

Drugs for Neglected Diseases initiative (DNDi)

Briefing note for the 75th Session of the World Health Organization Regional Committee for Africa – Lusaka, Zambia, August 2025

Overview

The Drugs for Neglected Diseases initiative ([DNDi](#)) is a not-for-profit research and development (R&D) organization, in official relations with the World Health Organization (WHO). It discovers, develops, and delivers new treatments for neglected patients. Since our creation in 2003 by public research institutions from Kenya, Brazil, France, India, and Malaysia, alongside Médecins Sans Frontières (MSF), and WHO TDR, we have developed 13 new and improved treatments for six deadly diseases, saving millions of lives through an alternative, collaborative, not-for-profit R&D model.

DNDi, in partnership with WHO, jointly established the Global Antibiotic Research and Development Partnership ([GARDP](#)), which has since become an independent organization. GARDP plays a vital role in supporting Member States to implement the Global Action Plan on Antimicrobial Resistance. DNDi is also an active member of the Global Accelerator for Paediatric Formulations Network ([GAP-f](#)), which promotes innovation of and access to quality, safe, efficacious, and affordable medicines for children.

With offices in Nairobi and Kinshasa, DNDi's wide footprint in Africa includes work in over 20 countries with more than 50 partner institutions and networks. These collaborations and initiatives have contributed to the successful development and rollout of nine new treatments for neglected diseases, including for sleeping sickness, leishmaniasis, paediatric HIV, and malaria. Furthermore, through proactive, equitable partnerships, DNDi contributes to strengthening the African R&D ecosystem.

This briefing note outlines DNDi's comments on the following agenda items for consideration by WHO AFRO Member States at RC75, to be held in Lusaka, Zambia, from 25–27 August 2025:

- **Agenda item 8:** Accelerating progress in the health and well-being of women, children, and adolescents by transforming health systems in the African Region ([Document AFR/RC75/5](#))
- **Agenda item 16.2:** Progress report on the implementation of the Strategy for scaling up health innovations in the African Region ([Document AFR/RC75/INF.DOC/2](#))
- **Agenda item 16.7:** Progress report on the Framework for health systems development towards universal health coverage in the context of the Sustainable Development Goals in the African Region ([Document AFR/RC75/7](#))
- **Agenda item 16.8:** Regulation of Medical Products in the African Region Regulation of Medical Products in the African Region ([Document AFR/RC/INF.DOC/8](#))
- **Agenda item 16.13:** Progress report on implementing the regional strategy for community engagement, 2023–2030 in the WHO African Region ([AFR/RC75/INF.DOC/13](#))

Agenda item 8: Accelerating progress in the health and well-being of women, children, and adolescents by transforming health systems in the African Region

DNDi's comments focus on flagship 2 (ii): 'Ensure access to quality health products and technologies that are of sufficient quality to make a difference in the lives of those who need them.' We highlight the critical gap in research and development (R&D) for health tools tailored to the specific needs of women and children. This is an area frequently overlooked and continues to hinder progress towards achieving SDG targets. **Member States have already committed to support R&D to address the unmet needs of children and pregnant and lactating women via the [resolution](#) 'Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality to achieve SDG targets 3.1 and 3.2'** adopted at WHA77. We request that Member States take note of the following issues during their discussions.

1. The impact of neglected diseases on women and children

Neglected tropical diseases (NTDs) continue to impact 1.65 billion people worldwide and often affect women and children disproportionately. **For instance, cutaneous leishmaniasis (CL), endemic in Ethiopia, Kenya, and Sudan, places an outsized burden on women by causing disfiguring skin lesions, often on the face and limbs, which leave permanent scars that can be particularly stigmatizing.**¹ Women affected by the disease often face rejection and isolation that impacts many aspects of their lives, particularly interpersonal relationships, social engagement, work, and marriage.

Schistosomiasis, particularly female genital schistosomiasis (FGS), is highly prevalent in several African countries, including Tanzania, Malawi, Zambia, and Ghana. The waterborne disease is transmitted through contact with contaminated water used for bathing, washing, and drinking. **Women are more exposed through daily activities like washing clothes and collecting water from contaminated sources.** FGS causes vaginal lesions and bleeding and increases susceptibility to HIV and HPV. Trachoma, another NTD, significantly affects women, given their function as primary caregivers with more frequent contact with infected children. Women are two to four times more likely to suffer permanent blindness due to repeated infection.²

At least 1.2 billion children and adolescents (<25 years) – one in six people globally – are affected by one or more NTDs.³ Children represent 34% of the 20 million DALYs that result from NTDs. Children affected by NTDs face profound and long-lasting harms, including disfigurement, stunted growth, chronic pain, malnutrition, and premature death. For example, in 2022, more than half of those infected with visceral leishmaniasis were less than 15 years old.⁴ School-aged children are also at higher risk of schistosomiasis due to their involvement in activities such as swimming or fishing in infected waters.

The impact of NTDs on children extends beyond physical health. NTDs can impact cognitive development, negatively affect school attendance, and lead to social stigma, with severe mental health consequences.

¹ Bennis I, De Brouwere V, Belrhiti Z, Sahibi H, Boelaert M. Psychosocial burden of localised cutaneous leishmaniasis: a scoping review. *BMC Public Health*. 2018;18:1236. Available from: <https://doi.org/10.1186/s12889-018-5260-9>

² Elizabeth A. Ochola, Susan J. Elliott and Diana M. S. Karanja, The Impact of Neglected Tropical Diseases (NTDs) on Women's Health and Wellbeing in Sub-Saharan Africa (SSA): A Case Study of Kenya, *nt. J. Environ. Res. Public Health* 2021, 18(4), 2180. Available from: <https://doi.org/10.3390/ijerph18042180>

³ The Lancet Child & Adolescent Health. A vote for childhood NTD elimination. *Lancet Child Adolesc Health*. 2024;8(3):161. Available from: [https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642\(24\)00022-1/fulltext](https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(24)00022-1/fulltext)

⁴ World Health Organization. Global leishmaniasis surveillance, 2022: assessing trends over the past 10 years. *Weekly Epidemiological Record*. 2022;97(40):471-487. Available from: <https://www.who.int/publications/i/item/who-wer9840-471-487>

2. The urgency of including women and children in research

Despite some recent improvements, clinical research focusing on women and children remains limited.

From 2000 to 2019, only about 6% of trials on clinicaltrials.gov and 16.7% on the World Health Organization International Clinical Trials Registry Platform (ICTRP) included paediatric participants, even though children make up 27% of the global population.⁵ As a result, children are left without access to safe, effective medicines that are specifically approved and formulated for paediatric use.

Many medicines are not available or adapted for children in terms of dosage, formulation, or safety. Each year, millions of children die prematurely or suffer from treatable diseases because many medicines are not available or adapted to their needs in terms of dosage, formulation, or safety. The treatment needs of children have long been an afterthought in profit-driven drug development because children represent lower-volume markets.⁶ Medicines are generally first developed for adults, and the development of paediatric formulations starts only after, if at all. One stark example is that the development of optimal paediatric formulations lagged 20 years behind that of adults.

Despite the heavy burden of NTDs in children, only 22 of the 47 medications available for NTDs are labelled for paediatric use.⁷ To improve access to paediatric medicines, we encourage Member States to support WHO's Global Accelerator for Paediatric Formulations (GAP-f). Its [2025–2030 strategy](#) aims to fast-track child-friendly formulations by strengthening the global R&D ecosystem for paediatric medicines to accelerate the development, approval, and uptake of child-friendly formulations.

Significant knowledge gaps persist in how medicines affect biological females, largely due to a historical focus on males in biomedical research. This limits the interpretation and generalizability of findings and underscores the need for inclusive study designs that consider sex as a biological variable.⁸ Women, especially those who are pregnant or lactating, are often excluded from clinical trials due to safety concerns, perceived legal risks, and regulatory uncertainty.⁹ As a result, there is insufficient evidence on the safety and efficacy of treatments during pregnancy and lactation, perpetuating a cycle of exclusion.

Women of childbearing potential and pregnant and lactating women should be protected through research, and not from research. Recent efforts are beginning to address this imbalance. Together with its partners, DNDi has proposed a safe and ethical clinical trial recruitment framework for women of childbearing potential. These and other proposals to ensure responsible strategies in gender-responsive drug development should be integrated into the actions needed to meet the SDG targets.

Including women and children in clinical research is essential to developing safer, more effective treatments, as biological differences influence how medications work. Without inclusive research, health tools and tailored interventions for women and children will remain out of reach, jeopardizing progress toward health and gender-related SDGs. Member States should support, as a political priority, the R&D

⁵ Bencheva V, Mann NK, Rombey T, Pieper D, Schmiedl S. Barriers and facilitators to enrollment in pediatric clinical trials: an overview of systematic reviews. *Syst Rev* 2024; 13:283. Available from: <https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-024-02698-8>

⁶ Watts G. WHO launches campaign to make drugs safer for children. *BMJ*. 2007 Dec 15;335(7633):1220. Available from: <https://doi.org/10.1136/bmj.39423.581042.DB>

⁷ Rees CA, Hotez PJ, Monuteaux MC, Niescierenko M, Bourgeois FT. Neglected tropical diseases in children: an assessment of gaps in research prioritization. *PLoS Negl Trop Dis*. 2019;13(1):e0007111. Available from: <https://journals.plos.org/plosntds/article?id=10.1371/journal.pntd.0007111>

⁸ U.S. Department of Health and Human Services, National Institutes of Health, Office of Research on Women's Health. Sex as a Biological Variable. Updated April 16, 2024. Available from: <https://orwh.od.nih.gov/sex-as-biological-variable>.

⁹ Concept Foundation; Medicines for Malaria Venture. Advancing Inclusion of Pregnant and Lactating Women in Clinical Trials in Africa: Symposium Report, Kigali, Rwanda, 18–19 March 2025. 2025 Jun. Available from: https://www.conceptfoundation.org/wp-content/uploads/2025/06/Concept-Foundation_MMV_PLW-in-clinical-trials-Symposium-Meeting-Report.pdf

needed to develop appropriate, affordable, and effective treatments to meet women and children's unique needs, including for pneumonia, malaria, diarrhoeal disease, and NTDs.

The WHO African region [technical report](#) on accelerating progress in the health and well-being of women, children, and adolescents underscores that strong health systems are essential for improving reproductive, maternal, newborn, child, and adolescent health (RMNCAH) in the African region. We welcome the report's call for transforming health systems through three strategic flagships because R&D is a cross-cutting enabler of all three.¹⁰

We urge Member States to:

- **Support implementation of the resolution 'Acceleration towards the Sustainable Development Goal targets for maternal health and child mortality in order to achieve SDG targets 3.1 and 3.2';**
- **Support research to understand sex- and gender-based barriers in accessing healthcare services,** including diagnosis and treatment, promote interventions that address these barriers, and ensure that health research is a core component of RMNCAH and UHC frameworks;
- **Support implementation of the recently launched GAP-f five-year strategy (2025–2030)** to ensure that safe, effective, quality, and affordable paediatric formulations are developed and made available to children who need them;
- **Ensure that regulatory requirements are streamlined and harmonized** to support the inclusion of groups currently underrepresented in research in ways that are ethical and appropriate, including children and pregnant and lactating women;
- **Encourage the rapid and coordinated development of age-appropriate treatment formulations** through public health-focused collaborations between academic institutions, key paediatric networks, product development partnerships, and public and private R&D organizations; and
- **Promote the collection, utilization, and reporting of sex- and age-disaggregated data** in ongoing and future programmes and research.

Agenda item 16.2: Progress report on the implementation of the Strategy for scaling up health innovations in the African Region

DNDi takes note of the WHO Africa Region's progress [report](#) on the implementation of the Strategy for scaling up health innovations in the African Region. The report provides valuable insights into the status of innovation ecosystems across Member States. DNDi's comments focus on the need to prioritize discovery, development, and local manufacturing of health technologies as Member States work towards their 2030 targets set out in the Strategy.

1. Supporting the full spectrum of innovation – including discovery and development of health tools in addition to manufacturing.

Medical innovation can significantly improve the prevention and treatment of health conditions affecting vulnerable and marginalized communities in Africa by increasing efficiency and advancing equity and improved health outcomes. To achieve the ambitions of the regional innovation strategy, investments are needed across the full R&D continuum, from human and physical infrastructure for basic and translational research to robust surveillance systems that guide R&D priority setting. The Lancet

¹⁰ Research and development can cut across the three flagships as follows: 1) **Stimulating Investments:** R&D must be prioritized in national health budgets and investment plans, with dedicated domestic funding for innovation; 2) **Capacitating Health Systems:** Effective regulation, local manufacturing, and resilient supply chains depend on sustained R&D investment; and 3) **Delivering Quality Services:** Evidence-based service packages require ongoing research to remain responsive and effective.

Commission on the future of health in sub-Saharan Africa¹¹ underscored the need for Africa-based, home-grown innovations to deliver better health outcomes. For this to be successful, Member States need to make key strategic shifts to prioritize innovation – a key ambition of the strategy. This will also enable the Africa region to discover, develop, and produce new health tools.

As part of the innovation strategy¹², Member States set a target that, by 2030, 80% will have established well-functioning country-level forums and innovation hubs to facilitate the generation of health innovations and effective knowledge management. Further, Member States set a 2030 target for at least 80% of countries to adopt educational and training approaches, along with other strategic investments, to support the development and widespread diffusion of new health innovations. Since setting these goals, however, major shifts have emerged in the health ecosystem. Many donors and pharmaceutical companies have further scaled back their support for infectious disease research and development alongside drastic cuts to global aid budgets for health and R&D. This retreat threatens progress toward critical health innovations, especially in regions such as Africa, where the burden of disease remains high.

Given these shifts, it is more important than ever for countries in the region to prioritize and invest not only in manufacturing and production but in early-stage research, discovery, and development of new health tools. Member States should prioritize building local capacity for innovation to ensure that the region can create the health tools it needs to respond to future challenges and protect vulnerable populations. These foundational building blocks are critical to expanding sustainable, responsive scientific ecosystems in Africa.

2. Regulation

As of now, only seven Member States have achieved WHO Maturity Level 3 in regulatory systems, which indicates a well-functioning and integrated regulatory system. This falls short of the regional target, which aims for 75% of Member States to have mechanisms in place to fast-track the review and approval of health innovations. The slow progress in establishing robust regulatory mechanisms limits the ability to rapidly scale up access to new health tools. We encourage Member States to strengthen regulatory systems and accelerate health innovation by reviewing and revising national laws and treaties, particularly to better utilize TRIPS flexibilities. We also urge countries to systematically scale up innovations by integrating them across all tiers of the health system to maximize their impact, establish accountability frameworks, and develop sustainability plans that include human resource capacity. Concrete measures should also be taken to strengthen regulatory systems to accelerate the review and approval of innovations, as detailed in our comments on Agenda item 16.8, below.

3. Local Manufacturing

Africa produces only 3% of global pharmaceuticals and 0.1% of vaccines, despite representing 17–20% of the world's population.¹³ This highlights the urgent need for investment in local manufacturing. The WHO

¹¹ Agyepong IA, Sewankambo N, Binagwaho A, Coll-Seck AM, Corrah T, Ezeh A, et al. The path to longer and healthier lives for all Africans by 2030: the Lancet Commission on the future of health in sub-Saharan Africa. *Lancet*. 2017;390(10114):2803–59. doi:10.1016/S0140-6736(17)31509-X. Available from: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)31509-X/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)31509-X/fulltext).

¹² World Health Organization Regional Office for Africa. Strategy for scaling up health innovations in the African Region. Report of the Secretariat, Seventieth session, Regional Committee for Africa, Virtual session, 25 August 2020. Brazzaville: WHO Regional Office for Africa; 2020 Aug 25. Available from: <https://www.afro.who.int/sites/default/files/2021-02/AFR-RC70-11%20Strategy%20for%20scaling%20up%20health%20innovations%20in%20the%20African%20Region.pdf>

¹³ Sakthivel Selvaraj. Ensuring access to medicines in East Africa: Lessons from India. Observer Research Foundation; 2019. Available from: <https://www.orfonline.org/research/ensuring-access-to-medicines-in-east-africa-lessons-from-india>

mRNA Technology Transfer Hub in South Africa is a key milestone in this regard, but regional readiness remains low.¹⁴

Local manufacturing enhances health sovereignty, reduces reliance on global supply chains, boosts innovation and equity, and improves access to critical health technologies. Member States should strengthen local production of diagnostics and essential medicines and adopt policies that support technology transfer, open science, and regional collaboration.

While the African Union and Africa CDC have outlined strategies, and WHO has a mandate to support local production, greater financial investment is needed. Countries should integrate innovation capacity and manufacturing into health strategies and align regulatory and procurement policies. Long-term investment is essential to building technical capacity, expanding R&D, and developing reliable sources of affordable active pharmaceutical ingredients.

Scaling up innovation is key to achieving UHC and health equity. We commend the WHO Regional Office for Africa's efforts and urge increased public funding to support sustainable, locally driven health innovation.

We urge Member States to:

- **Prioritize and invest not only in manufacturing and production, but also in early-stage research, discovery, and development** to assist in expanding and building local and regional capacity for innovation for the creation of health tools;
- **Develop national innovation strategies aligned with UHC goals** and institutionalize mechanisms to evaluate health demands, match innovations, and integrate them into health systems;
- **Strengthen regulatory system capacity as a strategic pillar for accelerating health innovations**, including by investing in skilled personnel, adopting international regulatory standards, and streamlining approval processes;
- **Promote inclusive innovation ecosystems** that engage academia, civil society, and the private sector;
- **Scale up local production by strengthening upstream R&D**, facilitating technology transfers, and improving regulatory systems; and
- **Promote regional and international partnerships to share knowledge, transfer technology, and engage stakeholders** in supporting local production and coordinated manufacturing across African countries.

Agenda item 16.7: Progress report on the Framework for health systems development towards universal health coverage in the context of the Sustainable Development Goals in the African Region

DNDi welcomes the WHO Africa Region's progress [report](#) on advancing health systems towards universal health coverage (UHC), noting that WHO estimates show that 39 Member States (83%) are expected to increase their UHC service coverage index between 2021 and 2025. However, disparities persist. We urge Member States to consider the following issues in their deliberations.

¹⁴ Only three Member States have completed training in mRNA vaccine manufacturing, and partnership agreements are still pending in many countries.

Research and development for health tools is essential to achieving UHC and SDGs

The true test of UHC is the extent to which it addresses the needs of vulnerable populations, such as those affected by neglected and socially determined diseases. These diseases often disproportionately impact vulnerable populations, including children, pregnant women, people with pre-existing health conditions, and communities with limited resources and limited access to healthcare, hygiene, and sanitation. Yet, access to appropriate, affordable health tools is essential for achieving UHC, particularly for neglected populations in Africa affected by diseases like NTDs. For many of NTDs, existing treatments are often toxic, complex, or unavailable. In some cases, treatments have never been developed at all. These serious limitations contribute to slow progress toward meeting the 2030 NTD Roadmap target of reducing the number of people requiring interventions against NTDs by 90%.

Research and development can support UHC by delivering safe, effective, affordable health tools adapted to patient needs and designed for use at the primary healthcare level – such as oral treatments and point-of-care diagnostics – limiting the need for specialist intervention in hospital settings. This reduces complexity and cost, not only for patients but also for health systems.

Innovations such as oral treatments and simplified diagnostics can reduce hospitalization and improve treatment adherence. DNDi and partners developed the first all-oral therapy for sleeping sickness, eliminating the need for injections and long hospital stays. It is now available free of charge in eastern and southern Africa. For visceral leishmaniasis, DNDi and partners developed safer, shorter regimens using existing drugs, replacing painful daily injections, reducing lengthy hospitalization, improving access to care, and reducing financial burdens for patients in eastern Africa, including in Sudan, Ethiopia, Kenya, and Uganda.

For diseases that are on the cusp of elimination, diagnostics and medicines that are specifically developed to meet the requirements of a sustainable elimination programme will be critical to avoid backtracking on hard-won progress. These should be highly effective, safe, and suitable for deployment in remote areas with limited public health infrastructure. Therefore, in addition to ensuring access to existing medicines, support for UHC must include support for medical innovation and the delivery of missing health tools needed to address unmet needs and ensure no one is left behind.

We urge Member States to:

- **Strengthen primary health care systems to deliver on UHC by prioritizing R&D for medical innovation and strengthening R&D capacity to deliver new tools needed to address unmet needs.**
- **Integrate R&D into national UHC strategies and action plans** to ensure dedicated innovation budgets and strengthen commitments to R&D in national and global UHC efforts.

Agenda item 16.8: Regulation of Medical Products in the African Region

DNDi welcomes the WHO Regional Office for Africa's progress report on the Regional strategy on regulation of medical products in the African Region, 2016–2025. We acknowledge the progress Member States and WHO have made so far and the commitment to continue strengthening regulatory systems. We request that Member States take note of the following issues in their consideration of this report and preparations to develop a new strategy for 2026-2035.

1. Strengthening regulatory capacity and governance

Access to safe, effective, and quality medical products is foundational to achieving universal health coverage (UHC). The Regional Strategy (2016–2025) sought to enhance regulatory systems, build the capacity of National Medicines Regulatory Authorities (NMRAs), minimize the prevalence of substandard and falsified (SF) medical products, and advance regulatory harmonization across Member States. NMRAs play a critical role in ensuring that health products meet international standards of quality, safety, and efficacy before public distribution.

Using the Global Benchmarking Tool (GBT), WHO assessed NMRAs and noted considerable progress in regulatory governance in Africa. The report shows an increase in NMRAs at Maturity Level 3, from two in 2018 to seven in 2025. While this marks progress, it remains modest, as only a handful of countries have functional NMRAs. The majority, 37 out of 47, remain at Level 1, with only basic regulatory systems in place. The report also indicates that 98% of Member States can conduct quality assessments and issue marketing authorizations more efficiently. However, due to inadequate funding and inadequate regulatory capacity, only 25 countries regularly perform market surveillance, exposing gaps in pharmacovigilance. **We urge Member States to increase investment in building regulatory capacity and to prioritize pharmacovigilance and market surveillance systems to reduce the challenge of SF in their respective countries.**

2. Regional harmonization and collaboration

Funding gaps, irregular assessments, and limited capacity for innovative product regulation have affected the provision of effective regulatory oversight for medicines in general and hinder drug development, including for women and children. The [African Medicines Agency \(AMA\) Treaty](#), which WHO supported the AU Commission in establishing, has now been ratified by 30 of 55 Member States. WHO has supported efforts to fully operationalize the AMA, resulting in the expansion of medicines regulation from two to all six subregions of the AU.

Efforts to support regulatory harmonization are welcome. Once fully operational, the AMA will promote regulatory convergence and reliance, enabling faster and more affordable access to advanced medical products by reducing both approval time and associated regulatory costs. However, the AMA is not yet fully operational, and there is currently no continent-wide regulatory guidance for medicines, including those for women and children. The slow pace of progress continues to hinder efforts to harmonize and strengthen regulatory systems at the continental level. **Member States should ensure that regulatory mechanisms are in place to address access disparities, especially for women, children, and marginalized communities. Countries should allocate resources and offer technical and other support to the AMA.** The AMA cannot function effectively without sustainable financing from countries.

3. Local production and innovation are key to health sovereignty

For local manufacturing of health products in Africa to succeed, regulatory frameworks must be strengthened and regional collaboration must be fostered. **Investment in upstream research and development is critical to ensuring new health tools are both developed and manufactured on the continent.** This includes fostering innovation ecosystems, supporting academic and research institutions, and facilitating partnerships between the public and private sectors to drive the creation of novel health technologies.

Local production and innovation are pivotal to strengthening Africa's health systems and ensuring equitable access to medical products. WHO supported seven countries – Botswana, Ethiopia, Kenya, Rwanda, Senegal, South Africa, and Uganda – in advancing local pharmaceutical manufacturing. These

efforts are critical for fostering self-reliance and improving equitable access to medical products. For example, the establishment of the mRNA vaccine technology transfer hub in Cape Town, South Africa not only empowers low- and middle-income countries to develop and produce innovative vaccines but also strengthens pandemic preparedness by elevating Africa's role as a key contributor to global health innovation.

To fully harness the benefits of local production, Member States should invest in regulatory infrastructure, skilled workforce development, and innovation ecosystems. Governments should put in place policies and conditions to create enabling environments for local production, including regulatory fast-tracking and quality assurance support. Regional collaboration through platforms like the AMA can further streamline efforts and ensure quality standards.

We urge Member States to:

- **Invest in building the capacity of their National Medicines Regulatory Authorities (NMRAs)** to ensure equitable access to safe, effective, and quality-assured medical products in Africa;
- **Intensify market surveillance, pharmacovigilance, and reporting of SF products;**
- **Support AMA operationalization** to have in place a more robust framework for regional collaboration and reliance mechanisms;
- **Create an environment conducive to sustaining local manufacturing**, including through improved policy coherence;
- **Forge equitable partnerships** among African manufacturers, global and regional innovators, and industry stakeholders to strengthen local capacity; and
- **Promote enabling policies** that foster innovation, advance self-reliance, and ensure that health solutions are responsive to local needs.

We call on WHO to:

- **Continue supporting the development of NMRA**
- **Support development of a new strategy for 2026–2035** that prioritizes sustainable financing, innovation regulation, and full AMA operationalization.

Agenda Item 16.13: Community Engagement Strategy

DNDi welcomes the WHO Regional Office's progress report on implementing the Regional strategy for community engagement, 2023–2030. We congratulate Member States for reaching key milestones, including mapping community assets and integrating engagement into national health sector guidelines. However, we note that gaps remain in formalizing standard operating procedures (SOPs), sustaining engagement beyond emergencies, and embedding genuine community voices in health system governance. We urge Member States to consider the following issues in their discussions.

1. Community engagement and health security

Empowering communities contributes to health security and achievement of the SDGs. The Strategy's emphasis on integrating community engagement into policy, service delivery, and monitoring is key. The mapping of community assets in 37 Member States and integration of community engagement frameworks into national health sector guidelines in 36 countries demonstrates strong momentum. Member States should continue to prioritize institutionalizing community engagement frameworks and to ensure that community voices are central to health system design and delivery. However, formal co-development of SOPs and guiding principles remains limited and requires further technical support.

DNDi integrates community and patient engagement throughout the R&D lifecycle, ensuring meaningful involvement of patients, caregivers, and communities in shaping treatment priorities and determining acceptable side effects and preferred formulations from the very outset of target product profile development. As an example, in DNDi's paediatric HIV programme, workshops with mothers of children living with HIV helped identify barriers to testing and shape outreach strategies. An implementation study involving over 1,000 children across three countries was conducted together with community organizations to identify at-risk children and connect them to care. Demonstrating the power of community-led solutions, this approach improved recruitment, built trust, and ensured children received timely care, regardless of whether they joined the study.

Patient and community engagement is an ethical imperative that enhances the relevance, effectiveness, and sustainability of health interventions. DNDi's experience shows that structured, inclusive engagement can transform R&D and access outcomes. Member States can embed these practices in their community engagement plans.

In our projects, DNDi has established Regional Community Advisory Committees (RCACs) to ensure community voices play a central role in decision-making. These diverse committees include people living with diseases in DNDi's portfolio, caregivers, activists, ethics advisors, and experienced patient representatives from chronic disease areas. We encourage Member States to adopt similar holistic and inclusive approaches that include co-production, co-learning, and co-evaluation to build community resilience and ensure continuity of engagement.

We urge Member States to:

- **Institutionalize community engagement** by embedding it in national health policies and budgets and mobilize sustained investments to ensure its integration within health systems;
- Align policies on primary health care, climate resilience, and multisectoral action to mainstream community engagement.
- **Promote gender-sensitive engagement by involving patient organizations** in identifying and addressing gender-based barriers to R&D and access.

We urge WHO to:

- Facilitate regional and cross-border knowledge exchange among Member States on best practices in patient and community engagement.