged to increase their positive health impact, and to reduce, prevent and mitigate the negative health impact arising from their products, services and/or practices, as well as to promote the knowledge and application of global health norms and standards.

Principle 3: Accountable and transparent governance

Any engagement should be anchored in an accountability framework that is defined in advance by the government. The framework should apply to all partners and should allow full transparency in the scope, roles, responsibilities, timelines, contributions and measurable outputs relating to public health, NCD goals, policies and strategies.

Main elements of the principle:

- All engagements must identify a specific NCD goal, including the scope of the engagement, the roles and responsibilities of the parties, activities, timelines, measurable outputs and measures to prevent and manage real, potential or perceived conflicts of interest in order to agree on the most appropriate form of agreement.
- Respect for the decision-making authority of the government and the health authorities, common understanding, trust and transparent dialogue must be maintained through all phases of the engagement, irrespective of the scope of operations of the private sector entity. Mutual respect for each other's mandates, obligations, independence and integrity should be considered by all parties when engaging in constructive disagreement, if necessary, under a risk mitigation protocol.

Application of the principles by each party:

- **Public sector (whole-of-government)**
    - Governments are expected to disclose information to the public, as and when appropriate, and to promote transparency on engagements with private sector entities.
- **Public sector (health authorities)**
    - Health authorities are expected to maintain their prerogative to decide on the engagement and its direction. A health authority may also exercise its right to terminate the engagement if it does not, for instance, deliver on its promises or if any of the core principles are not upheld by the private sector entity[9] or if public health objectives are compromised.
    - Health authorities are expected to respect the terms of engagement (including the corresponding legislative, executive, administrative and related measures), honour their commitments and carry out collaboration based on fair and equitable standards and the agreed accountability framework.
- **Private sector entities**
    - Private sector entities are expected to respect the decision-making authority of the government and/or health authorities and to conform to the terms of engagement, including – and in line with applicable legislative, executive, administrative and/or other related measures – to honour their commitments and carry out collaboration on the basis of the agreed accountability framework.
    - Private sector entities are further expected to ensure compliance with the terms of engagement among their employees and collaborators. This includes adopting and implementing policies and good practices on compliance with the terms of the engagement (e.g. capacity development, internal communication campaigns) to make sure that the engagement is integrated at the level of the private sector entity and its workforce.

9 In accordance with the policy coherence approach underlined in Principle 2 (added value to the NCD response), it is expected that alignment will be reached on this matter across different sectors of the government.

Phased approach: Assess – Analyse – Decide

Reaching a decision on whether, at what stage and on what terms to enter into an engagement with a private sector entity should be based on a systematic assessment and analysis of critical aspects of the potential engagement using the best available information. The tool offers a methodology for evidence-informed decision-making, following a three-phase process (Figure 1).

PHASE I

Assess

It means how users assess the need to consider private sector engagement as a potential viable course of action to support national NCD responses. It is in this assessment phase that the potential objectives and purpose of a potential engagement are characterized, potential private sector actors are identified and categorized, and the most appropriate mechanism (or type of engagement) is identified for mobilizing the identified resources needed from the private sector actor. Phase I is complemented with an assessment of the public sector current capacity to manage engagements with the private sector.

PHASE II

Analyse

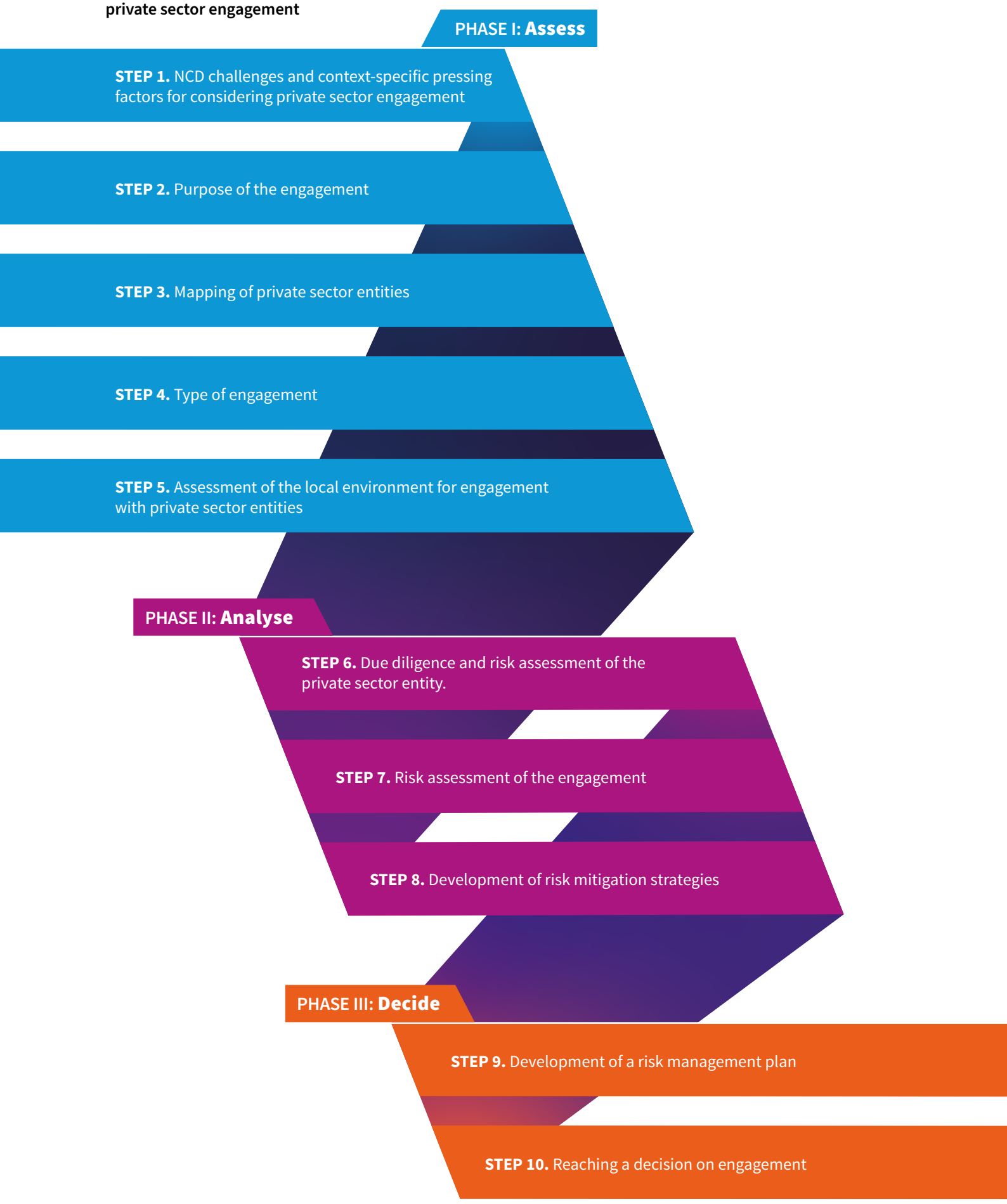
It describes the phase during which users analyse a specific engagement opportunity with an identified private sector actor. In this phase, users analyse whether the prospective private sector collaborator meets the criteria to be considered a legitimate stakeholder through a due diligence process, including assessment against exclusion criteria. The analysis phase also includes assessing which risks, including their likelihood, impact and possible mitigation strategies, are associated with the specific engagement opportunity.

PHASE III

Decide

It is the phase where users utilize the information gathered and analysed in phases I and II to make a conscious – and reach an explicit – decision on whether to proceed, or not, with the engagement opportunity.

Figure 1. Phased approach for an informed decision-making process on private sector engagement



PHASE 1

Assess

The purpose of Phase I is to assist health authorities in assessing the need for considering private sector engagement to address their specific NCD challenges. This includes understanding the local NCD context and identifying the purpose and the potential contributions of the private sector. This phase also guides the selection of the most appropriate type of engagement, mapping of potential private sector entities and assessment of the public sector's capacity to engage with the private sector.

STEP 1

NCD challenges and context-specific pressing factors for considering private sector engagement

Identifying the challenges and the necessary actions for achieving the NCD goals is critical to the success of collaboration [45, 46]. A first step is to understand what the urgent issues are and to assess where the private sector can complement public health efforts to achieve NCD goals. To do this, governments need to gather evidence, not only on the impact and burden of NCD risk factors and diseases across different population subgroups, but also on the bottlenecks that hinder progress towards the NCD goals (Box 3). There is a need to understand factors such as the political commitment, the influence (or interference) of commercial forces in public health goals, the gaps in financing and service delivery when scaling up responses, and the extent of collaboration with other non-health sectors [47]. This first assessment is necessary before considering engagement with private sector entities.

BOX 3

Examples of WHO resources for assessing the context related to the prevention and control of NCDs

- NCD Progress Monitor [13].
- NCD Country Capacity Survey [48].
- STEPwise Approach to NCD Risk Factor Surveillance (STEPS) [49].
- Global Adult Tobacco Survey (GATS) [50].
- Guidance for NCD investment cases [51] (or national NCD investment cases, if available).
- Legal Environment Assessment for the Prevention of NCDs [52].

WHO Member States, particularly LMICs, are lagging behind in the achievement of SDG target 3.4 despite the existence of a comprehensive package of cost-effective interventions (Box 4). This is in part due to opposition from vested interest groups and limited capacity – including in policy implementation and advanced technical expertise – for building and managing multisectoral and multistakeholder collaborations for NCD prevention and control [17].

BOX 4

Examples of WHO technical packages for the prevention and control of NCDs

- Very cost-effective and affordable interventions for all Member States (previously referred as the "best buys") for the prevention and control of NCDs (Appendix 3 of Global NCD Action Plan 2013–2030) [53].
- Package of Essential Noncommunicable (PEN) disease interventions for primary health care [54].
- SHAKE technical package (salt reduction) [55].
- SAFER technical package (reduction in harmful use of alcohol) [56].
- REPLACE technical package (elimination of industrially-produced trans-fatty acids) [57].
- MPOWER measures (reduction in demand for tobacco) [58].
- HEARTS technical package (cardiovascular disease management in primary health care) [59].
- ACTIVE technical package (increased physical activity) [60].

Member States are expected to have a clear understanding of their national situation with regard to the prevention and control of NCDs [11], as this will help define their NCD targets and identify barriers that could be addressed through targeted, well-managed engagements with private sector entities.

Any potential engagement with the private sector must be aligned with the country's specific needs for an effective NCD response and must be clearly articulated as to why the NCD goals cannot be achieved with government resources alone. This involves identifying priorities and capacity gaps, and policies relevant to engaging with the private sector both within and outside the health sector. Developing a theory of change by outlining the assumptions, conditions and connections between activities and outcomes to achieve the intended NCD goals could provide initial insights into potential benefits of private sector engagement in addressing country-specific NCD challenges.

STEP 2

Purpose of the engagement

The purpose for engaging with the private sector for the prevention and control of NCDs can vary based on specific NCD challenges, identified priorities and the resources required to achieve the intended public sector goals. The underlying assumption is that the private sector entity can, under certain conditions, bring potential contributions to the public sector for the NCD responses through its expertise, resources and innovative approaches. The engagement would therefore support public sector-led activities that would be unlikely to have the desired impact with the government's resources alone (see Table 1). Additionally, Box 5 gives details of WHO's Country Connector on the Private Sector in Health which aims to promote a whole-of-health-system approach entities.

Table 1. Examples of potential contributions from private sector entities to government-led activities according to the purpose of the engagement

	Purpose of engagement	Potential contributions of the private sector entities
Financing	• Mobilize private capital flows for NCD programmes or initiatives through various financial instruments • Leverage health financing tools such as strategic purchasing to improve the performance of the private sector vis-à-vis NCD service delivery [61]	• Mobilization of funding and of private investors' interest in needed NCD interventions • Alignment of private health providers' financial incentives with government goals (e.g. on delivery of primary prevention interventions)
Service delivery	• Maximize the impact of health-service delivery to deliver effective, affordable, safe and quality care to those who need it most, including poor and marginalized populations, when needed [4, 62] (see Box 5)	• Capacity and resources to innovate end-to-end delivery systems, addressing capacity gaps through task-shifting, clinical decision support and digital technologies • Training of health professionals, knowledge transfer, data and evidence generation • Increased availability of affordable, quality health services, particularly for groups that have been made socially and economically vulnerable to achieve equity and equality in the delivery of NCD services
Affordability and access to medicines and health technologies	Development, expansion or improvement of access to safe, effective and quality medicines and health technologies	• Capacity and expertise on supply chain management to improve access to medicines and health technologies • Facilitation of technology transfer and optimization [63] • Accelerated adoption of best practices and specific standards for the private sector, including basic requirements for warranty and maintenance contracts • Adoption of sustainable business practices that promote equitable access to innovative medicines

	Purpose of engagement	Potential contributions of the private sector entities
Product development	• Support and encouragement of research and development (R&D) of products or services to address unmet NCD needs through mechanisms of collaboration [64]	• Expertise in conducting R&D to accelerate innovation and maximize capacity within the private sector to address NCD goals • Capacity to innovate and develop market-based solutions of socially responsible and health-promoting products, services and technologies
Product reformulation	• Reformulation of existing products or services, where possible, to be consistent with scientific evidence and national and international guidelines for promoting good health and well-being and the prevention of NCDs	• Availability of, and access to, services and products that are aligned with public health guidelines and that influence behavioural change towards healthier lifestyles • Capacity to innovate and develop market-based solutions of socially responsible and health-promoting products, services and technologies, where possible
Knowledge and information-sharing	• Generation of scientific information and knowledge on NCDs and related areas • Promotion, development or implementation of learning-oriented interactions to identify and exchange science-based information, experiences and best practices • Promotion, development or implementation of policies or programmes to generate their adoption and behavioural change	• Access to real-world data and information that is relevant for planning and surveillance of NCD interventions • Promotion and dissemination of evidence-based information to accelerate adoption of best practices and specific standards by the business sector • Capacity to develop, adopt and/or scale up innovation and knowledge in line with public health standards and guidelines
Health literacy	• Dissemination of evidence-based public health messages and prevention of misinformation; support the development of public health campaigns by engaging with communities using different media and evidence-based approaches to generate, raise or enhance public awareness on policies and regulations, health behaviours or practices for the prevention and control of NCDs	• Scale up evidence-based public health messages that motivate and do not mislead the target audience towards actions, encourage behavioural change that leads to healthier lifestyles, and increase access to, and use of, services and products through diverse media channels and outlets that reach a wider audience and hard-to-reach groups [65]

Note: This table is not an exhaustive list. It aims to support governments in the process of identifying complementary resources from private sector entities to complement public sector actions. The categories presented are adapted from the identified areas of private sector contribution towards accelerating the global response to address NCDs, as outlined in the third High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases.[10]

Note to users

- While the private sector might be consulted during the information-gathering phase to assess the feasibility of different policy measures, it is important to emphasize that policy-making remains the sole responsibility of the government. Private sector entities, including other entities not at arm's length from private sector sponsors, should refrain from developing public policies and providing inputs into the government's decision-making processes.

10 Paragraphs 16, 30, 43, 44 and 46 of the political declaration of the third High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases [16].

BOX 5

Governance of mixed health-care systems: the WHO Country Connector on the Private Sector in Health

Convened by WHO, the country connector is an online platform designed for Member States that aims to promote a whole-of-health-system approach to health systems strengthening and align the work of the public and private sectors with the common objectives of universal health coverage, collective health security and system resilience. The country connector's website [66] offers resources that can complement the Decision-making tool during the Assess, Analyse and Decide phases. Some examples include:

- Engagement Factors Self-Assessment Tool and Engagement Factors Progression Model.
- Country Readiness Diagnostic for Public-Private Partnership.
- Resources on Private Sector Engagement in Health.
- Guidebook on Public–Private Partnership in Hospital Management.

Source: WHO Country Connector [66]

STEP 3

Mapping of private sector entities

Once the need, purpose and potential contributions of private sector entities are identified, the next step is to map the landscape of private sector entities that could potentially contribute to the achievement of specific NCD goals. This is a crucial step because it helps not only to identify stakeholders who add value and complement government efforts, but also ensures and protects the credibility and integrity of the potential collaboration.

Evidence indicates that a lack of stakeholder alignment regarding the principles, aims and expectations of a potential engagement is the leading cause of unsuccessful collaboration between the public and private sectors [67]. Mapping private sector entities helps to initiate the profiling of entities and pre-selection of those that might be able to bring their unique expertise and resources to address specific challenges in preventing and controlling NCDs. In this step, two dimensions are considered to identify and initially assess the private sector entities: (i) their added value to government-led NCD responses, and (ii) their alignment with public health and NCD goals.

The added value refers to the complementary resources (financial or non-financial) that adequately support health authorities in overcoming the identified challenge. The alignment refers to the nature of the work and the practice and behaviours of private sector entities in relation to public health and NCD goals. See Web Annex B (Phase I, step 3) for examples of questions to guide the mapping exercise. These mapping questions aim to assess whether the private sector entity is in *no alignment*, *limited alignment* or *alignment* with public health and NCD goals. This classification of private sector entities informs the subsequent steps in Phase II of the decision-making process. The following actions apply:

- **No alignment with public health and NCD goals**: It indicates that the private sector entity's goods, services and/or practices are incompatible with public health and NCD goals. Therefore, no further consideration should be given to the entity's engagement for NCD responses. It is important to distinguish situations in which due process requires that excluded entities must be involved in the policy implementation of certain NCD measures. In such cases, interactions between the private sector entity and the government shall be limited to the minimum, ensuring transparency, with an appropriate risk management plan and mitigation protocol in place.

- **Limited alignment with public health and NCD goals**: It indicates that the private sector entity's goods, services and/or practices may conflict with public health and NCD goals. Further due diligence to better profile the private sector entity and a thorough risk assessment of the engagement (Phase II) are required in order to reach an informed decision (Phase III).

- **Alignment with public health and NCD goals**: It indicates that the private sector entity's goods, services and/or practices may be in alignment with or complement public health and NCD goals. Further due diligence to better profile the private sector entity and a thorough risk assessment of the engagement (Phase II) are required in order to reach an informed decision (Phase III).

Note to users

- A private sector entity formally excluded from engaging with the government should not be considered for engagements in the prevention and control of NCDs and may be classified as being in *no alignment* with public health.
- A private sector entity producing and/or commercializing products and/or services that contribute to (i) the prevalence of modifiable behavioural risk factors such as tobacco use, physical inactivity, unhealthy diet, and harmful use of alcohol, and/or (ii) an adverse impact on the determinants of health, and/or a private sector entity whose goods, services or practices harm public health, is in *no alignment* with public health. Engagement with such entity must be limited to minimal, publicly transparent consultations to support the implementation of a public health policy or regulation.
- If public health policies could be perceived to reduce demand for the goods and/or services of the private sector actor, governments should be aware of industry tactics to stop, delay or weaken such policies. In this case, health authorities may classify the private sector entity as being in *no alignment* or *limited alignment* with public health.

STEP 4

Type of engagement

Based on the NCD challenges and the purpose of the engagement identified in previous steps, engagement with private sector entities may take different forms (Table 2). The different types of engagements depend on factors such as the stage of the government policy cycle, the type of private entity required to address gaps in the NCD response and the capacity of the government to carry out such engagement [68].

The types of arrangements for each engagement have different transactional costs for the government (e.g. staff time, internal procedures, reporting, logistics) and may imply public financing commitments and capacity-building efforts. In addition, each type of engagement requires a form of agreement which defines its governance, accountability, resources and roles and responsibilities. Together with context-specific circumstances, this defines the complexity of the engagement.

Table 2. Examples of types of arrangements that governments may consider[11]

Types of engagement	Description of engagement
Donation	A process that usually involves voluntary contributions, either financial or in kind (including pro bono contributions of time and expertise) to the public sector entity to enable that entity to implement its mission without in-depth interaction with the donor and without its involvement in shared risks and responsibilities, joint programming and decision-making.
Dialogue	Consultative processes to promote dialogue whereby information flows from one party to the other and vice versa (e.g. information sessions) [1]. Dialogues may also include awareness-raising and advocacy initiatives to seek support from private sector entities to encourage the implementation of public health policies.
Sponsorship	Any form of monetary or in-kind payment or contribution to events, activities or individuals that directly or indirectly promote a company's name, brand, products or services. Sponsorship is a commercial transaction, not a voluntary contribution [69].

11 For the purpose of this tool, tailored definitions of the types of arrangement have been considered.

Types of engagement	Description of engagement
Grant	Financial assistance to an approved project proposal or activity submitted by the public sector entity that provides a basis for accountability and expectations through a formal agreement. Grants are typically awarded to the public sector entity through a competitive process or on the basis of predetermined assessment criteria. No substantial programmatic involvement of the grantor is expected with the recipient during the performance of the activities.
Procurement	A contractual agreement for services or goods, in which the public sector seeks best value for money when contracting a private sector entity as a service provider to deliver predetermined goods or services based on technical specifications, quality and price [70].
Alliance	This type of arrangement establishes formal or informal networks based on similar interests, defined roles and responsibility, complementary skills and capacity to address complex development challenges through knowledge exchange and information-sharing on new methods, tools and innovative approaches (e.g. network platforms, roundtables, specialized hubs) [71].
Partnership	Formal engagements involving the highest level of collaborative relationship and interaction, including negotiations on shared accountability, commitments, risks and joint programming, where private sector entities are expected to complement public health efforts to achieve common goals (e.g. public-private partnership for health service delivery) [29, 72].

Note to users

- The type of arrangement determines the level of complexity and formality required between the parties, which may have implications for accountability, roles and responsibilities, governance and internal management processes. These are therefore important points for consideration by decision-makers.

STEP 5

Assessment of the local environment for engagement with private sector entities

Engagement between the public and private sectors that addresses NCD prevention and control requires accountable and transparent governance. Governments have a stewardship role in building this environment [73], which entails understanding their local context in terms of: (i) political leadership; (ii) applicable regulations and legal frameworks; and (iii) experience and capacity on engagement with private sector entities. Web Annex B (Phase I, step 5) presents the guiding questions to assist health authorities gather essential information and assess their existing capacities and gaps.

Limited or absent information on the local environment should not be seen as a reason to stop progressing to the next phase. Rather, this limitation is an important issue to address when assessing the risks and developing the corresponding mitigation strategies of potential engagements, as described in Phase II of this tool.

PHASE 2

Analyse

Building on the findings of Phase I, the objective of Phase II is to provide guidance on the analysis of three interrelated elements related to a specific engagement opportunity: (i) the due diligence process of the private sector entity; (ii) risk assessment, including risk identification, risk magnitude and prioritization; and (iii) risk mitigation strategies associated with the potential engagement.
Governments should use this guidance as a framework for developing and/or strengthening their own due diligence process, risk assessment and risk mitigation systems. Users are encouraged to explore additional information or resources to conduct a more in-depth analysis.

STEP 6

Due diligence and risk assessment of the private sector entity

The due diligence process involves finding and verifying information about an entity before starting the negotiation and decision-making regarding a potential engagement. The process consists of three elements: (i) profiling an entity and screening against exclusionary criteria; (ii) identifying major controversies; and (iii) assessing compatibility with the principles of engagement with private sector entities.

When conducting due diligence, governments should gather information about the governance structure of the private sector entity being considered. Health authorities are recommended to record the results of the due diligence, make them accessible to other government sectors and update them as necessary to help reduce the bureaucratic burden of the process in case other engagement opportunities with the same private sector entity arise in the future.

Table 3. Examples of required information and relevant sources to support due diligence

Components	
Search for information	Seeking information about the private sector entity in relation to exclusionary criteria (Box 6), major controversies (Box 7) and compatibility with principles of private sector engagement. The search may also include background checks and triangulation of information regarding operations, products and services of private sector entities
Examples of sources [74, 75, 76]	Seeking information provided by the private sector entity and sought from other sources in the public domain, such as: • media reports, articles and press releases; • corporate websites, financial reports, sustainability reports on environment, social and governance (ESG), data on product/service portfolio and composition; • studies and reports, including database of information prepared by specialized entities, NGOs and academic institutions; • data produced by government agencies on environment, health, social and governance, public registries; • lobbying registers. • Additional sources of information sought but not available in the public domain could be: • community consultations and stakeholder interviews; • key documents requested from the private sector entity (e.g. internal audit reports); • impact assessments commissioned by governments or other parties; • country cooperation networks, etc.

Exclusionary criteria

The exclusionary criteria for private sector entities, within the context of this tool, should be defined by the government in order to exclude engagement with private sector entities that harm public health. Exclusionary criteria may apply to private sector actors that are deemed to be not aligned with public health and NCD goals **(Phase I, step 3)**. This includes entities involved in the production and/or commercialization of health-harming products such as tobacco, alcohol and/or highly processed foods and beverages that are often high in unhealthy fats, added sugars and/or salt.

The exclusionary criteria can also refer to the core business, practices or behaviours of a private sector entity, including obligations as determined by national rules, policies and norms and international conventions and treaties. For instance, governments that are party to the WHO Framework Convention on Tobacco Control (FCTC) must limit engagement with the tobacco industry (other than to the extent required to afford procedural fairness in policy processes). WHO FCTC articles 5.3 and 13, and corresponding guidelines **[22, 77]**, oblige governments to protect their public health interests from interference by the tobacco industry and those working to further its interests. Also, under the FCTC, governments should de-normalize activities described as "socially responsible" (including donations, contributions or sponsorships by the tobacco industry) as there is an inherent contradiction between the industry's core functions and the goals of public health policies. Box 6 gives examples of exclusionary criteria set by WHO and other United Nations agencies.

Note to users

- If private sector entities fall under the exclusionary criteria during the due diligence process, they should not be considered further for engagements with the government.
- Health authorities may be required to consult with the private sector during the process of developing policies to address NCD risk factors. In these circumstances, the engagement is transactional in nature and the purpose is to inform the implementation of such policies or measures in accordance with government obligations, ensuring procedural fairness for private sector entities while safeguarding public health policies from undue influence and conflicts of interest.

BOX 6

Examples of exclusionary criteria from WHO and other United Nations agencies

In line with its Framework of Engagement with non-State Actors, WHO does not engage with the tobacco industry or non-State actors that work to further the interests of the tobacco industry. WHO also does not engage with the arms industry. [1]. Non-State actors that work to further the interests of the tobacco industry include, but are not limited to:

- entities and subsidiaries engaged in the manufacturing, distribution and/or sale of tobacco or tobacco-related products;
- entities working specifically to further the interests of the tobacco industry through lobbying, advertising, legal advice or similar activities;
- entities being funded, supported or influenced in their governance by tobacco-related entities; and
- entities having the tobacco industry or its representatives among their members.

WHO does not engage with the arms industry [1]. In the case of entities linked to the arms industry, a case-by-case assessment is made on the acceptability of receiving funding from such entities.

WHO also exercises particular caution when considering possible engagements with non-State actors whose policies or activities negatively affect human health and which are not in line with WHO's policies, norms and standards. This is especially the case in the area of NCDs and their determinants [1].

Together with UNICEF, WHO sets as a principle the avoidance of all partnerships with entities from the food and beverage industry that violate the International Code of Marketing of Breast-milk Substitutes.

In addition, UNICEF also sets principles to avoid engagement with ultra-processed food and beverage industries [78]. Other organizations within the UN system, such as the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Development Programme (UNDP), also extend the exclusionary criteria to the gambling (except lottery) and pornography industries [34, 38].

The UN Sustainable Development Group provides additional exclusionary criteria for screening unsuitable private sector entities on the basis of their corporate practices [39], as follows:

- direct involvement or complicity in systematic or egregious human rights abuses through operations, products or services;
- inclusion on the United Nations Security Council Sanctions List [79] or the United Nations Ineligibility List [80], or in violation of UN sanctions, relevant conventions, treaties and resolutions;
- systematic failure to demonstrate a commitment or to meet in practice the principles of the United Nations, including statements or principles that are consistent with and reflect the UN Global Compact [81] or the United Nations Guiding Principles on Business and Human Rights [42].

Major controversies

If the private sector entity does not fall under the exclusionary criteria, the next step is to determine whether the entity is involved in major controversies that conflict with the core principles of engagement with private sector entities. Major controversies could relate to adverse impacts on human health and safety, the environment, social issues and matters of governance (Box 7). Health authorities are recommended to verify whether the situations described under this step apply to the private sector entity [82]. Please consult Web Annex B (Phase II, step 6) for examples of questions to guide this analysis.

BOX 7

Examples of major controversies[12]

Health and safety:

- safety concerns;
- controversial products or services (e.g. carcinogenic products);
- tobacco and entities furthering the interest of tobacco industry;
- promotion and marketing of breast-milk substitutes, alcohol products, sugar-sweetened beverages, and unhealthy foods contrary to WHO's international codes, technical products and guidance;
- inappropriate occupational health and safety practices;
- exploitative pricing of essential medicines, health, technologies and service provision.

Environment:

- air, water and soil pollution;
- adverse impact on ecosystems and landscapes;
- inappropriate or overuse of natural resources;
- inadequate waste management;
- mistreatment of animals and wildlife.

Social:

- discrimination in the workplace on the basis of gender, skin colour, nationality, ethnic or national origin, religion or belief, age, civil status, disability, pregnancy or sexual orientation;
- restrictions on freedom of association and the right to collective bargaining;
- poor employment conditions contrary to declarations of the International Labour Organization;
- sexual exploitation and abuse and sexual harassment;
- adverse impact on livelihoods;
- social discrimination and exclusion;
- adverse impact on indigenous persons.

Governance:

- corruption;
- fraud;
- tax evasion;
- non-cooperation with justice;
- deliberate, persistent or foreseeable non-compliance with existing national policies, norms and regulations;
- controversies related to the individuals owning, governing, managing or representing the company.

12 Adapted from Ref. [34].

Once the screening against exclusionary criteria is conducted and there are no indications of involvement of the private sector entity in major controversies, health authorities may continue the due diligence process by assessing the entity's compatibility with the principles guiding private sector engagement.

Note to users

- It is recommended to carry out further review to verify the information and assess whether and how the identified controversies are being addressed by the private sector entity.
- In situations where the involvement of the private sector entity in any major controversy is confirmed, and there is no proof of satisfactory corrective measures taken by the private sector actor, the government may exercise its right to not consider the engagement further.

Compatibility with the principles guiding private sector engagement

The principles of private sector engagement, as described earlier, establish the foundation, mandatory attributes and expectations of engagements between health authorities and private sector entities (Box 8). The due diligence should also include profiling the entity in relation to its compatibility with the principles of engagement. Web Annex B (Phase II, step 6) provides a set of questions for the analysis of compatibility with the principles guiding private sector engagement.

The due diligence should take into consideration the size of the private sector entity in terms of the scope of its operations (national, multinational or transnational) and its direct or indirect impact on both public health and the government's operational capacity.

Note to users

- In situations where there are many negative and/or "unknown" responses to the questions listed in Web Annex B (Phase II, step 6), it is important to address and discuss the identified issues with the respective private sector entity.
- If health authorities do not consider the answers or proof of corrective actions from the private sector entity as adequate, there could be an incompatibility with the principles guiding private sector engagement. In such a situation, the government may exercise its right to not consider the engagement further.

BOX 8

Expectations from private sector entities to comply with the guiding principles

Principle 1: Sustainable and responsible practices

- To accept responsibility to respect human rights, including labour rights and the right of all people to the highest standard of health, the environment and good corporate governance and anti-corruption measures.
- To agree not to undermine and, to the contrary, strengthen their commitments and contributions to public health.

Principle 2: Added value to the NCD response

- To act according to the terms of engagement in order to meet the targeted NCD results.
- Not to interfere with health authorities' integrity, impartiality and independence in exercising their functions of developing, monitoring and evaluating NCD goals, policies and strategies.
- To increase positive health impact and reduce, prevent and mitigate the negative health impact, and to promote the knowledge and application of global health norms and standards.

Principle 3: Accountable and transparent governance

- Respect and conform to the terms of engagement, honour their commitments and conduct the engagement on the basis of the agreed accountability framework.
- Promote awareness of the terms of engagement, including adopting and implementing policies and good practices on compliance with the terms of the engagement (e.g. capacity development, internal communication campaigns etc.) to make sure that the engagement is integrated at the level of the private sector entity and its workforce.
- Ensure that the terms of the engagement are accurately represented in all communications.

STEP 7

Risk assessment of the engagement

After conducting due diligence and profiling the private sector entity, where appropriate, the next step is to carry out a risk assessment on the potential engagement. The risk assessment comprises identification of risks, assessment of the likelihood of risk occurrence and impact, risk magnitude and prioritization, and respective risk mitigation measures [83]. Box 9 shows some WHO resources on conflicts of interest with specific private sector industries.

Risk identification

Risk identification refers to identifying situations that may negatively affect the engagement with the private sector entity and the government's ability to maintain its integrity and independence to develop and implement evidence-based policies. For the purpose of this tool and the intent to reach an informed-decision on engagement, five major categories of risk are proposed: conflict of interest, reputational, governance, political, and operational risks (see Table 4). Other risks such as budgetary, fiscal, legal and performance risks are beyond the scope and aims of this tool.

Note to users

- Risks are the expression of the likelihood and potential impact of the occurrence of an event that can affect an organization's ability to achieve its objectives [84].
- The risks described in Table 4 are not exhaustive and should be applied with caution and adapted as needed to a specific context.
- It is fundamental to have completed Phase I of this tool prior to conducting the risk assessment (step 7) in order to obtain a comprehensive perspective on limitations or gaps that could potentially become risks if an engagement is pursued.

BOX 9

Examples of WHO resources developed for Member States on conflicts of interest with specific private sector industries

WHO has developed complementary tools for Member States that offer tailored guidance on the identification and management of conflicts of interest in relation to specific policy areas and/or with private sector industries (tobacco, alcohol, food and non-alcoholic beverages, and pharmaceutical industries). In such cases, users are recommended to complement the analysis of risk assessment (step 7) and risk mitigation (step 8) with the respective guidance, such as the examples shown in Figure 2.

Figure 2. Examples of guidance on conflicts of interest with private sector industries

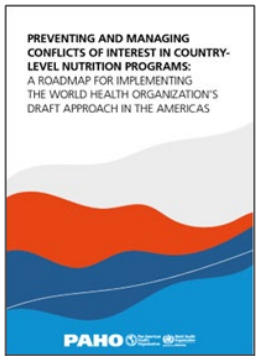
Tobacco industry

See Ref. [22]

Alcohol industry

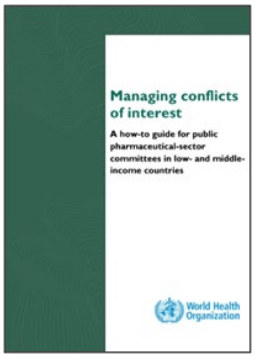
See Ref. [26]

Food and non-alcoholic beverage industry



See Ref. [27]

Pharmaceutical industry



See Ref. [28]

Table 4. Examples of risks related to engagement with private sector entities according to the five categories

Risk category	Underlying risk
Conflict of interest This arises in circumstances where there is potential for a secondary interest (a vested interest in the outcome of government's work in a given area) to influence unduly, or where it may be reasonably perceived to unduly influence, either the independence or objectivity of professional judgement or actions regarding a primary interest (protection of population health). The existence of conflict of interest does not mean that improper action has occurred, but rather that there is a the risk of such improper action occurring. Conflicts of interest are not only financial, but can take other forms as well.	**R1**. Monetary or material resources mobilized through the engagement with private sector entities have the potential to unduly influence the judgement or action of the health authorities (actual conflict of interest) [24].
	R2. Non-monetary influences related to the engagement have the potential to exert, or be reasonably perceived to exert, undue influence over the judgement or action of health authorities (perceived conflict of interest) [24].
	R3. The engagement may facilitate access of private sector entities to decision-makers, policy-making or policy-implementation processes and thereby put those entities in a position to unduly influence policy development or outcomes in ways that are inconsistent with public health goals and may undermine, weaken or delay NCD prevention measures [24].
Reputational risks For the purpose of this tool, reputational risks relate to negative reputation that may occur with regard to the engagement with an entity, resulting from actions, events, or behaviours that could be perceived negatively by stakeholders, the public, or other interested parties, yielding an adverse impact on public trust in the health authorities in delivering their core functions in line with expected ethical norms and standards of public institutions.	**R4**. The due diligence outcomes reveal bad reputation of the entity, bad press and/or involvement in major controversies. This may be prejudicial or damaging to the government, if a collaboration is pursued with the private sector entity.
	R5. The engagement may give the private sector entity an unfair advantage over competitors and may disrupt fair competition, thus damaging the perception of the public sector as independent and impartial.
	R6. The engagement may produce benefits for the private sector that subjectively outweigh the positive public health or social impacts.
	R7. The engagement may imply a government's endorsement of the private sector entity, or its products or services.
Governance risks These refer to situations in which the engagement may contribute to disrupting the capacity of health authorities to appraise and make decisions autonomously for the benefit and on behalf of the public.	**R8**. The power imbalance between the public and private sectors may create situations where the private sector entity unduly oversees and influences government policies and decisions.
	R9. The engagement may undermine the public sector's leadership and credibility in developing and implementing evidence-based public health policies.
	R10. The engagement may affect, or be seen to affect, the public sector's independence in identifying its own NCD priorities and/or in implementing and enforcing NCD measures.
	R11. The terms of the engagement may restrict the government's work with other entities.

Risk category	Underlying risk
Political risks These are external and uncontrolled contextual events, such as political changes or instability, which may undermine the engagement and its intended results.	**R12**. The engagement may be cancelled unexpectedly due to changes in policies, laws or regulations that affect commitments made by health authorities.
	R13. Changes in the government (e.g. elections, reform of public services, emergencies) may result in loss of political support, delays or the termination of the engagement.
	R14. Changes in the leadership of the private sector entity may result in loss of support, delays or the termination of the engagement.
Operational risks This category of risk encompasses situations related to the engagement that may affect the current or future programmatic focus and resource allocation of health authorities.	**R15**. The public sector may not have the resources to assess the engagement adequately, manage it effectively, exercise operational authority over it and/or deliver on the engagement's goals.
	R16. The engagement may weaken, delay or otherwise have a negative impact on the effectiveness of current or future NCD interventions, and/or other health and social policy areas.
	R17. The engagement may require additional and/or continuous public financial commitments beyond the planned activities.
	R18. The private sector entity may not have the capacity and financial resources needed to meet the goals of the engagement.

Likelihood of risk and risk impact

After identifying potential risks, the next step is to anticipate the likelihood that they will occur and the impact they may have on the integrity and independence of the public sector. For the purpose of this tool, this can be captured on a scale of low, medium and high, as described below.

Risk likelihood:

- **Low likelihood**. Situations of risk are unlikely to occur or there may not be a perception of their occurrence.
- **Medium likelihood**. Situations of risk are somewhat likely to occur or there may be some perception of their occurrence.
- **High likelihood**. Situations of risk are likely or very likely to occur or there may be a high perception of their occurrence.

Risk Impact:

- **Low impact**. If the situation occurs, the integrity and independence of the public sector and its ability to develop and implement measures effectively to prevent and control NCDs may be compromised if no mitigation measures are in place.
- **Medium impact**. If the situation occurs, the integrity and independence of the public sector and its ability to develop and implement measures effectively to prevent and control NCDs may be compromised with potential loss of credibility and public trust despite having mitigation measures in place.
- **High impact**. If the situation occurs, the integrity and independence of the public sector and its ability to develop and implement measures effectively to prevent and control NCDs may be severely compromised with loss of credibility and public trust despite having mitigation measures in place.

- Web Annex B (Phase II, step 7) provides a template to analyse the likelihood and impact of risks using the five risk categories (i.e. conflict of interest, reputation, governance, political and operational).

Risk magnitude and prioritization

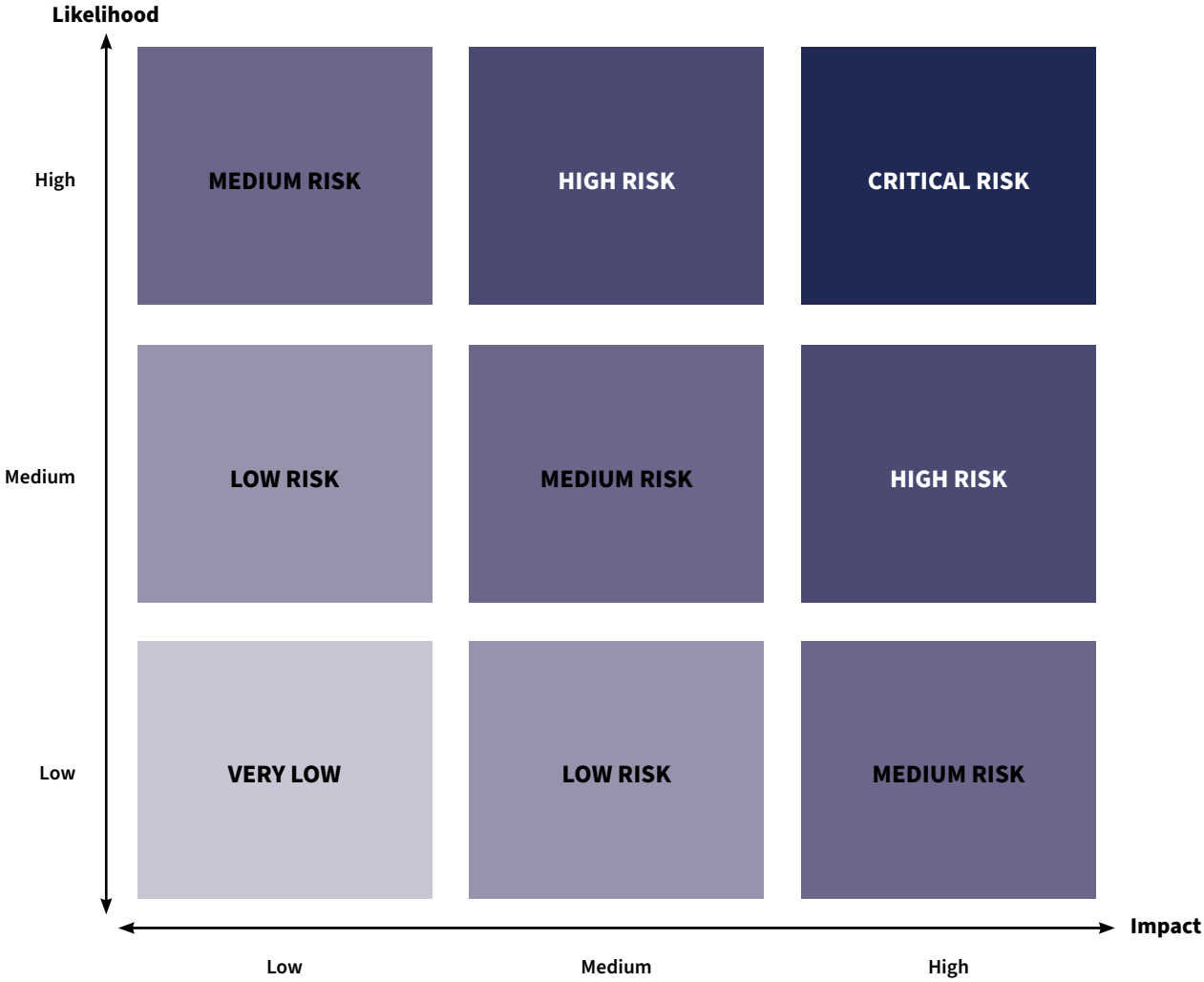
Once the risks are identified, along with their likelihood of occurrence and their potential impact on the integrity and independence of the public sector, it is possible to plot them in a "likelihood–impact" matrix and to subjectively rate individual risks as very low risk, low risk, medium risk or high risk [83] (Figure 3).

The rating of individual risks helps not only to prioritize corrective actions but also to understand whether the engagement would involve an acceptable level of risk. It is important to note that risk rating informs an integrated analysis of all identified risks in order to prioritize relevant mitigation strategies for the most relevant (i.e. critical and high) risks.

Note to users

- Addressing risks entails costs – transactional or direct – to the public sector. Not all risks may require immediate corrective actions, whereas some may need only to be monitored (e.g. low and medium risks).

Figure 3. Risk magnitude matrix based on the likelihood of occurrence and potential impact of each relevant risk



STEP 8

Development of risk mitigation strategies

When the risks are adequately identified and assessed, the next step is to develop mitigation strategies for the most relevant risks in order to prevent or reduce the overall risk exposure of the government.

Risk mitigation strategies involve planning and creating locally-adapted measures to minimize threats to the government or to the engagement. The aim is to eliminate the root cause of the risks (risk avoidance) or to reduce the probability that they will occur and/or minimize their impact (risk reduction). In some situations, risk mitigation strategies may include implementing countermeasures to decrease the impact of the risks. Web Annex B (Phase II, step 8) provides a template for developing appropriate risk mitigation strategies. Examples of possible risk mitigation measures are presented in Table 5.

Table 5. Examples of risk mitigation measures to address potential challenges that Member States may face when engaging with private sector entities

Examples of risk mitigation measures
Developing and endorsing a national or subnational policy, strategy or action plan that sets clear goals for the prevention and control of NCDs.
Developing exclusionary criteria for engagement between the government and the private sector.
Excluding or restricting representatives of private sector entities from policy development where a potential conflict of interest exists, including in setting policy objectives, planning or consultations on policy prioritization.[13]
Developing, implementing and enforcing laws, policies and processes for identifying, avoiding and managing conflicts of interest of members of parliament, policy-makers and civil servants in engagement with the private sector.
Developing, implementing and enforcing laws, policies and processes to manage bribery and corruption, to ensure transparency and prevent undue influence by restricting lobbying and by placing limits on and requiring public disclosure of political donations.
Implementing measures and mechanisms to identify, avoid or manage conflicts of interest and/or interference through the involvement of representatives of private sector entities during the process of policy implementation by, for example, publishing details of meetings with private sector entities as well as the terms and outcomes of private sector engagements.
Developing and enforcing clear rules and criteria to include or exclude representatives of private sector entities from participating in government meetings organized or attended by health authorities, as well as mechanisms to activate actions related to non-compliance.

13 For example, in the regulation of products and practices which contribute to NCD risks, it may be more appropriate to consult with the private sector only through transparent processes (e.g. through hearings and targeted consultations, making publicly available the terms of the engagement and minutes of meetings with private sector entities, opportunities for public information sessions, and publishing the evaluation of the engagement outcomes).

Examples of risk mitigation measures
Soliciting support and input from private sector entities through an inclusive and transparent process (e.g. through website, open calls etc.).
Making the terms of private sector engagement publicly available and offering opportunities for public participation and comments in relation to proposed private sector engagements.
Seeking the views of nongovernmental organizations and academic institution with relevant expertise on information to facilitate assessment of engagement opportunities with private sector entities
Allocating roles and responsibilities within the government to manage effectively the relationship with private sector entities throughout the lifetime of the engagement.
Conducting an evaluation of the engagement with the private sector through an independent evaluation process and, when possible, publishing those reviews.
Developing and enforcing clear rules on use of the government's logo, promotion of the engagement by private sector entities, as well as mechanisms to activate actions related to non-compliance.
Developing agreements for all types of engagements with private sector entities in order to specify the goals of the collaboration, the roles and responsibilities of the parties and the mechanisms to activate actions relating to non-compliance.
Leveraging skilled human resources with other government sectors to provide punctual support in managing the relationship and the engagement with private sector entities.
Building the capacity of relevant health authorities to conduct due diligence, negotiation and risk management, to develop agreements to manage relationships, and to identify and mitigate risks with private sector entities.

Note to users

- The examples of mitigation strategies are not exhaustive. There are other forms of risk mitigation measures, such as legislation on public procurement, that apply to the health sector and beyond.
- Context-specific adaptation of the risk mitigation strategies is necessary to ensure that they are commensurate with the likelihood and level of impact of risk as well as with the country's capacity to implement the mitigation strategies.
- Given that risks are unlikely to remain static throughout the engagement, regular monitoring of the risk level is also a mitigation strategy that ensures that the engagement is managed within accepted levels of risk.

PHASE 3

Decide

Systematic assessment and analysis of evidence and contextual information on the potential engagement contribute to reaching an informed decision-making [85]. In this phase, the information gathered in previous steps is used to facilitate reaching an informed decision on whether to pursue or discontinue an engagement with a private sector entity. This phase has two final steps - step 9, a risk management plan and step 10, reaching informed decision, considering its associated benefits and risks.

Note to users

- If not established previously, it is recommended that relevant health departments establish a multidisciplinary team to prepare and, after consultation, validate the information gathered in Phases I and II, before moving to Phase III. Such team should be composed of staff from departments that are free from conflicts of interest with regard to the engagement. This team will make a recommendation to the decision maker(s).

STEP 9

Development of a risk management plan

On the basis of the analysis of the risk magnitude and mitigation measures described in previous steps, decision-makers should be able at this stage to prioritize actions to avoid or reduce potential threats to the government. The risk management plan offers decision-makers a summary of the risks and corresponding mitigation strategies as well as key elements on which to base the decision about the engagement. Its purpose is to facilitate an overall understanding within the government and to create shared awareness of the risks and assumptions related to the potential engagement with the private sector.

To facilitate this understanding, it is recommended to develop a risk matrix, summarizing all identified risks and their corresponding magnitude and mitigation strategies, as described in steps 7 and 8 of Phase II (see Web Annex B, Phase III, step 9) for a template of risk matrix and mitigation measures). This matrix is designed to assist in reviewing the risks and the corresponding mitigation measures.

Following the preparation of the risk matrix, decision-makers can use a checklist (see Web Annex B; Phase III, step 9) to review key elements comprehensively in order to support reaching an informed decision. Documenting each of the elements collected in previous steps will allow decision-makers to review the rationale for the potential engagement.

STEP 10

Reaching a decision on engagement

In this final step, health authorities should have a clear understanding of the potential benefits and risks and the capacities required for engaging with the private sector. This understanding will enable health authorities to make an informed decision by explicitly outlining the expected benefits and associated risks.

For potential new engagements, the tool should help generate, after applying all previous steps, one of two possible decision scenarios:

- **Engagement with a private sector actor**. This is when the expected contributions from the private sector to national NCD responses outweigh the risks and the engagement generates an estimated net benefit that warrants government consideration. It also applies when the engagement is transactional in nature (e.g. consultation or policy implementation) and/or is a procedural requirement by the government. It requires a well-resourced risk management plan to ensure adequate monitoring throughout the duration of the engagement, including adjusting the terms and conditions of the engagement to manage identified risks.

- **No engagement with a private sector actor**. When the risks of engagement outweigh the potential benefits, and the risks have a negative impact on public health even with a risk management plan in place, it is not advisable to proceed with the engagement. In this case, the reasons for not engaging should be documented and actionable recommendations should be provided to strengthen national capacity to mitigate risks associated with similar engagements in the future.

If the tool is used to monitor or evaluate existing private sector engagements, decision-makers may have two possible options:

- **Continue engagement with a private sector actor**. This includes situations in which the private sector actor respects the terms and conditions of the engagement, including the three core principles, and the engagement makes definite contributions towards achieving the NCD goals set by the government. The decision to continue an engagement should be supported by effective risk mitigation and monitoring, including assessment of any new critical or high risks that may have arisen since the engagement began.

- **Disengagement from the private sector actor**. This includes situations in which the private sector actor fails to deliver on its commitments and/or compromises the public health objectives, or when the three core principles of engagement are not upheld. Terminating an ongoing engagement may also be necessary when the initial risk assessment did not accurately reflect the level of risk exposure or the mitigation strategies have proved to be ineffective in reducing the government's exposure to risks. The reasons for disengaging should be documented and actionable recommendations should be provided to strengthen national capacity to mitigate risks associated with similar engagements in the future.

Final remarks

The Decision-making tool offers Member States a systematic methodology for assessing, analysing and deciding on engagement with private sector entities to complement or enhance public sector efforts to address the prevention and control of NCDs. This approach underscores critical elements for informed decision-making that will enhance the transparency and accountability of government decisions, while taking steps to protect public health policies from any undue influence by commercial actors.

The Decision-making tool was designed to be practical and applicable across diverse contexts and scenarios. Its phased approach offers flexible yet structured guidance for users from different countries who are considering engagement opportunities.

Governments, and in particular ministries of health, should exercise prudence when engaging with private sector entities involved in the production and commercialization of products or services that contribute to the modifiable behavioural risk factors for NCDs. In situations where the engagement with a private sector actor is transactional in nature or mandated by the government during the policy implementation process, certain steps outlined in this tool may not be fully applicable. Additional steps or processes may be necessary to safeguard public health policies and to ensure compliance, while the engagement should be kept to a minimum and preferably be limited to transparent consultations and dialogues.

The decision derived from the application of the tool will depend on the quality (e.g. relevance, specificity, comprehensiveness, accuracy) of the information collected and analysed. It is not advisable that a single individual in the Ministry of Health applies the tool in isolation. Rather, health authorities should consider this tool as a catalyst approach for inducing interdepartmental dialogues and collaboration across government sectors. Local NGOs and academic institutions play an important role as key stakeholders in supporting health authorities during the implementation of the Decision-making tool. They bring their unique expertise and resources, and can provide information, views and evidence in accordance with the guidance provided throughout the tool. This collaborative effort will greatly enhance transparency and foster trust among stakeholders.

When implementing the tool, some countries may identify capacity gaps in policies, regulations and operational processes, including in relation to knowledge and expertise. These limitations should be acknowledged, documented and, when necessary, addressed prior to any decision on engaging with a private sector actor. Addressing these limitations may range from simple mitigation measures to more complex policy changes and capacity-building within the public sector. This self-assessment can better prepare governments to address inherent risks when considering private sector engagement and to build the necessary capacity to maximize potential opportunities with the private sector in support of national NCD responses.

In light of limited domestic budgets for NCDs, insufficient or overutilized public sector infrastructure and competing global health priorities, governments, particularly in LMICs, are under tremendous pressure to address their growing NCD burden effectively. Collaboration with non-State actors, including the private sector, in support of NCD responses cannot be overlooked. However, countries must prioritize informed decision-making processes that focus on population health and equity over private commercial interests. This tool provides countries with guidance to strengthen and scale up their internal processes and make informed decisions on engagement opportunities with the private sector.

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