

WHO GLOBAL DIABETES COMPACT

WORKSTREAM 1: ACCESS TO INSULIN AND ASSOCIATED HEALTH TECHNOLOGIES



World Health
Organization

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Discussion Note:

Background to the WHO asks

*Strengthening the commitment and contribution of the
pharmaceutical industry (medicines & technology) to the NCD
response*

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1. Global Diabetes Compact

Worldwide, more than 420 million adults live with diabetes.ⁱ This number is estimated to rise to 578 million by 2030 and to 700 million by 2045.ⁱⁱ Diabetes is among the top 10 causes of deathⁱⁱⁱ. It is the only major NCD for which a 5% increase in premature deaths (in adults aged 30–69 years) has been observed since 2000^{iv}. Most NCDs, including diabetes, can be treated with off-patent medicines included in WHO's Model List of Essential Medicines (EML).^v For diabetes, the EML includes insulin (soluble short-acting and intermediate-acting insulin in vial form), metformin, and gliclazide.

All people with type 1 diabetes, and about 60 million people with type 2 diabetes, need insulin. Globally, it is estimated that only about 50% of people with type 2 diabetes get the insulin they need, often because of limitations linked to supply, unaffordability (especially for the poor or uninsured), or the way in which the health system is organized with respect to diabetes care^{vi}.

In order to improve outcomes for people living with diabetes, insulin and its associated health technologies need to be available and affordable. WHO is scaling up its work on diabetes, including the establishment of the WHO Global Diabetes Compact (GDC) and relevant workstreams that bring together stakeholders from around the world and across sectors, to reduce the risk of diabetes and to ensure that all people who are diagnosed with diabetes have access to equitable, comprehensive, affordable, and quality management.^{vii}

2. Approach

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.

The WHO Department of Noncommunicable Diseases, in collaboration with the Health Products Policy and Standards, and Regulation and Prequalification Departments, are convening a series of biannual dialogues with the private sector to define meaningful and effective contributions to the implementation of national responses for the prevention, management, and control of noncommunicable diseases (NCDs) and the attainment of related Sustainable Development Goal (SDG) targets. The dialogues will focus on mobilizing commitments and contributions by the private sector toward national NCD responses to achieve SDG targets 3.4, 3.8, and 3b by improving access to and affordability of safe, effective, and quality-assured medicines and health technology products. Improving access to medicines and health technology products for the diagnosis, management, and treatment of diabetes is multifaceted and part of broader challenges to ensuring access to health care. It requires a robust health system that includes good leadership and governance, adequate

financing, access to information and evidence, quality service delivery, a strong health workforce, and equitable access to essential medicines and health technology products of assured quality, safety, efficacy, and cost-effectiveness.

Effective interventions will require enhanced collaboration and commitment for greater impact at country-level. In response, WHO will provide leadership and coordination in promoting and monitoring global action to fulfill the commitments made in these resolutions and will use the approach outlined below:

1. 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 NCDs, while giving due regard to managing conflicts of interest.
2. 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 NCDs.
3. Strengthen the collaboration between WHO, intergovernmental agencies, and non-state actors in accordance with the Framework of Engagement with Non-State Actors (FENSA) in a meaningful way towards the development of contributions and commitments by the relevant private sector entities to improve access to insulin and associated health technology products for the diagnosis, monitoring, and treatment of diabetes.
4. Coordinate and align international partners, including the private sector at country level, through national policies.
5. Promote and facilitate high-level discussions between CEOs and the Director-General of WHO, subject to commitments and contributions.
6. Register, monitor, and publish contributions from the pharmaceutical and associated health technology industry.

3. Proposed Coverage Targets

Resolution WHA74.4^{viii} requested that WHO develop recommendations to strengthen and monitor diabetes responses within national NCD programmes, including potential targets, for consideration by EB150 and WHA75. The Secretariat, supported by an academic group, developed an approach to setting diabetes coverage targets from which a proposal was drafted. The draft of proposed coverage targets was discussed at a technical consultation to seek additional expert advice on refining the methods and results. The expert consultation was held on 28-29 July 2021, and a technical paper will be submitted for publication^{ix}.

Following this process, the Secretariat developed a discussion paper, including the proposed five voluntary global diabetes coverage targets to be established and achieved by [2030^x](#):

1. 80% of people with diabetes are diagnosed;
2. 80% of people with diagnosed diabetes have good control of glycaemia;
3. 80% of people with diagnosed diabetes have good control of blood pressure;
4. 60% of people with diabetes receive statins;
5. 100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring.

4. Access to essential diabetes products

All people should have access, without discrimination, to nationally determined sets of promotive, preventive, curative, and rehabilitative basic health services and essential, safe, affordable, effective, and quality medicines. At the same time, it must be ensured that the use of these services does not expose users to financial hardship, particularly poor and vulnerable populations.

As discussed in section 3, the five proposed voluntary global diabetes coverage targets will contribute to the achievement of SDG target 3.4 (one-third premature mortality reduction from noncommunicable diseases). The five targets are also aligned with the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020^{xi}, the UN High-Level Meeting on Prevention and Control of Noncommunicable Diseases (2018)^{xii} and health systems strengthening for social protection and universal health coverage, as set out in United Nations General Assembly resolution 72/81. The role of the private sector is included in key documents as highlighted in the 23-24 February discussion paper Annex A^{xiii}, with the WHO NCD Global Action Plan also providing voluntary targets which include^{xiv}:

1. **Target 6:** 25% relative reduction in the prevalence of raised blood pressure, or contain the prevalence of raised blood pressure, according to national circumstances
2. **Target 7:** Halt the rise in diabetes and obesity
3. **Target 8:** At least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes
4. **Target 9:** 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities

Reaching any treatment target for diabetes will require that barriers in accessing insulin and associated health technologies are overcome. The WHO discussion paper, which includes the proposed coverage targets^{xv}, provides a target of 100% of people with type 1 diabetes having access to insulin and blood glucose self-monitoring and 80% of people with diagnosed diabetes having good control of glycaemia. All people with type 1 diabetes and about 60 million people with type 2 diabetes need insulin^{xvi}. Achieving these voluntary targets will

necessitate inclusive dialogue and multi-stakeholder collaboration and cooperation. The expected impact of the asks developed by WHO to the pharmaceutical and health technology industry to improve access to insulin and associated health products are briefly highlighted in the following section.

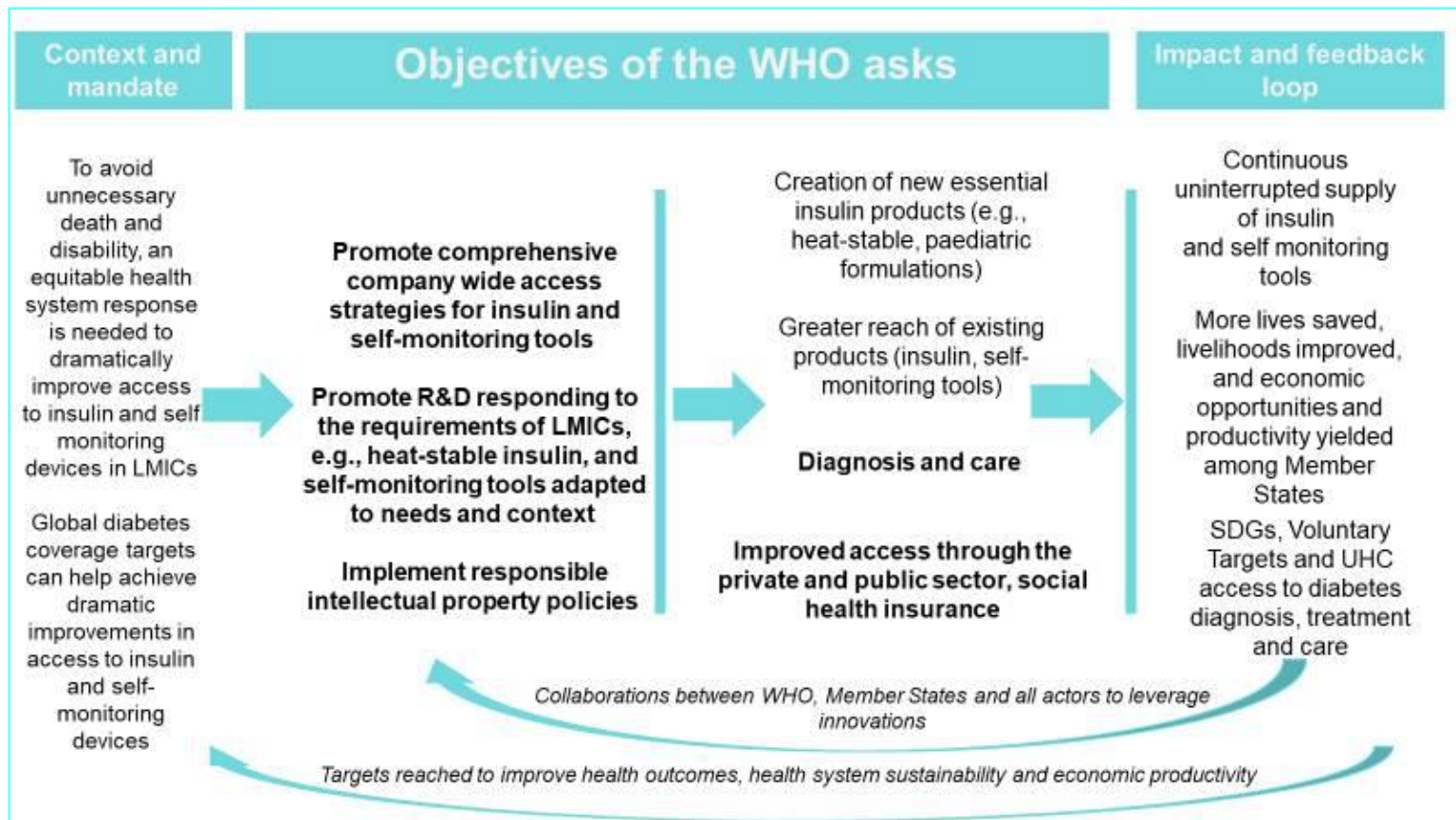
5. WHO asks to the pharmaceutical and associated health technology industry

The focus of WHO's asks to the private sector for commitments on diabetes is on global commitments and governance structures by companies, with the aim of dramatically improving access to essential diabetes medicines and health technology products in low-and middle-income countries (LMICs), as well as in humanitarian emergencies. This includes specific company activities at country-level to implement such corporate access strategies for essential diabetes products for all people at the bottom of the economic pyramid, in collaboration with Member States and other actors, in accordance with WHO guidance^{xvii}. WHO's asks aim to direct and maximize the potential contribution of the pharmaceutical and associated health care industry towards improving equitable and sustainable access to insulin and self-monitoring tools.

6. Rationale and objectives of the WHO asks

- 1) Promote comprehensive company-wide access strategies for insulin and glucose self-monitoring tools.
- 2) Promote access to insulin and glucose self-monitoring tools in the public and private sectors in LMICs, as well as in humanitarian emergencies.
- 3) Promote R&D responding to the requirements of LMICs, e.g. heat-stable insulin, and self-monitoring tools adapted to needs and context.
- 4) Develop and implement responsible intellectual property policies, where relevant.

The WHO asks focus on commitments and contributions that can have a significant impact on access in LMICs. Recognizing that many important activities in support of access fall under the responsibility of national governments and other actors (Figure 2), the asks are directed toward global policies and activities where the manufacturers are largely responsible and can provide a meaningful contribution, such as innovation, intellectual property, marketing, and pricing. The detailed explanation for each of the asks are available upon request. **Figure 1 below provides an illustration of the Theory of Change model, with those highlighted in bold representing key areas the asks will address.**



7. Monitoring progress

The WHA74.4 resolution marks an historic milestone in our collective efforts to address the global diabetes epidemic, urging Member States to raise the priority given to the prevention, diagnosis, and control of diabetes as well as the prevention and management of risk factors such as obesity. Another milestone is the establishment of the Global Diabetes Compact (GDC), which provides an opportunity for the global diabetes community to come together to address barriers to accessing insulin and associated health technologies. Opportunities exist to facilitate solutions to challenges. The WHO asks envisage all actors playing a role in meeting the voluntary targets and strengthening the diabetes response.

The asks follow the access framework used for the Access To Medicine Index (ATMI), as adapted to diabetes. The monitoring system will focus on measurable actions with a proven positive impact on access to medicines and is articulated in the discussion note for the development of an approach that can be used to register and publish contributions of the pharmaceutical and health technology industry. The approach will take into consideration the need to prevent additional or duplicative reporting by the biopharmaceutical originator manufacturers already reporting via ATMI, which collects relevant data from companies' websites, and information submitted to ATMI directly by the companies. It also draws on other published information databases and organizations such as WHO, Policy Cures Research, Access Observatory, and the Medicines Patent Pool. Similarly, the metrics developed for the biosimilar, generic, and health technology industries will draw on a panel of experts focusing on ease of reporting for measurable data and leveraging of existing data sources and analysis.

Figure 2: WHO current 31 asks (Annex 1) segmented across the product lifecycle with proposed roles and responsibilities for the pharmaceutical and health technology industries

Product Lifecycle; Components of access	R&D Innovation IPR policy	Manufacturing Licensing	Registration Quality assurance	Pricing Access Initiatives	Procurement Supply	Prescribing dispensing use
Proposed Roles and responsibilities	Primary Role: Private Sector				Supportive Role: Private Sector	
	WHO and Member States with support of international partners					
WHO current 31 asks: A= immediate B= short-term C= medium term D= long-term	A 4	A 1	A 2, 5, 6	B 7, 8	A 3	B 11
	B 3, 6	D 5	B 1, 5	C 2	C 3	C 5
	C 4, 6, 7					
D 2, 4						
	Company strategies, access plans, reporting: A 7, 8; B 2, 4, 9, 10; C 1; D 1, 3					

8. Annex 1

31 WHO asks from the pharmaceutical and associated health technology industry

A) Immediate Commitments from pharmaceutical and associated health technology industry
<ol style="list-style-type: none"> 1. Guaranteed ongoing production and uninterrupted supply of human insulin for LMICs 2. Participation in the WHO/UN prequalification programme for insulin and associated health technologies 3. Agreement to participate in UN or international procurement mechanisms, when these are established 4. Public disclosure of patent status of all diabetes products, including technologies 5. Rapid filing for registration of all essential diabetes products in LMICs, with public disclosure of registration status of all products, by country 6. Rapid reporting on product shortages by country and industry, substandard, and falsified products to national regulatory authorities and WHO

<p>7. Developing and publicly sharing access strategies in LMICs for diabetes products, with specific components such as: intellectual property strategy and licensing, ethical marketing and supply strategy, equitable access strategies (including pricing), humanitarian emergencies, and company incentives for access-to-medicines initiatives</p> <p>8. Report and participate in the reporting mechanism that WHO will use to register and publish contributions of the private sector</p>
<p>B) Short-term: Commitments from pharmaceutical and associated health technology industry encouraged by 2021</p>
<p>1. Submission of first file to WHO/UN PQ; or request review</p> <p>2. Development of first product-specific access plans for LMICs</p> <p>3. Data on heat stability of human insulin products shared with WHO</p> <p>4. Full transparency and public disclosure of all company commitments, actions, and outcomes in support of universal access to essential diabetes products with public reporting and to WHO on company progress in relation to these commitments</p> <p>5. Filing of regulatory submissions in LMICs</p> <p>6. Company commitment not to file or enforce patents in LMICs and some upper middle-income countries with high burden of disease (diagnostics and pens)</p> <p>7. Transparency about prices for public sector procurement in LMICs</p> <p>8. Transparency on all long-term product donations (geographic range, targets, actual volumes donated, and transition plans)</p> <p>9. Diagnostics trade association: prepare a report on company access initiatives on diagnostics, differential pricing, licensing, and donations</p> <p>10. Biosimilar trade association: prepare a report on company access initiatives including differential pricing, licensing, and donations</p> <p>11. Capacity strengthening in LMICs public and NGO sector, in diabetes diagnosis, care, and patient education, in collaboration with Member States and other actors, and adhering to WHO guidance ^{xviii}</p>
<p>C) Medium-term: Commitments from pharmaceutical and associated health technology industry encouraged by February 2022</p>
<p>1. A company-wide Access to Medicines and Devices Strategy, integrated into the global corporate strategy</p> <p>2. Intra-country differential pricing started in several LMICs, based on ability to pay by economic quintile</p> <p>3. Participation in UN and other international global and regional procurement schemes</p> <p>4. Research and development (R&D) responding to the needs of LMICs (e.g. heat-stable insulin, self-monitoring tools)</p> <p>5. Responsible sales and business practices (e.g. no sales-related salary incentives, no direct-to-consumer advertising of insulin analogues, no marketing of analogues in public sector of LMICs, public disclosure of all</p>

<p>value transfers to health professionals and relevant NGOs, and compliance controls)</p> <ol style="list-style-type: none"> 6. No evergreening of patents (e.g. insulin pens and testing devices) 7. Corporate Intellectual Property (IP) strategy that is conducive to access to medicines and in line with the company's public position on the Doha Declaration on TRIPS and Public Health, as well as including transparent non-exclusive voluntary licensing with wide geographic coverage through the Medicines Patent Pool or other mechanisms
<p>D) Long-term: Commitments from pharmaceutical and associated health technology industry encouraged by February 2023</p> <ol style="list-style-type: none"> 1. Corporate Access to Medicine Strategy, with details on management oversight with board-level representation, measurable targets, incentives, headquarters accountability for actions by national offices, and a routine monitoring system that can be independently assessed, with public disclosure of targets and outcomes of access-related activities 2. Public disclosure of company resources dedicated to R&D 3. Routinely-developed access plan for LMICs and vulnerable populations for all new diabetes products from Phase-2 onwards, with details on registration, supply, IP strategy, licensing, and affordability 4. Support to increasing national capacity in clinical trials in LMICs, following good practice standards 5. Capacity building in domestic manufacturing and supply chain management (including cold storage), following good practice standards

ⁱ <https://www.who.int/news-room/fact-sheets/detail/diabetes>

ⁱⁱ Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, Colagiuri S, Guariguata L, Motala AA, Ogurtsova K, Shaw JE, Bright D, Williams R; IDF

Diabetes Atlas Committee. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International

Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract 2019;157:107843

ⁱⁱⁱ <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>

^{iv} <https://www.who.int/news-room/fact-sheets/detail/diabetes>

^v <https://www.who.int/publications/i/item/WHOMVPEMPIAU2019.06>

^{vi} Basu S, Yudkin JS, Kehlenbrink S, Davies JL, Wild SH, Lipska KJ, Sussman JB, Beran D. Estimation of global insulin use for type 2 diabetes, 2018-30: a microsimulation analysis. Lancet Diabetes Endocrinol. 2019 Jan;7(1):25-33. doi: 10.1016/S2213-8587(18)30303-6. Epub 2018 Nov 21. Erratum in: Lancet Diabetes Endocrinol. 2019 Jan;7(1):e1. PMID: 30470520.

^{vii} World Health Organization. (2021). Report of expert and stakeholder consultations on the WHO Global Diabetes Compact.

World Health Organization. <https://apps.who.int/iris/handle/10665/340322>. License: CC BY-NC-SA 3.0 IGO

^{viii} https://apps.who.int/gb/ebwha/pdf_files/WHA74/A74_R4-en.pdf

^{ix} <https://www.who.int/publications/m/item/who-discussion-paper-draft-recommendations-to-strengthen-and-monitor-diabetes-responses-within-national-noncommunicable-disease-programmes-including-potential-targets>

^x <https://www.who.int/publications/m/item/who-discussion-paper-draft-recommendations-to-strengthen-and-monitor-diabetes-responses-within-national-noncommunicable-disease-programmes-including-potential-targets>

^{xi} <https://www.who.int/publications/i/item/9789241506236>

^{xii} https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

^{xiii} <https://www.who.int/news-room/events/detail/2021/02/23/default-calendar/dialogue-with-the-private-sector-on-medicines-and-technologies-for-diabetes-care-february-2021>

^{xiv} <https://www.who.int/publications/i/item/9789241506236>

^{xv} <https://www.who.int/publications/m/item/who-discussion-paper-draft-recommendations-to-strengthen-and-monitor-diabetes-responses-within-national-noncommunicable-disease-programmes-including-potential-targets>

^{xvi} Basu S, Yudkin JS, Kehlenbrink S, et al. (2019) Estimation of global insulin use for type 2 diabetes, 2018-30: a microsimulation analysis. *The Lancet Diabetes & Endocrinology* 7(1): 25-33. 10.1016/S2213-8587(18)30303-6

^{xvii} World Health Organization (2017) EMP policy brief series no. 2.0. 2017. Responding to industry programs to increase access to medicines and other health technologies in countries. Available from <https://apps.who.int/iris/bitstream/handle/10665/259359/WHOEMP-2017.04-eng.pdf;sequence=1>

^{xviii} World Health Organization (2017) EMP policy brief series no. 2.0. 2017. Responding to industry programs to increase access to medicines and other health technologies in countries. Available from <https://apps.who.int/iris/bitstream/handle/10665/259359/WHO-EMP-2017.04-eng.pdf;sequence=1>

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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