



Private Sector Dialogue on SDG 3.4 Noncommunicable diseases

***Strengthening the commitment and contribution of the private sector
(medicines & technology) to the NCD response***

Discussion paper to support Dialogue 1: Diabetes – Global Diabetes Compact

23-24 February 2021, Geneva, Switzerland (Zoom videoconference)

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Disclaimer

The World Health Organization (WHO) welcomes views from all participants prior to, during, and after the Dialogue to be held on 23 and 24 February 2021. The discussion paper 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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1. Executive Summary

United Nations Secretary-General, António Guterres, and World Health Organization (WHO) Director-General, Dr Tedros Adhanom Ghebreyesus, have announced that a Global Diabetes Compact will be launched on 14 April 2021 to mark the 100-year anniversary of the discovery of insulin for the treatment of diabetes. The centenary offers a window of opportunity for the global diabetes community to come together to reflect on addressing barriers in accessing insulin and associated health technology products. It is an opportune time to forge a common vision among all stakeholders to develop a multisectoral plan of action to address these barriers and ensure that no person living with diabetes goes untreated.

The WHO Department of Noncommunicable Diseases, in collaboration with the Division of Medicines and Health Products, is 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 a broader challenge of ensuring access to health care. It requires a robust health system which 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. The first dialogue in the series, which is being held on 23 and 24 February 2021, will focus on improving access to insulin as guided by the essential medicines list, including associated health technology products for diabetes as part of the Global Diabetes Compact. Subsequent dialogues will focus on other NCDs, such as cardiovascular disease, cancer, lung diseases, oral health, rehabilitation, sensory impairments and disability.

This first dialogue aims to encourage inputs, commitments, and contributions from the pharmaceutical and health technology product industries to support WHO's activities to improve access to medicines and health technology products for diabetes, including for the 14 April 2021 launch of the Global Diabetes Compact.

Dialogue Objectives - 23-24 February 2021

1. Provide an update on progress in the prevention and management of NCDs with a special focus on diabetes as part of the WHO Global Compact on Diabetes and initiatives to improve access to diabetes medicines and associated health technology products - major barriers, challenges, opportunities and solutions.
2. Strengthening 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 diagnosis, monitoring, and treatment of diabetes.
3. Discuss a preliminary draft set of WHO Secretariat asks for the pharmaceutical and associated technology product industries.
4. Discuss an approach to register the contribution of the pharmaceutical and associated health technology products industry.
5. Agree on achievements possible to improve access for people living with diabetes in 2021.

This background paper is supplemented by two annexes.

- [Annex A](#): enumerates the role of the private sector as included in key documents
- [Annex B](#): provides a brief background, including:
 - [Annex B1](#): Epidemiological context and access to essential diabetes medicines and health technology products
 - [Annex B.2](#): Roles and responsibilities
 - [Annex B.3](#): Documenting and reviewing contributions of the private sector to NCD product access
 - [Annex B.4](#): Summary of key private sector NCD access initiatives to date.

2. Dialogue 1: Diabetes – Global Diabetes Compact

2.1. Purpose

The private sector has a critical role in ensuring universal access to essential medicines and the associated health technology products for diabetes care. Following the September 2011 United Nations (UN) High-Level Meeting on the Prevention and Control of NCDs, the first in a series of three high-level meetings, WHO has led a series of consultations with Member States, UN agencies, NGOs, and the private sector to fulfil commitments made in the UN Political Declaration on NCDs. The three UN High-Level Meetings on the Prevention and Control of NCDs in 2011, 2014, and 2018 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 NCDs in order to reach SDG target 3.4 on NCDs, 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 NCDs to reach health and development objectives by contributing to further improving access to and the affordability of safe, effective, and quality medicines and associated health technology products in the prevention and control of NCDs.

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 toward the achievement of the nine voluntary NCD targets by 2025 and SDG target 3.4 by 2030.^a

^a Follow-up to the high-level meetings of the United Nations General Assembly on health-related issues A72/19 https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_19-en.pdf

2.2. Meeting background: building on past WHO efforts to improve access to essential noncommunicable medicines and associated health technology products for diabetes

This work builds on previous engagements between the private sector and WHO, including:

- A roundtable meeting under Chatham House rules (London, June 2018)[1]
- A supply chain consultation by WHO, United Nations International Children's Emergency Fund (UNICEF), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) to discuss global and regional supply chain strategies and initiatives related to global health (WHO HQ-Geneva, August 2018)
- An informal discussion on increasing access to NCD medicines and associated health technology products based on lessons learned from HIV, tuberculosis, malaria, and reproductive health, hosted by the WHO-led UN Inter-Agency Task Force on the prevention and control of NCDs and PATH as the secretariat for the Coalition for Access to NCD Medicines and Products (February 2020)

In addition, specifically for insulin, WHO has also initiated the following:

- Inclusion of insulin in WHO Prequalification Programme (PQ) in November 2019 [2]
- Meeting titled “Insulin and associated devices: access for everybody” in September 2020 [3]
- Expert and Multi-stakeholder consultations (Autumn 2020) leading to the announcement of the launch of the Global Diabetes Compact in November 2020 [4]

These activities also build on the latest report of the WHO Expert Committee on Selection and Use of Essential Medicines in 2019 [5], which makes specific reference to developing a response for insulin, and recommends:

- Establishment of a WHO technical working group on access to insulin
- Consultation with Member States and other stakeholders to identify/clarify barriers to access at country-level
- Strategies to address current regulatory barriers for biosimilar insulins, including the expansion of the WHO PQ Programme to include insulin
- Development of a comprehensive approach to address insulin prices, including new mechanisms for pooled procurement through UN procurement agencies and through providing support for countries
- Identification of evidence and research gaps regarding insulin use and supply, including setting-specific differences in clinical practice and health systems

2.3. Meeting structure: moderated breakout room sessions

The two-day meeting will feature three moderated breakout room sessions, divided into insulin originating manufacturers, insulin biosimilar manufacturers, and associated health technology product manufacturers.

The purpose of the breakout room sessions is to discuss:

- 1) The preliminary draft set of WHO Secretariat asks for the pharmaceutical and associated health technology product industries with focus on those outlined for April and August 2021.
- 2) An approach towards registering the contributions of the private sector towards these asks.

Each stream is encouraged to discuss the proposed preliminary draft set of WHO Secretariat asks for April and August 2021 and consider any of those in the tiers, namely (in section 2.4):

- Priority for the Global Diabetes Compact Launch for April 2021
- Short Term before the next meeting in August 2021
- Medium Term to work on, until February 2022
- Longer Term to work, on until February 2023

During these sessions, participants will be invited to express views on the preliminary draft set of WHO Secretariat asks, with the following guiding questions:

Day 1: 14:05 – 15:45

- 1) Which are the most meaningful and effective commitments and activities with the highest potential benefit to promote universal access to insulin and associated health technology products for the diagnosis, monitoring, and treatment of diabetes?
- 2) Which commitments for April and August 2021 represent clear achievements and targets possible to improve access to insulin and associated health technology products for the diagnosis, monitoring, and treatment of diabetes?

Day 2: 13:10 – 14:00

- 3) What are the critical features of the reporting mechanism for transparent reporting to ensure independent review, and accountability of company commitments and performance?

Each Moderator will have 10 minutes to report back to the plenary session on the key outcomes of the session. During the breakout sessions, participants are encouraged to be concise, to accommodate, and to invite as many views possible.

2.4. WHO draft list of preliminary asks

The focus of the preliminary asks by WHO to the insulin and associated health technology products sectors are:

- (1) 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).
- (2) 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 [6].

The draft summary list of the WHO preliminary asks is presented in Table 1. The table is divided into four tiers, starting with a list of eight asks to be made before or at the launch of the WHO Diabetes Compact and the 100th year anniversary of the discovery of insulin in 14 April 2021. The list continues with draft preliminary asks in three time-tiers: short-term, medium-term, and long-term. Within each time-tier, a number of prioritized preliminary asks for discussion are in **blue, bolded text**.

Table 1. WHO draft list of preliminary asks and activities to improve access to insulin and associated health technology products for the diagnosis, monitoring and treatment of diabetes

**Participants are encouraged to provide views on the prioritized preliminary asks highlighted for April and August 2021*

A) Commitments from pharmaceutical and associated health technology industry encouraged by 14 April 2021
<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 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 8. Report and participate in the reporting mechanism that WHO will use to register and publish contributions of the private sector

B) Short-term: Commitments from pharmaceutical and associated health technology industry encouraged by August 2021
<ol style="list-style-type: none"> 1. Submission of first file to WHO/UN PQ; or request review 2. Development of first product-specific access plans for LMICs 3. Data on heat stability of human insulin products shared with WHO 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 5. Filing of regulatory submissions in LMICs 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) 7. Transparency about prices for public sector procurement in LMICs 8. Transparency on all long-term product donations (geographic range, targets, actual volumes donated, and transition plans) 9. Diagnostics trade association: prepare a report on company access initiatives on diagnostics, differential pricing, licensing, and donations 10. Biosimilar trade association: prepare a report on company access initiatives including differential pricing, licensing, and donations 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 [6]
C) Medium-term: Commitments from pharmaceutical and associated health technology industry encouraged by February 2022
<ol style="list-style-type: none"> 1. A company-wide Access to Medicines and Health Technology Product Strategy, integrated into the global corporate strategy 2. Intra-country differential pricing started in several LMICs, based on ability to pay by economic quintile 3. Participation in UN and other international global and regional procurement schemes 4. Research and development (R&D) responding to the needs of LMICs (e.g. heat-stable insulin, self-monitoring tools) 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 value transfers to health professionals and relevant NGOs, and compliance controls) 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 Medicine Patent Pool or other mechanisms

D) Long-term: Commitments from pharmaceutical and associated health technology industry encouraged by February 2023

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

3. Conclusion

The dialogues with the private sector based on preliminary asks aim to promote appropriate contributions and support to Member States' national responses to preventing and controlling NCDs. Improving access to insulin and associated health technology products for the diagnosis, monitoring, and treatment of diabetes is complex, and interventions require collaboration and commitment for greater impact at country level. Through a WHO Global Diabetes Compact and the private sector dialogues, WHO will work across programs and with partners to support countries to mobilize resources and accelerate structural transformations that together will support the scale-up of essential diabetes medicines and associated health technologies, the inclusion of diabetes diagnosis and treatment in primary healthcare and universal health coverage packages, and the reduction of major population-level diabetes risk factors such as obesity. This represents a valuable opportunity to build public-private partnerships, as well as partnerships between governments, care providers, patient advocates, and non-governmental organizations as we move toward ensuring access to the 100-year-old medicine and its associated health technology products.

Annex A: Role of the private sector as included in key documents

SDGs: Support the achievement of the voluntary targets for 2025 and SDG targets for 2030

- SDG target 3.8: “Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all”
- SDG Target 3b: “Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health and, in particular, provide access to medicines for all”
- SDG 17.16: “Enhance the global partnership for sustainable development, complemented by multi-stakeholder partnerships that mobilize and share knowledge, expertise, technology and financial resources, to support the achievement of the sustainable development goals in all countries, in particular developing countries”
- SDG 17.17: “Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships”

WHO NCD Global Action Plan on the role of Multi-sectorial actors:

- “Exchange of information on best practices and dissemination of research findings in the areas of health promotion, legislation, regulation, monitoring and evaluation and health systems strengthening, building of institutional capacity, training of health personnel, and development of appropriate health care infrastructure.”
- “Promote the development and dissemination of appropriate, affordable and sustainable transfer of technology on mutually agreed terms for the production of affordable, safe, effective and quality medicines and vaccines, diagnostics and medical technologies, the creation of information and electronic communication technologies (eHealth) and the use of mobile and wireless devices (mHealth).
- “Strengthen existing alliances and initiatives and forge new collaborative partnerships as appropriate, to strengthen capacity for adaptation, implementation, monitoring and evaluation of the action plan for prevention and control of noncommunicable diseases at global, regional and national levels.”
- Specific targets included:
 - Target 6: A 25% relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure, according to national circumstances
 - Target 7: Halt the rise in diabetes and obesity
 - Target 8: At least 50% of eligible people receive drug therapy and counselling (including glycaemic control) to prevent heart attacks and strokes
 - Target 9: An 80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major NCDs in both public and private facilities

WHO: Recommendations from the report of the WHO Independent High-Level Commission on Noncommunicable Diseases:[8]

- “It is critical to note that responsibility also lies with the private sector to take initiative on and be accountable for these issues. Dialogue should be encouraged to identify contributions the private sector can make to public health goals. Public-private partnerships can be an important tool to contribute to effective NCD responses. It is important that conflicts of interests are adequately addressed, with transparency and focus required to ensure that public policies and public-private

partnerships are in the public interest, provide public value, and do not undermine the sustainability of financing health systems.”

- “Devise clear rules and rigorous approaches for the engagement with the private sector, preventing, identifying, and managing real or potential conflict of interest and ensuring that such engagements tie back to specific objectives in the national NCD response”
- “Increase in the number of dialogues with the private sector to secure more effective and meaningful contributions towards SDG target 3.4”
- “The promotion and independent assessments of voluntary commitments by the private sector in response to specific “asks” from WHO, considering WHO recommendations and guidance, to be recorded, made publicly accessible, monitored, evaluated, and followed up.”
- “The creation of a repository of case studies, good practices, approaches, accountability mechanisms, and evidence on effective models of appropriate engagement with the private sector, including case studies on how the private sector has supported governments in the implementation of national responses to prevent and control NCDs and mental health conditions.”

WHO GCM/NCD Working Group on how to realize governments’ commitments to engage with the private sector for the prevention and control of NCDs (Working Group 3.1):[9]

- Included specifically with regards to medicines and technologies: “Contribute to efforts to improve access to and affordability of medicines and technologies in the prevention and control of non-communicable diseases”

Overarching principles when engaging the private sector to strengthen its commitment and contribution to the implementation of national diabetes responses. FENSA as applied to diabetes:[10]

Any engagement of national governments with the pharmaceutical industry must:

- Demonstrate a clear benefit to people living with diabetes
- Conform with national diabetes programmes
- Respect the primary role and responsibility of governments in policy making and responding to the challenge of diabetes
- 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
- Effectively manage conflict of interest and other forms of risk to WHO
- Comply with the principles of transparency, openness, inclusiveness, accountability and amenability to independent verification
- Recognize the fundamental conflict of interest between some industries and public health
- Meets alignment criteria:
 - Aligned with relevant WHO treaties, frameworks, strategies, action plans and recommendations agreed by Member States
 - Takes into account lessons learnt from other similar NCD initiatives and frameworks engaging private sector entities, while recognizing the specificity of this efforts
- Meets impact criteria:
 - Pharmaceutical companies should focus primarily on contributions with the highest impact, in particular contributions related to activities that (a) directly minimize the potential negative impact of their core business on the global burden of noncommunicable diseases, and (b) improve universal access to NCD prevention and treatment
- Meets participation criteria:

- Geographical context and coverage, sector, and size should benefit the lowest-income countries first

Annex B: Background

B.1. Epidemiological context and access to essential diabetes medicines and health technology products

Noncommunicable diseases (NCDs) are responsible for 7 of the world's top 10 causes of death, according to the latest WHO Global Health Estimates 2019. This is an increase from 4 of the 10 leading causes in 2000. These estimates highlight the need for an intensified global focus on preventing and treating cardiovascular diseases, cancer, diabetes, and chronic respiratory diseases, as set out in the agenda for the United Nations (UN) Sustainable Development Goals (SDGs) [11]. The 2019 Global Monitoring Report for Universal Health Coverage (UHC) shows very limited progress—irrespective of income level—towards the Service Coverage Index (SCI) for NCDs since 2000 [12].

Box 1. Key Sustainable Development Goal (SDG) Targets

SDG 3.4: By 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being.

SDG 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

Diabetes is one of the five main NCDs. WHO estimated there were 422 million adults with diabetes in 2014 [13]. Ongoing work by WHO and other experts estimate that the number of people with type 1 diabetes is approximately 10 million individuals globally. Between 2000 and 2016, there was a 5% increase in premature mortality from diabetes [14]. In high-income countries, the premature mortality rate due to diabetes decreased from 2000 to 2010, but has since increased in 2010-2016. In low- and middle-income countries (LMICs), the premature mortality rate due to diabetes increased across both periods. Following from the 2011 United Nations High-Level meeting on NCDs, WHO developed the NCD Global Action Plan (GAP), which included a target of “80% availability of the affordable basic technologies and essential medicines, including generics, required to treat major noncommunicable diseases in both public and private facilities.” [15] Data on access to insulin and other related diabetes supplies show that this target is far from being met [13, 16-20].

In order to reach UHC in LMIC there is an urgent need to address the issue of access to essential diabetes diagnostics, medicines, and associated health technology products [21]. A key component of health services is access to medicines and associated health technology products. According to the regularly conducted WHO NCD Country Capacity Survey, 1 out of 2 countries have national guidelines available for all four of the main NCDs; 1 out of 2 countries have the six essential technologies for early detection, diagnosis and monitoring of NCDs available in primary care facilities of the public health sector; and 1 in 5 countries have 6 (or fewer) of the 11 essential medicines available [20].

Most NCDs, including diabetes, can be treated with off-patent medicines included in WHO's Model List of Essential Medicines (EML) [22, 23]. Included in the WHO Model EML for diabetes are: insulin (soluble and intermediate-acting insulin in vial form), metformin and gliclazide. Access to medicines is especially important for people with type 1 diabetes, for whom constant access to insulin is

necessary for survival. For people with diabetes, the high monthly cost of insulin is a significant barrier to treatment, especially for the poor and/or uninsured. Although access to insulin for people with type 2 diabetes is needed for better control versus survival it is estimated that globally one in two people with type 2 had access to the insulin they needed; in Sub-Saharan Africa, this number was found to be only one in seven people, highlighting the impact of poor health systems, access to insulin, and other tools necessary for the proper delivery of diabetes care [24].

Access to diabetes diagnostic and self-monitoring tools are also part of an essential package needed to ensure appropriate diagnosis and follow-up within the health system, as well as self-monitoring at home. In 2018, WHO published the first edition of the Model Essential Diagnostics List (EDL), with updates in 2019 and 2021 [25]. In the case of diabetes, tests included are those for glucose (urine dipsticks, glucometers and clinical chemistry and immunoassays), glycated haemoglobin (small analysers and clinical chemistry and immunoassays), and diabetic ketoacidosis (electro-analytical method handheld analyser). Other guidance produced by WHO, the Package of Essential NCD Interventions (PEN), focuses on primary healthcare (PHC) [26] and includes a set of diagnostic tools for the diagnosis and management of diabetes. However, both at facilities and for individuals, the tools needed are often unavailable and unaffordable, with access to diagnostic tools in WHO Service Availability and Readiness Assessments showing low availability of tools for diabetes [27]. In many LMICs, the monthly cost to families with a child with type-1 diabetes of blood glucose strips is 2-3 times the monthly cost of insulin.^b

B.2. Roles and responsibilities

Governments have the primary role and responsibility to generate effective responses for the prevention and control of diabetes^c, including, inter alia, by promoting increased access to affordable, safe, effective, and quality diabetes medicines and diagnostics and other associated health technology products^d, and progressively extend coverage to additional people with quality essential diabetes services and quality, safe, effective, affordable and essential diabetes medicines, vaccines, diagnostics and associated health technology products, with a view to covering all people by 2030^e.

Other stakeholders also share responsibility and can contribute in creating an environment conducive to preventing and controlling diabetes. The need to bring together civil society and the private sector to mobilize all their available resources for the implementation of national responses for the prevention and control of diabetes is widely recognized^f. Civil society's role is to advocate for governments to develop ambitious national diabetes responses and to contribute to their implementation, forge partnerships and alliances that mobilize and share knowledge, assess progress and hold governments and other actors accountable, provide services, and amplify the voices of and raise awareness about people living with and affected by diabetes^g.

While giving due regard to managing conflicts of interest, the private sector, ranging from micro-enterprises to cooperatives to multinationals, can contribute to further improving access to and the

^c In accordance with paragraph 3 of A/RES/66/2.

^d In accordance with paragraph 36 of A/RES/73/2

^e In accordance with paragraph 24(a) of A/RES/74/2

^f In accordance with paragraph 16 of A/RES/73/2

^g In accordance with paragraph 42 of A/RES/73/2

affordability of safe, effective and quality diabetes medicines and associated health technology products^h.

The role and responsibilities of Member States, supported by WHO, other UN organizations and international financial institutions

Member States have important roles to play to address the above-mentioned barriers to access to insulin and associated supplies. Some of these roles are detailed in Table 2.

Table 2 – Responsibilities of Member States

Governance	<ul style="list-style-type: none"> - Coordination of institutions and organizations responsible for ensuring access to quality-assured affordable essential diabetes products - Accountability towards patients and citizens in reporting on progress towards national targets
Marketing Registration	<ul style="list-style-type: none"> - Support and expand the WHO/UN Prequalification Programme - Strengthen national regulatory capacity - International regulatory collaboration and harmonization
Selection, Pricing and Reimbursement	<ul style="list-style-type: none"> - Routine monitoring of availability, price and affordability, with independent review and corrective actions based on results - Comprehensive set of policies to achieve affordable prices - National capacity to create medicines benefit packages that guide procurement and reimbursement of essential diabetes productsⁱ - Evidence based selection of diabetes products on national essential medicines lists (EML) - Development of national Essential Diagnostics Lists (EDL) - Inclusion of essential diabetes products in public and social health insurance packages
Procurement and Supply	<ul style="list-style-type: none"> - Good procurement practices, with effective and transparent quality assurance mechanisms - National and international procurement mechanisms - Strong supply chains, with regulated mark-ups
Prescribing	<ul style="list-style-type: none"> - Strengthened delivery of diabetes diagnosis and care - Development and use of adapted training and guidelines - Evaluation of the appropriate use of medicines and technologies, followed by corrective action
Dispensing	<ul style="list-style-type: none"> - Strengthened delivery of diabetes care at PHC level - Innovative delivery models, including role of pharmacists and pharmacies
Use	<ul style="list-style-type: none"> - Training of health professionals in diabetes diagnosis and care - Education and empowerment of persons living with diabetes - Guidelines for the use of self-blood glucose monitoring

^h 44(f) of A/RES/73/2

ⁱ Diabetes products are human insulin (originator and biosimilar) and self-monitoring tests

B.3. Documenting and reviewing contributions of the private sector to NCD product access

Pharmaceutical and health technology product companies lead a variety of initiatives that aim to improve access to medicines and associated health technology products. These initiatives can be categorized as: access initiatives; health systems strengthening and capacity building initiatives; and financing of Ministry of Health activities. Access initiatives generally focus on provision of medicines or medical devices through donation, reduced prices or special discounts. Health system strengthening and capacity building initiatives help provide resources required to strengthen institutions and workforce capacity, typically to improve access to pharmaceuticals and health technology products. Financing of activities which fall under the mandate of the government is another approach that is used.

The United Nations General Assembly has 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 [28].

In order to address the increasing number of individual access initiatives by the pharmaceutical industry and a lack of a global framework or guideline to assist Member States, WHO has developed technical guidance highlighting both opportunities and challenges of these programs, and proposing the following checklist of key considerations for such initiatives [6, 29]: alignment with countries' national health and development plans, needs, capacity, laws and policies; strong mechanisms to ensure financial, performance, and public accountability; strong risk management and mitigation strategies; and clear transitioning plans for long-term sustainability.

B.4. Summary of key private sector NCD access initiatives to date

Since the UN High Level Meeting in 2011, the private sector has developed and implemented initiatives for NCD product access. To date, the most visible company initiatives in the area of access have predominantly focused on donation programs, differential pricing, and health system strengthening efforts.

It is not within the remit of WHO to evaluate, review, endorse or recommend the Access to Medicines Foundation (AMF) Index or Access Accelerated Initiative. However, as two of the most significant reporting and evaluation efforts of NCD access initiatives by the private sector to date, this section of the annex briefly outlines their efforts and findings, as they are likely to come up in discussion in the breakout sessions and may provide some lessons learned for efforts going forward.

The AMF reports in their longitudinal study over 2008-2018 that the issue of access to medicines has gained prominence within the pharmaceutical industry over the past 10 years, and describes how pharmaceutical companies have used three main tools to address access to medicines, namely differential pricing, product licensing, and donations [30]. Several companies run small-scale access initiatives; from 17 access to medicine initiatives in all disease categories in 2000, an increase to 102 initiatives in 2015 has been seen [31]. Forty-eight percent of these initiatives used a donation strategy and 44% used a price reduction strategy. Of great concern is that only seven initiatives were evaluated, and most of these evaluations were of low or very low quality [31]. It is promising to see that an increasing number of companies are developing additional business models targeting low-income populations, with a specific access strategy as part of the global corporate strategy.

The AMF further states that the main focus of increased access to medicine has been on Neglected Tropical Diseases (NTDs), vaccines, HIV/AIDS, malaria and tuberculosis [30]. From a Research and Development (R&D) perspective, medicines for NCDs account for the largest proportion of the pipeline included in the latest Access to Medicines (ATM) Index of 2021, but the focus of this is on the needs of high-income countries (HICs) and not LMICs. Moreover, fewer than 30% of new NCD products in late development stage are covered by any specific access plans directed at access and affordability for poor and vulnerable populations [32].

To date, the main access initiative for NCD medicines developed by the pharmaceutical sector is Access Accelerated (AA). AA was launched at the World Economic Forum (WEF) 2017 in Davos to “lead private sector engagement in driving access to NCD prevention, treatment and care”, with the aim to reach the UN SDGs and the 2030 target to reduce premature NCD deaths by one-third. AA is a Chief Executive Officer-led initiative hosted by the IFPMA. In 2019, AA reported 27 member companies and five implementing partners, the World Bank Group, City Cancer Challenge, NCD Alliance, PATH, and World Heart Federation, involved in different initiatives [33]. In AA’s latest annual report on its third year of activity (2019), 107 company initiatives addressing NCDs in 136 countries are mentioned. Within AA, a monitoring and evaluation platform has been developed with Boston University, creating the Access Observatory [34]. The Access Observatory was developed and funded by Access Accelerated, which is hosted by and funded by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

At the end of 2019 the Access Observatory reported 75 active access programs operating in 114 countries [34]. The report highlights that many programs were focused on a few countries in sub-Saharan Africa and Southeast Asia with these using “community activities that aimed to increase awareness of disease symptoms and treatment options; health service strengthening activities, most notably health provider training courses; and direct health service delivery” approaches [34]. Of these initiatives, 19% focused on diabetes. One of the weaknesses mentioned by the Access Observatory was a lack of reporting on any initial needs assessments carried out prior to starting the program. This is important given WHO guidance to Member States on such initiatives [6].

Specifically, different support programs with a component of insulin donation as well as blood glucose meters and strips, such as the Life for Child Program and Novo Nordisk’s Changing Diabetes in Children Program, have shown improvements in the diagnosis and treatment of type 1 diabetes in LMIC countries [35]. It should be noted that donations, price reductions, and other support programmes by biosimilar companies and associated device manufacturers have not been reported. Independent analysis of these programs and their effects on health systems and global markets has not been undertaken systematically, which is a limitation in the monitoring and evaluation of these efforts.

4. References

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