Access to essential medicines, diagnostics and medical devices for NCDs

PRIORITIES FOR THE 4TH UN HIGH-LEVEL MEETING ON NCDs











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In 2024, we find ourselves at a critical juncture. The world is off-track in meeting the global target of 80% availability and affordability of essential medicines and basic technologies for noncommunicable diseases (NCDs) by 2025. In most low- and middle-income countries (LMICs), access to essential NCD medicines, vaccines, diagnostics and medical devices for NCD treatment and care remains inadequate, increasing health inequities globally.

These barriers also impact access to medicines to treat complications and comorbidities, palliative care, and strategies to address antimicrobial resistance (AMR). Within countries, marginalized groups, including the economically disadvantaged, rural populations, and ethnic minorities, often face limited access to medicines and basic technologies due to their unavailability and/or unaffordability, as well as populations impacted by humanitarian emergencies.

Addressing these disparities and strengthening health systems and the healthcare workforce are essential for overcoming these barriers and enhancing access to NCD medicines, which is integral to universal health coverage (UHC), promoting health equity, improving health outcomes, and reducing the global NCD burden.

Access to medicines has been addressed at global level since the World Health Organization (WHO) first defined the concept of 'essential medicines' in 1977. WHO Member States have since made commitments (see Annex)*, reflected and reaffirmed in political declarations and resolutions, to improve global access to medicines. Access to diagnostics and other medical devices has only recently gained attention—starting with the first WHO resolution on diagnostics in 2023, nearly 50 years after the definition of essential medicines. Given these commitments and frameworks, this brief focuses on medicines, while recognizing that people with NCDs need a full package of services for adequate treatment, care, and management.

The 4th UN High-Level Meeting on NCDs is a unique chance to renew focus on access to essential medicines for NCDs and set the agenda to address barriers to diagnostics and medical devices. The gap in commitments for NCDs is particularly wide (*see Annex*).

As global organizations working on access to medicines and technologies, we urge Member States to commit to strengthening health systems by advancing UHC. This means fully integrating essential medicines, diagnostics and medical devices for NCDs into UHC, with a focus on the public health sector, especially primary care, and ensuring referral pathways to specialist care when necessary. The following five recommendations are intended to support WHO Member States in making meaningful progress towards this goal and accelerating action on existing commitments.

The NCD Alliance, NCD Policy Lab and the University of Geneva developed this policy brief in collaboration with the following organizations:







































^{*}Statements, resolutions and political declarations on global commitments on access to medicines and technologies for NCDs have been compiled in the annex of this document.

Promote and facilitate the transfer of technology, skills and know-how for essential NCD medicines and technologies:

Expand voluntary licensing agreements in line with the <u>Doha Declaration</u> and <u>WHO's Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property</u>, particularly through initiatives such as the Medicines Patent Pool'; scale up the production of affordable, quality-assured NCD medicines, diagnostics, and health technologies.



- 2. Ensure affordability of essential NCD medicines and health products for governments and individuals by:
 - → Developing national pricing policies for medicines and technologies to reduce out-of-pocket payments, in line with <u>WHO guidance</u>:
 - Assess the impact of reference pricing, cost-effectiveness and health technology assessments, tendering, negotiations, and pooled procurement;
 - Assess the impact of regulations for mark-ups in the supply and distribution chain, and tax exemptions;
 - Facilitate differential pricing and public-private partnerships to ensure that essential NCD medicines and technologies are affordable and accessible to all.
 - → **Promoting pricing transparency:** Publicly share information on the net prices of key NCD medicines and technologies, including marketing costs, subsidies, and incentives, as well as patent status and clinical trial data, as called for at the 72nd World Health Assembly, as a key mechanism for ensuring fair pricing of medical products.
 - → Supporting the local production of quality assured medicines and health technologies: Promote and incentivize the establishment of affordable and quality-assured local manufacturing to boost the production of affordable generics and biosimilars, ensuring sustainable access to essential NCD treatments.

Access to essential medicines, diagnostics and medical devices for NCDs presents challenges for many LMICs.

The WHO has also published various technical briefs with language on licensing, technology transfer and the Medicines Patent Pool (MPP). See Road Map for Access to Medicines, Vaccines and Other Health Products (2019–2023), which calls for the 'Promotion of public health-oriented licensing agreements and transparency regarding the patent status of existing and new health technologies; Information provided on country experiences promoting public health approaches in the implementation of health-related provisions of the TRIPS agreements, including relevant TRIPS flexibilities and intellectual property management; a review of mechanisms and incentives for access to affordable health technologies enabled by publicly funded research and development; support for the expansion of the Medicines Patent Pool to patented essential medicines and patented medicines included in WHO treatment guidelines through identification of potential products for licensing.

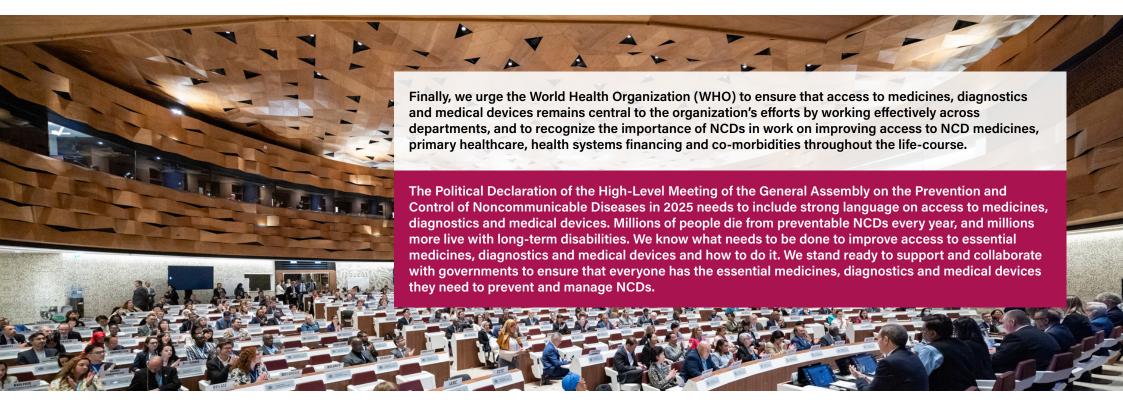
See also WHO Technical Report Series, No. 1035 The Selection and Use of Essential Medicines (2021), which mentions the MPP: 'The Committee reiterated the important role of the Medicines Patent Pool in facilitating affordable access to essential medicines through negotiation of public health-oriented licences with patent holders to allow generic manufacture and supply of medicines in low- and middle-income countries. The Committee welcomed the expansion of the Medicines Patent Pool's mandate to patented essential medicines beyond HIV, hepatitis C and tuberculosis, to include Executive summary xxv other small molecules included in the Model Lists, and medicines with strong potential for future inclusion.'

3. Promote equitable access to NCD medicines and health products, by:

- → Ensuring their rational selection and procurement in UHC health benefit packages, aligned with national health burdens, and based on up-to-date guidelines and essential medicine and diagnostics lists, aligned with WHO guidance;
- → Implementing the <u>Package of Essential NCD</u> Interventions (PEN), and the <u>WHO 'Best Buys'</u>

- 4. Promote regulatory harmonization for faster access to NCD medicines and technologies:
 - → Streamline regulatory processes across countries to accelerate approval for essential NCD treatments.
 - → Explore the expansion of WHO prequalification to cover a broader range of NCD medicines and technologies, including cancer therapies, diabetes medications, and cardiovascular medicines, as well as diagnostic tests to ensure their quality, safety, efficacy, and affordability, particularly in low-and middle-income countries.
 - → Streamline registration processes via <u>stringent</u> regulatory authorities and collaborative registration, for WHO accelerated approval.

- 5. Strengthen forecasting, supply chain management and resilience and enhance regional and national procurement of NCD medicines and technologies:
 - → Build capacity to improve planning and forecasting to ensure the consistent availability of essential NCD medicines and technologies.
 - → Strengthen initiatives such as pooled procurement to reduce the cost of NCD medicines and technologies through bulk purchasing and negotiated pricing agreements, increase efficiency in their distribution and ensure quality.



WHA77. Photo: WHO/Pierre Albouy

Overview of access barriers and solutions for access to NCD medicines by disease area

DIABETES

Diabetes affects hundreds of millions worldwide, yet over half of those living with the condition remain undiagnosed.² Every year, this gap in diabetes diagnostics contributes to 82,000 avoidable deaths and 4.57 million disability-adjusted life years (DALYs). A major contributing factor is limited access to essential diagnostics such as blood glucose tests.

The barriers are multiple: lack of testing available at primary care facilities, insufficient inclusion of diagnostics under universal health coverage (UHC), and systemic infrastructure challenges. These include shortages in the global health workforce, gaps in training for healthcare providers, unreliable quality assurance systems, and limited public awareness of the symptoms and risks of diabetes.



Event supporting diabetes diagnosis and treatment with Burundi NCD Alliance.

For those already diagnosed, access to treatment, including insulin and supplies, blood glucose self-testing devices and other antidiabetic medicines, can be similarly limited. Global data reveals that half of all individuals living with type 2 diabetes cannot access prescribed insulin. In some regions, including parts of Africa, this figure climbs to 86%. Those using other glucose lowering medications to treat type 2 diabetes face barriers to access or inappropriate treatment. Reasons include; high or unaffordable prices, fragile supply chains that lead to unavailability, and limited UHC coverage for insulin, supplies and self-glucose testing devices.



Nupur Lalvani, founder of Blue Circle Foundation, in mini-film <u>Going</u> Full Circle.

Addressing these challenges requires urgent action. Access to quality-assured diagnostics devices, insulin, self-glucose testing devices and other diabetes medicines must be integrated into UHC schemes. Supply chains must be monitored to ensue uninterrupted supplies of medicine and devices. For diagnostics, decentralized point-of-care (POC) devices can bring testing closer to many, pre-market validation of diagnostic tools can ensure reliability, and strengthened laboratory networks and robust quality assurance systems can further address gaps.

CANCER

Cancer is a leading cause of death worldwide,³ with nearly 10 million deaths and 20 million new cases reported in 2022.⁴ The World Health Organization forecasts that most cancer deaths in the next decade will occur in low- and middle-income countries (LMICs), which do not have the health systems and infrastructure necessary for early detection and treatment.

Achieving global cancer control requires sustained access to affordable, quality essential medicines and diagnostics. However, gaps remain: a 2019 study of 137 national essential medicines lists revealed that many lacked alignment with the WHO Model List of Essential Medicines. Similarly, a 2020 global analysis of 157 national cancer control plans found that only 14% included pathology and lab medicines. ⁵

² Fleming KA, et al. 2021. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021;398(10315):1997-2050. doi: 10.1016/S0140-6736(21)00673-5.

³ World Health Organization (WHO). Cancer Fact Sheet. Available from https://www.who.int/news-room/fact-sheets/detail/cancer. Accessed December 11, 2024.

⁴ Global Cancer Statistics 2022: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries.

⁵ Parra-Herran C, Romero Y, Milner D. 2021. Pathology and Laboratory Medicine in cancer care: A global analysis of national cancer control plans. International Journal of Cancer. 2021; 148: 1938–1947. https://doi.org/10.1002/ijc.33384

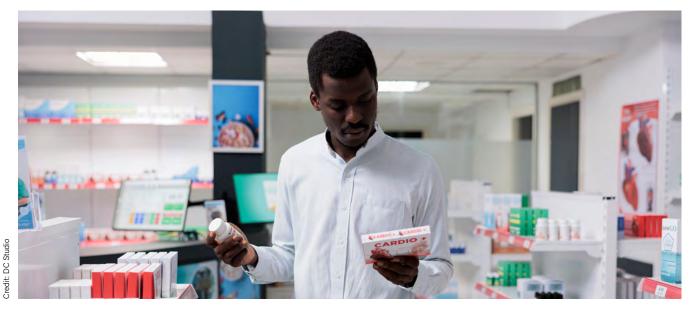
Barriers to access include high costs of cancer medicines, with some exceeding \$100,000 annually, making them inaccessible to patients.⁶ Other challenges include inadequate diagnostics and pathology services, insufficient regulatory frameworks, inefficient procurement and frequent stock-outs.⁷ Quality is another challenge, as seen with substandard asparaginase, for childhood leukaemia, placing 70,000 children at risk globally.⁸

Ensuring availability of cancer medicines and diagnostics, as outlined in WHO guidance, is crucial. This must be accompanied by efforts to strengthen regulatory capacity, implement robust pricing policies and ensure appropriate use. To address these barriers, the Access to Oncology Medicines (ATOM) Coalition—led by UICC and comprising over 40 global partners, was created to tackle the issues of affordability, availability, and appropriate use of cancer medicines in low- and lower-middle-income countries (LLMICs).

CARDIOVASCULAR DISEASES

Cardiovascular diseases (CVDs) are a leading cause of death, fuelled by gaps in access to essential medicines and diagnostics, especially in low- and middle-income countries (LMICs). High blood pressure and elevated cholesterol alone are responsible for 10.9 and 3.6 million deaths annually, yet many individuals in LMICs remain underserved.

Only 32% of people with CVDs in LMICs receive antihypertensive medications, and 16% take statins for secondary prevention. For primary prevention, just 31% of hypertensive adults are treated for high blood pressure, and only 7% of statin-eligible patients receive the medications they need.⁹ Compounding this crisis, 61% of hypertension cases go undiagnosed. Reducing this diagnostic gap to just 10% could save over 526,000 lives and prevent 10.2 million disability-adjusted life years (DALYs) every year.¹⁰



LMICs face wide disparities in the pricing and availability of essential medicines.

⁶ Leighl NB, Nirmalakumar S, Ezeife DA, Gyawali B. 2021. An Arm and a Leg: The Rising Cost of Cancer Drugs and Impact on Access. American Society of Clinical Oncology educational book. American Society of Clinical Oncology. 2021;41:1-12. doi:10.1200/EDBK_100028.

⁷ Union for International Cancer Control (UICC). Cancer control in Africa: paving the way to Universal Health Coverage. [Online]. Cited 2021 Feb. 23. Accessed December 12, 2024. https://www.uicc.org/resources/cancer-control-africa-paving-way-universal-health-coverage.

Furneaux R and Margottini L. Which Brands of Asparaginase are Substandard? The Bureau of Investigative Journalism.

Available from https://www.thebureauinvestigates.com/explainers/which-brands-of-asparaginase-are-substandard/. Accessed November 19, 2023.

²hu JZ, Manne-Goehler J, Agarwal A, et al. 2023. Medication use for cardiovascular disease prevention in 40 low- and middle-income countries. J Am Coll Cardiol. 2023;81(6):620-622. doi:10.1016/j.jacc.2022.12.003; Marcus ME, Manne-Goehler J, Theilmann M, et al. 2022. Use of statins for the prevention of cardiovascular disease in 41 low-income and middle-income countries: a cross-sectional study of nationally representative, individual-level data. Lancet Glob Health. 2022;10(3). doi:10.1016/S2214-109X(21)00551-9.

Forouzanfar MH, Liu P, Roth GA, et al. 2017. Global burden of hypertension and systolic blood pressure of at least 110 to 115 mm Hg, 1990-2015. JAMA. 2017;317(2):165-182. doi:10.1001/jama.2016.19043; Zheng J, Wang J, Zhang Y, et al. 2022. The global burden of diseases attributed to high low-density lipoprotein cholesterol from 1990 to 2019. Front Public Health. 2022;10:891929. doi:10.3389/fpubh.2022.891929

The 2022 Under Pressure report by Resolve to Save Lives and Médecins Sans Frontières highlights the huge disparities in the pricing and availability of hypertension drugs in LMICs.¹¹ With focused resources and technical support, health workers can improve drug inventory reporting, forecasting, and procurement practices to ensure that essential CVD medicines and diagnostics are available and affordable. Pooled regional procurement has the potential to reduce CVD medicine and diagnostic prices, especially for small countries with limited negotiating power.

Local manufacturing of CVD medicines and diagnostics has the potential to improve access, ensure medicine quality, and overcome the supply chain disruptions seen during peak Covid-19. Global control of high blood pressure and high cholesterol together will reduce the number of premature CVD deaths and lead to longer, more productive lives for millions of people at risk.

NEUROLOGICAL DISORDERS

Neurological disorders such as epilepsy, Parkinson's disease, multiple sclerosis, and stroke reveal stark inequities in access to essential medicines. In low-income countries, 75% of epilepsy patients are untreated due to high costs, limited availability in rural areas, and fragmented supply chains. Treatments for Parkinson's disease are similarly scarce, with key medications often absent from healthcare facilities.

These disparities extend to multiple sclerosis, for which disease-modifying therapies (DMTs) are largely unavailable in low-income settings. Stroke patients also face severe shortages of key medicines like warfarin, driven by poor registration processes, supply chain inefficiencies, and unaffordable pricing. These gaps leave millions at risk of preventable disability or death.

Addressing these challenges requires registering multiple formulations and generic brands of neurological medicines, integrating these into national essential medicines lists (NEMLs), and including them in reimbursement schemes.¹² Streamlining supply chain forecasting, registering and importing paediatric formulations, regulating mark ups and using reference pricing will also be critical to ensuring consistent availability, particularly for antiseizure medications. Equally important is the registration and import of pediatric formulations, often overlooked but essential for younger patients. Investments in quality assurance systems and supply chain improvements are critical to reducing shortages and ensuring consistent access to safe medicines.





¹¹ Resolve to Save Lives. Under Pressure: Strategies to improve access to medicines to treat high blood pressure in low- and middle-income countries. Available from https://resolvetosavelives.org/cardiovascular-health/hypertension/under-pressure/. Accessed November 19, 2023.

¹² WHO Model List of Essential Medicines, 23rd List, 2023. 2023. Accessed November 19, 2023. https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02

CHRONIC RESPIRATORY DISEASES

Chronic obstructive pulmonary disease (COPD) and asthma rank as the third leading cause of death globally, with the heaviest burden falling on lowand middle-income countries (LMICs). Essential medications, such as long-acting bronchodilators for COPD and combination rapid-onset beta-agonist-corticosteroid inhalers for asthma, remain out of reach for many in these regions. This is often due to barriers such as inadequate in-country registration, lack of availability through the national dispensary or on national medicines lists. Where they are available, high costs limit patient access.

Where safe and effective inhaled therapies are unavailable, patients often rely on less effective and potentially harmful treatments sourced from local dispensaries. The quality assurance of locally produced medications is further hindered by lack of resources and expertise, leaving many patients without reliable care.

Tackling these challenges requires a multifaceted approach. Updating the WHO's PEN guidelines to include the latest evidence-based inhalation therapies can help LMICs align their treatment protocols with best practices. Bulk purchasing, prequalification, and promoting generic alternatives can reduce costs.

Training healthcare providers, especially in primary care settings, in diagnosing and managing asthma and COPD is essential to improving treatment outcomes.

Additionally, member states should prioritize the inclusion of key therapies—such as long-acting bronchodilators, inhaled corticosteroids, and combination inhalers—on national reimbursement lists. Paediatric care should also be addressed by including metered-dose inhalers with spacers for children. WHO should also support the transition to environmentally safe inhalers without compromising patient access.



Air pollution is aggravating the NCD burden. especially for chronic respiratory diseases.

ANNEX

Existing global commitments on access to medicines for NCDs

This table compiles statements, resolutions and political declarations where Member States and WHO have made global commitments on access to medicines and technologies for NCDs, so that existing commitments are clearly presented.

TOPIC	STRONG LANGUAGE ON ACCESS TO NCD MEDICINES		
	Resolution/Declaration	Wording	
Selection			
UHC (Universal Health Coverage)	Political Declaration of the 3 rd High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases (2018)	35. 'Strengthen health systems and reorient them towards the achievement of universal health coverage and improvement of health outcomes, and high-quality, integrated and people-centred primary and specialized health services for the prevention, screening and control of non-communicable diseases and related mental health disorders and other mental health conditions throughout the life cycle, including access to safe, affordable, effective and quality essential diagnostics, medicines, vaccines and technologies, and palliative care, and understandable and high-quality, patient-friendly information on their use, as well as health management information systems and an adequate and well-trained and equipped health workforce.'	
Pricing /Reimburs	sement		
Intellectual Property/TRIPS	Political Declaration of the 3 rd High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases (<u>2018</u>)	36. Promote increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies, reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as amended, and also reaffirming the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and notes the need for appropriate incentives in the development of new health products.	
	United Nations Secretary-General Report on the progress made in the prevention and control of NCDs (Third Report) (2013)	(f) To strengthen international cooperation in support of national, regional and global plans for the prevention and control of non-communicable diseases, inter alia, by promoting the development and dissemination of appropriate, affordable and sustainable transfer of technology on mutually agreed terms and the production of affordable, safe, effective and quality medicines and vaccines.	

ТОРІС	STRONG LANGUAGE ON ACCESS TO NCD MEDICINES			
	Resolution/Declaration	Wording		
Pricing /Reimbur	sement			
Pricing	Bridgetown Declaration on NCDs and Mental Health (2023)	In accordance with Paragraph 14 of the 2023 Bridgetown Declaration on NCDs and Mental Health, SIDS undertake the following Actions, in line with their national priorities:		
		 Lead health financing reforms in SIDS for enhanced efficiency gains (including through taxes and ending of government subsidies for unhealthy commodities that contribute to NCD risk factors) that allocate adequate funds to cover all people in SIDS by 2030 with climate change-resilient and environmentally-sustainable quality essential health services and quality, safe, effective, affordable, and essential medicines, vaccines, diagnostics and health technologies for the prevention and control of NCDs and the promotion, protection and care of mental health conditions across the continuum of care; Establish financial and social protection programs, such as social health insurance, including essential benefits packages, to enable equitable access to quality services, medicines, and health technologies, especially for persons 		
		and groups in situations of vulnerability based on their inputs and contributions;		
	United Nations Secretary-General Report on the progress made in the prevention and control of NCDs (Second Report) (2011)	 It is recommended that Member States (g) Revitalize primary health care and promote access to cost-effective interventions for non-communicable diseases, including access to essential medicines and technologies; It is recommended that the private sector (b) Contribute to improved access and affordability for the essential medicines and technologies for non-communicable diseases. 		
Procurement				
Procurement and distribution	Political Declaration of the High- Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases (2011)	According to national priorities, give greater priority to surveillance, early detection, screening, diagnosis and treatment of non-communicable diseases and prevention and control, and to improving the accessibility to the safe, affordable, effective and quality medicines and technologies to diagnose and to treat them; provide sustainable access to medicine and technologies, including through the development and use of evidence-based guidelines for the treatment of non-communicable diseases, and efficient procurement and distribution of medicines in countries; and strengthen viable financing options and promote the use of affordable medicines, including generics, as well as improved access to preventive, curative, palliative and rehabilitative services, particularly at the community level.		
	Political Declaration of the High- Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases (2011)	provide sustainable access to medicines and technologies, including through efficient procurement and distribution of medicines in countries.		

TOPIC STRONG LANGUAGE ON ACCESS TO NCD MEDICINES		TO NCD MEDICINES
	Resolution/Declaration	Wording
Procurement		
	United Nations Secretary-General Report on the progress made in the prevention and control of NCDs (Second Report) (2011)	61. Governments, in collaboration with the private sector, should give greater priority to treating chronic diseases and improving the accessibility of medicines to treat them. Important mechanisms for providing sustainable access to medicines include the development and use of evidence-based guidelines for the treatment of non-communicable diseases, efficient procurement and distribution of medicines in countries, the establishment of viable financing options and promoting the use of generic medicines. Subsidies should be established to help the poorest segments of the population. In addition, the development of new medical treatments and technology is needed. Necessary policies regarding research and development, intellectual property and other areas can be modelled after successes that improved access to new medicines for HIV/AIDS and tuberculosis.
Supply		
Regulatory approval and	Bridgetown Declaration on NCDs and Mental Health (2023)	In accordance with Paragraph 14 of the 2023 Bridgetown Declaration on NCDs and Mental Health, SIDS undertake the following Actions, in line with their national priorities:
harmonization		 Strengthen regional and national regulatory mechanisms for the production, prequalification and trading of essential medicines and technology by including essential and quality NCD medicines, diagnostics, and products in national essential medicines and diagnostics lists and in national drug procurement systems;
Private sector	Political Declaration of the 3 rd High-Level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases (2018)	 44. 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: (a) – (e) (f) 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.

Commitments on access to medicines that are applicable to NCDs

This table compiles statements, resolutions and political declarations where Member States and the WHO have made global commitments on access to medicines in general (not specific to NCDs) to show where specific mentions of NCD medicines could have been included.

TOPIC COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs			
	Resolution/Declaration	Language	Recommendation
General	United Nations Secretary- General Report on the progress made in the prevention and control of NCDs (Fourth Report) (2017)	 Initiatives to improve access to good-quality essential health-care services and to safe, effective, good-quality and affordable essential medicines and vaccines for the prevention and control of non-communicable diseases have not been scaled up in the majority of developing countries. Challenges to the implementation of the "best buys" and other recommended interventions for the prevention and control of NCDs: Lack of access for all to affordable, safe, effective and good-quality essential medicines and vaccines for non-communicable diseases. The Working Groups of the Global Coordination Mechanism on the Prevention and Control of NCDs addressed the question: Improve access to affordable medicines for non-communicable diseases. 	The report highlighted that initiatives to improve access to essential medicines for NCDs have not been scaled up in most developing countries. Despite this, specific recommendations on scaling up access to NCD medicines were not integrated into the final recommendation. This represents a missed opportunity to incorporate NCD-specific access targets into the recommendations.
Procurement			
Procurement	WHA 76.5 Strengthening diagnostics capacity (<u>2023</u>)	Considering alternative procurement mechanisms, including pooled procurement, bundled procurement – including reagents and accessories – public-private partnerships (PPP), leasing, etcetera.	WHA72.8 and WHA67.22 urge member states to strengthen cost-effective procurement and governance of pharmaceutical systems. Both focus on essential medicines but fail to emphasize NCD medicines specifically. There could have been a mention of access to NCD medicines, particularly in developing pooled procurement mechanisms for NCDs, similar to those used for infectious diseases, which could reduce costs and improve access in LMICs.
	WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products (2019)	URGES Member States to strengthen national capacities for cost-effective procurement.	
	WHA67.22 Access to essential medicines (2014)	URGES Member States to strengthen good governance of pharmaceutical systems – including regulatory, procurement and distributions systems.	
	A/Res/61.21 Global strategy and plan of action on public health, innovation and intellectual property (2008)	 The actions to be taken to improve delivery and access are as follows: (6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system () (g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate. 	
Local production	WHA 74.6 Strengthening local production of medicines and other health technologies to improve access (2021)	 URGES Member States, where appropriate, based on the national context: (1) to strengthen their leadership, commitment and support in promoting the establishment and strengthening of quality and sustainable local production of medicines and other health technologies that follows good manufacturing practices. 	

TOPIC	COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation
Technology T	ransfer		
Technology transfer	A/Res/61.21 Global strategy and plan of action on public health, innovation and intellectual property (2008)	(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products.	A/Res/61.21 Global Strategy on IP and Health and the Pandemic Agreement Proposal (Article 11) focus on preventing the abuse of intellectual property rights and facilitating technology transfer, but only in the context of pandemic-related products in the context of pandemic-related products. Specifically mentioning NCD medicines would facilitate technology transfer for essential NCD medicines and vaccines, particularly for LMICs. Moreover, people living with NCDs can be particularly vulnerable to infectious diseases.
	Proposal for a Pandemic Agreement, as of 15 November 2024, Article 11 (<u>2024</u>)	 Article 11. Transfer of technology and know-how for the production of pandemicrelated health products. 1. Each Party shall, in order to enable the sustainable and geographically diversified production of pandemic-related health products for the attainment of the objective of this Agreement, as appropriate: (a) Promote and otherwise facilitate or incentivize transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries, through measures which may include, inter alia, licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures.* 	
	Political Declaration of the High-Level Meeting on Universal Health Coverage (2023)	Promote increased access to affordable, safe, effective and quality medicines, including generics, vaccines, diagnostics and health technologies, reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirming the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and notes the need for appropriate incentives in the development of new health products.	
Innovation			
	WHA 76.5 Strengthening diagnostics capacity (2023)	"Recognizing the increasing burden of noncommunicable diseases and the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2030, which includes addressing the lack of diagnostics for noncommunicable diseases through multistakeholder collaborations to develop new technologies that are affordable, safe, effective and quality controlled, and improving laboratory and diagnostic capacity and human resources."	

^{*}This text does not have final approval from all Member States.

TOPIC	COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation
Supply			
Supply chain	WHA 69.25 Addressing the global shortage of medicines and vaccines (2017)	Recognizing that the continuous supply of quality, safe, effective and affordable medicines is one of the building blocks of every well-functioning health system, which requires a reliable supply chain;	WHA69.25 and WHA72.8 address strengthening supply chain capacities for medicines and vaccines. Ensuring
	WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products (2019)	URGES Member States to improve national capacities for supply chain management	a continuous supply chain for NCD medicines could have been mentioned, given their increasing global demand. A/Res/61.21 highlights monitoring supply
Distribution	A/Res/61.21 Global strategy and plan of action on public health, innovation and intellectual property (2008)	 Countries should monitor carefully supply and distribution chains and procurement practices to minimize costs that could adversely influence the price of these products and devices. Recommendation to the Secretariat: Develop tools and policy guidance on monitoring affordability along the supply and distribution chain when delivering health products to patients. 	- chains for essential health products. An explicit focus on ensuring efficient and cost-effective distribution of NCD medicines could improve access in vulnerable regions.
	WHA 69.25 Addressing the global shortage of medicines and vaccines (2017)	URGES Member States to ensure that best practices for medicines and vaccines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;	
	WHA67.22 Access to essential medicines (2014)	Requests the Director-General to support Member States in developing and implementing their national medicines policies and supply systems especially with regard to regulation, financing, selection, procurement, distribution, pricing, reimbursement and use, in order to increase their efficiency and ensure the access to safe, effective and quality-assured essential medicines, including high price essential medicines;	

TOPIC	COMMITMENTS ON ACCES	SS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation	
Pricing/Reim	bursement			
Pricing	WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products (2019)	Requests the Director General to support research on and monitor the impact of price transparency on affordability and availability of health products, including its effect on differential pricing, especially in LMICs and small markets, and provide analysis and support to Member States in this regard as appropriate. And To continue WHO's efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products.	WHA72.8 and WHA67.22 do not specifically address the pricing challeng of NCD medicines. A/Res/61.21 emphasizes differential pricing policies but again lacks direct mention of NCD medicines. Encouraging differential pricing for	
	WHA67.22 Access to essential medicines (2014)	Requests the Director General to support Member States in developing and implementing their national medicines policies and supply systems especially with regard to regulation, financing, selection, procurement, distribution, pricing, reimbursement and use, in order to increase their efficiency and ensure the access to safe, effective and quality-assured essential medicines, including high price essential medicines.	NCD medicines, as has been done for infectious diseases like HIV/AIDS, could improve affordability in LMICs.	
	A/Res/61.21 Global strategy and plan of action on public health, innovation and intellectual property (2008)	Recommendation 21: The WHO Secretariat to provide guidance to Member States on promoting and monitoring transparency in medicine prices and on implementation of pricing and reimbursement policies. (d) Encourage pharmaceutical companies and other health-related industries to		
		consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law.		
		(e) Consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing.		
Financial protection	Political Declaration of the High-Level Meeting on Universal Health Coverage (2023)	Pursue efficient health financing policies, including through close collaboration among relevant authorities, including finance and health authorities, to respond to unmet needs and to eliminate financial barriers to access to quality, safe, effective, affordable and essential health services, medicines, vaccines, diagnostics and health technologies, reduce out of pocket expenditures leading to financial hardship and ensure financial risk protection for all throughout the life course, especially for the poor and those who are vulnerable or in vulnerable situations, through better allocation and use of resources, with adequate financing for primary health care, in accordance with national contexts and priorities;		

TOPIC	COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation
Transparency	WHA72.8 Improving the transparency of markets for medicines, vaccines, and other health products (2019)	 URGES Member States in accordance with their national and regional legal frameworks and contexts: (1) to take appropriate measures to publicly share information on the net prices of health products; (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality; 	Improving the transparency of markets for all medical products would have spillover benefits for NCD medicines.
		 (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives; 	
		 (4) to facilitate improved public reporting of patent status information and the marketing approval status of health products; 	
		(5) to improve national capacities, including through international cooperation and open and collaborative research and development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including health products for the diseases that primarily affect them, as well as for product selection, cost-effective procurement, quality assurance, and supply chain management.	
	Political Declaration of the High-Level Meeting on Universal Health Coverage (2023)	Improve availability, affordability and efficiency of health products by increasing transparency of prices of medicines, vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies across the value chain, including through improved regulations and building constructive engagement and a stronger partnership with relevant stakeholders, including industries, private sector and civil society, in accordance with national and regional legal frameworks and contexts, to address the global concern on high prices of some health products and in this regard encourage WHO to continue its efforts to biennially convene the Fair Pricing Forum with Member States and all relevant stakeholders to discuss the affordability and transparency of prices and costs relating to health products.	

TOPIC	COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation
Selection			
Regulatory approval and harmonization	A/Res/61.21 Global strategy and plan of action on public health, innovation and intellectual property (2008)	Recommendation 23: The WHO Secretariat to continue to support Member States in strengthening national regulatory capacity, regional harmonization and other collaborative initiatives for improving access to new and existing quality-assured medicines and health products.	Including NCD-specific regulatory frameworks and capacity building would ensure timely access to essential NCD medicines in developing countries.
		(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system () Strengthen the WHO prequalification programme.	
	WHA 67.20 Regulatory system strengthening for	URGES Member States (1) to strengthen national regulatory systems, including – as appropriate and voluntarily – by:	
	medical products (2014)	 (a) undergoing self-evaluations, including with WHO support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory system strengthening, including through WHO-coordinated institutional development plans; 	
		 (b) collecting data on regulatory system performance to enable analysis and benchmarking for improved systems in the future; 	
		 (c) developing strong legal foundations and political leadership to underpin a regulatory system with a clear focus on patient safety and transparency in decision- making; 	
		 (d) identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance; 	
		• (e) developing needed competencies as an integral part of, although not limited to, the health workforce, and encouraging the development of the regulatory field as a profession;	
		 (f) facilitating the use of relevant guidance and science-based outputs of WHO expert committees and good regulatory practices at the national, regional and international levels; 	
		 (g) devising and implementing strategies to address the increasing complexities of supply chains; 	
		 (2) to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products; 	

TOPIC	COMMITMENTS ON ACCESS TO MEDICINES THAT ARE APPLICABLE TO NCDs		
	Resolution/Declaration	Language	Recommendation
Regulatory approval and harmonization	WHA 67.20 Regulatory system strengthening for medical products (2014)	(3) to promote international cooperation, as appropriate, for collaboration and information sharing, including through electronic platforms;	
		(4) to support regulatory systems for medical products with appropriate funding as an essential component of the health system;	
		(5) to support regulatory system strengthening as an essential component of the development or expansion of local or regional production of quality, safe and efficacious medical products;	
		(6) to achieve access to and rational use of quality, safe, efficacious and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious and affordable medical products;	
		(7) to support WHO's institutional capacity relating to promoting access to and rational use of quality, safe, efficacious and affordable medical products in the context of universal health coverage;	
		(8) to strengthen the national and regional initiatives of regulatory authorities to improve regulatory capacities for review of medical products, promoting WHO's long-term objective of supporting the strengthening of national regulatory authority capacity among Member States;	
		(9) to support WHO's prequalification programme, including exploring modalities in consultation with Member States1 for improved sustainability of this critical programme;	
		(10) to identify the need to strengthen regulatory system capacity, collaboration and cooperation in the technically complex areas where substantial gaps may still exist, such as the regulation of biotherapeutic products, blood products, and in vitro diagnostics;	
	WHA67.22 Access to essential medicines (2014)	URGES Member States to provide adequate resources, as required, for the development and implementation of comprehensive national medicine policies, as appropriate, to strengthen good governance of pharmaceutical systems – including regulatory, procurement and distributions systems – and to coordinate responses to address the complex and interrelated activities that affect access to essential medicines, in order to improve their availability, affordability, quality and rational use.	
		In WHO's assessment instrument for measuring transparency in the public pharmaceutical sector (document WHO/EMP/MAR/2009.4), "good governance" refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, in particular medicines regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption.	



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