

WHO GLOBAL DIABETES COMPACT

WORKSTREAM 1: ACCESS TO INSULIN AND ASSOCIATED HEALTH TECHNOLOGIES



World Health
Organization

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Discussion Note:

*Development of an approach that can be used to register
and publish contributions of the pharmaceutical and
associated health technology industry*

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1. Background

Following from the September 2011 UN High-Level Meeting on the Prevention and Control of Non-Communicable Diseases (NCDs), WHO has led a series of consultations with Member States, United Nations (UN) agencies, NGOs, academic institutions, philanthropic foundations, and the private sector to promote and monitor global action in realizing the commitments made in the UN Political Declarations on the Prevention and Control of NCDs in 2011, 2014 and 2018.

In particular, these three resolutions adopted at the UN General Assembly include commitments from governments to:

- Engage with the private sector, taking into account national health priorities and objectives for its meaningful and effective contribution to the implementation of national responses to non-communicable diseases in order to reach Sustainable Development Goal target 3.4 on non-communicable diseases, while giving due regard to managing conflicts of interest;
- Invite the private sector to strengthen its commitment and contribution to the implementation of national responses to prevent, control, and treat non-communicable diseases to reach health and development objectives by contributing to further improving access to and the affordability of safe, effective, and quality medicines and technologies in the prevention and control of non-communicable diseases.

At the same time, the United Nations General Assembly called upon WHO to develop an approach that can be used to register and publish contributions of the private sector, philanthropic entities and civil society to the achievement of the nine voluntary NCD targets for 2025 and SDG target 3.4 for 2030.

In response to the WHO leadership and coordination role in promoting and monitoring global action to fulfill the commitments made in these resolutions, the WHO Department for NCDs, in collaboration with the Health Products Policy and Standards, and Regulation and Prequalification Departments, are convening a series of biannual private sector dialogues with representatives from international business associations, pharmaceutical, and associated health technology industries. The dialogues focus on mobilizing commitments and contributions by the private sector towards National NCD Responses on NCDs to achieve SDG target 3.4 by improving access and affordability of safe, effective, and quality medicines and associated health technology products.

The second meeting with industry is planned for 1 and 2 September 2021 and will continue to focus on improving access to affordable (safe, effective, and quality) medicines and health technologies for diabetes, taking into account:

- 1) Resolution WHA74.4ⁱ (Reducing the burden of NCDs through strengthening and control of diabetes) adopted at the World Health Assembly in May 2021;
- 2) The [Global Diabetes Compact](#), which aims to reduce the risk of diabetes, as well as ensure that all people who are diagnosed with diabetes have access to equitable, comprehensive, affordable, and quality treatment and care;
- 3) The policy brief responding to industry initiatives to increase access to medicines and other health technologies in countriesⁱⁱ.

The meetings that follow, will focus on other major NCDs. (Cardiovascular Disease, Cancer, Lung diseases, Oral health, Rehabilitation, Sensory impairments and disability).

2. Rationale

Part of the Global Diabetes Compact (GDC) is the commitments and contributions of the pharmaceutical and health technology industry to implement national responses for the prevention, management, and control of NCDs, including access to and affordability of safe, effective and quality-assured insulin and associated health technology products. Although the commitments and contributions are an important first step to promote access, these should be underpinned by specific overarching principles, including:

- Demonstrate a clear benefit to people living with NCDs
- Support the achievement of the nine voluntary global targets for 2025 and SDG target 3.4.1 by 2030
- Respect the primary role and responsibility of governments in policy-making and responding to the challenge of NCDs
- Conform with WHO's Constitution, mandate and General Programme of Work
- Support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work
- Protect governments and WHO from any undue influence, in particular on the processes in setting and applying policies, norms and standards
- Not compromise governments' and WHO's integrity, independence, credibility, and reputation
- Comply with the principles of transparency, openness, inclusiveness, accountability, integrity and amenability to independent verification when monitoring and evaluating progress towards these commitments. This will support the acknowledgement of progress, identification of remaining gaps, and development of best practices to accelerate access.
- Effectively manage conflict of interest and other forms of risk to WHO
- Ensure consistency with the WHO Framework for Engagement with non-State actors
- Recognize the fundamental conflict of interest between some industries and public health

The food and non-alcoholic beverage industry, as well as the sports goods industry, have already made commitments and contributions towards national NCD responses aimed at achieving SDG target 3.4 on NCDs.ⁱⁱⁱ These include contributions related to two areas:

- a) activities that directly minimize the impact of their core business on the global burden of NCDs;
- b) initiatives of a philanthropic nature proven to have a direct and significant impact on NCDs (such as providing financial or in-kind support to the implementation of interventions included in the list of "Best buys and other recommended interventions for the prevention and control of NCDs")

As a result, WHO has created two global independent reporting systems (with separate alignment, impact and participation criteria) to document advances in the commitment on nutrition (Global database on the Implementation of Nutrition Action-GINA)^{iv} and promotion of physical activity^v over the past decade.

Since 2017, the pharmaceutical industry has supported a measurement and reporting mechanism for Access Accelerated^{vi}, an initiative launched together with the World Bank and the Union for

International Cancer Control (UICC) to promote access NCD prevention and treatment. The Access Observatory is a public repository housed at the Boston University School of Public Health that receives and reports measurement on Access Accelerated indicators from over 20 biopharmaceutical companies, City Cancer Challenge, and the World Bank.

Over the past decade and a half, the Access to Medicine (ATM) Foundation has carried out independent reporting on pharmaceutical companies' commitments and performance on access to medicines in low- and middle-income countries. It uses confidential as well as publicly available information to rank individual pharmaceutical companies on a set of criteria. Table 1 summarizes relevant reporting initiatives related to the food, physical activity, and medicines.

Table 1: Examples of reporting systems to monitor and evaluate food, physical activity and pharmaceutical industry commitments to the SDGs

Industry	Name of the system	Organization managing/supporting the system	Funder	Year of establishment	Unit of analysis	Website
Food- and non-alcoholic beverage industries	Global database on the Implementation of Nutrition Action (GINA)	George Institute	Bill and Melinda Gates Foundation, Netherlands Ministry of Health	2016	Country	https://extranet.who.int/nutrition/gina/en/about
Sports good industries	Global Register of Voluntary Commitments by Non-State Actors to support achievement of global targets on physical activity	WHO	WHO	2021	Country	Under construction
Pharmaceutical	The Access Observatory	Boston University School of Public Health	IFPMA	2017	Access program	https://www.accessobservatory.org/
Pharmaceutical	ATM Index	ATM Foundation	Dutch lottery, BMGF and others	2008	Company	https://accesstomedicinefoundation.org/access-to-medicine-index

This concept note is the start of the exploration process towards the development of a global reporting mechanism to register and publish contributions for NCD medicines and health technology products, as a pathfinder to all essential products. The approach will take into consideration the need to prevent additional or duplicative reporting by the biopharmaceutical originator manufacturers. Similarly, the metrics developed for biosimilar, generic and health technology industries will draw on a panel of experts focusing on ease of reporting for measurable data as well as leveraging of existing mechanisms.

3. Objectives:

1. Develop an approach that can be used to register and publish contributions of the pharmaceutical and associated health technology industry to the achievement of the nine voluntary NCD targets for 2025 and SDG target 3.4 on NCDs for 2030.
2. Agree on criteria for alignment, impact, and participation.
3. Explore methodological options to measure the performance of the pharmaceutical and associated health technology industry in relation to SDG target 3.4 on NCDs (e.g. through an overarching assessment framework, including minimum requirements and parameters).

4. Activities

The objectives will be achieved via the following six activities:

1. Define principles that guide the development of the reporting mechanism that WHO will use to register and publish these contributions.
2. Develop indicators and a data dictionary that allow for standardized and replicable measurement and reporting of industry commitments and performance on access to NCD medicines and associated health technology products.
3. Build a public reporting platform that ensures accurate dissemination of data gathered and reported into the platform.
4. Pilot the reporting mechanism and revise based on the results of the pilot.
5. Provide training on the measurement and reporting of the industry commitments and performance on access to NCD medicines and associated health technology products.
6. Maintain the public reporting platform and disseminate the reporting results regularly

5. Definitions of the guiding principles

The first step in the development of the global reporting mechanism is defining the guiding principles. The choice of what is measured and how it is reported is grounded in principles which should be explicit and agreed among stakeholders. While the development of metrics will partly depend on the contributions and commitments made by the pharmaceutical and health technology industry, the overall development and operation of the global mechanism needs to be guided by principles. Table 2 summarizes some principles that should be considered guiding the operation of the platform.

Table 2: Principles that should be considered when designing the M&E framework

Principle	Description
Transparency	No confidential information is accepted. All information submitted to the global reporting mechanism will be public.
Openness	The mechanism will be fully open in its design and methods.
Inclusiveness	Includes participation from small and medium pharmaceutical industries in low- and lower-middle income countries.
Independency	The reporting mechanism does not depend on industry funding. It is led by a group of independent experts. A Steering Committee provides oversight.
Standardization	The framework includes standardized metrics that are well-accepted and widely used in measuring access to medicines and health technologies.
Accountability	The mechanism asserts that a private sector entity is accountable to all parts of society.
Amenability to independent verification	The methods used to collect data, analyze, and report need to be verifiable.

ⁱ https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R4-en.pdf

ⁱⁱ <https://apps.who.int/iris/bitstream/handle/10665/259359/WHO-EMP-2017.04-eng.pdf?sequence=1>

ⁱⁱⁱ https://cdn.who.int/media/docs/default-source/physical-activity/sports-dialogue-reports/who-fifth-dialogue-sport-report.pdf?sfvrsn=42261c39_7&download=true

^{iv} <https://extranet.who.int/nutrition/gina/en/commitments/summary>

^v <https://www.who.int/activities/engaging-with-private-sector>

^{vi} <https://accessaccelerated.org/about-us/our-pledge/>

Disclaimer

The World Health Organization (WHO) welcomes views from all participants prior to, during, and after the Dialogue to be held on 1 and 2 September 2021. The discussion note should be viewed as a work in progress developed to support the objectives of the meeting. It encourages inputs, commitments, and contributions from the pharmaceutical and associated health technology product industry to support WHO's activities to strengthen and improve access to medicines and health technology products for diabetes.

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