

Project Proposal	
Donor	Government of Belgium
Project / programme title	Advancing geographically diversified and sustainable manufacturing towards accelerating global equitable access to health products and health technologies
Division	Health Systems, Access and Data (HSD)
Department	► Health Products, Policy and Standards (HPS) ► Regulation and Prequalification Department (RPQ)
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Contact details of focal point	Dr Yukiko Nakatani Assistant Director-General Health Systems, Access and Data Division Office: +41 22 791 39 57 E-mail: nakataniy@who.int
Technical contacts	Dr Deus Mubangizi Tel no. +41 22 791 18 64 - Email: mubangizid@who.int Dr Claudia Nannei Tel no. +41 22 791 50 78 - Email: nanneic@who.int
Executive summary	
The renewed commitment to the Universal Health Coverage (UHC) in 2023, post-COVID, highlighted the need to redouble efforts to accelerate progress towards UHC by 2030. Access to health products and technologies serves as the backbone to achieving UHC, due to its significant impact on health financing. Based on the learnings from the COVID-19 pandemic, a key recommended action is to advance geographically diversified and sustainable manufacturing of quality-assured health products and technologies for future pandemics and to address other public health priorities. This proposal builds on the concrete gains achieved from the prior collaboration with the Government of Belgium and is driven by two specific objectives: ► Specific Objective 1: Strengthen established production capabilities to guarantee long-term sustainability and to deliver health products and technologies for pandemic preparedness and response; and ► Specific Objective 2: Enable sustainable regional production ecosystems capable of delivering innovative health products and technologies to respond to other public health priorities, including those essential for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliative care.	

Advancing geographically diversified and sustainable manufacturing towards accelerating global equitable access to health products and health technologies

Background

The 2023 Political Declaration¹ on “Universal Health Coverage (UHC): expanding our ambition for health and well-being in a post-COVID world” reaffirmed world leaders’ commitment to accelerate progress towards UHC by 2030. It highlighted the need to redouble efforts, acknowledging that UHC is the backbone of SDG3 and a key driver of progress across all the SDGs. Access to health products and technologies plays an integral role for countries’ progress to UHC. They are essential for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliative care. Hence, medicines and health products often represent a significant share of the health expenditures for governments and households in many countries. Their impact on health financing makes them at the core of all UHC-related strategies and discussions.

In 2019, about 2 billion people faced financial hardship due to health-related costs, including 1 billion experiencing catastrophic out-of-pocket health spending. Furthermore, the COVID-19 pandemic highlighted the inequities in access to safe, effective, quality-assured and affordable health products, exposing significant inequities such as in access to vaccines, with only 34% of the population in low-income countries vaccinated compared to nearly 73% in high-income countries by June 2023. Majority of the administered vaccines originated from manufacturers based in high-income countries while low- and middle-income countries (LMICs) experienced significant delays in accessing them.

At the Seventy-fourth World Health Assembly (WHA74) in May 2021, Member States adopted resolution WHA74.6, emphasizing the need to improve access to quality, safe, effective and affordable medicines and other health technologies particularly in LMICs. This resolution underscores the importance of capacity building for regional manufacturing, voluntary and mutually agreed technology transfer, and support for initiatives such as patent pools and the WHO COVID-19 Technology Access Pool (C-TAP), which has since evolved into the Health Technology Access Programme (HTAP).

This was reinforced by a 2023 report on the learnings from the COVID-19 pandemic², which highlighted the need for accelerated and equitable access to medical countermeasures (MCMs), especially in resource-constrained settings, to prevent undue strain on health systems. Recommended actions include encouraging innovation through incentives, advancing manufacturing of health products needed in future pandemics and for diseases affecting marginalized populations, building sustainable manufacturing capacity at national and/or regional levels diversifying supply chains, and enhancing workforce production capacity, and repurposing facilities for operational readiness for both emergency and routine production of medicines, diagnostics, and vaccines.

Additionally, the shifting of demographic, epidemiologic, environmental, and economic trends are placing new burdens on health outcomes and increasing the needs for health products and

¹ <https://www.who.int/news/item/21-09-2023-world-leaders-commit-to-redouble-efforts-towards-universal-health-coverage-by-2030>

² <https://iris.who.int/server/api/core/bitstreams/603334aa-1fa4-48fa-84cc-31a976efdfd3/content>

technologies to address those burdens. WHO's work on geographically diversified and sustainable manufacturing enables more effective translation of public health driven R&D for both pandemic preparedness and response as well as other public health priorities into improved affordability and enhanced acceptability of innovative health products and technologies. This area of work leverages on the strengths and insights gained from the complementary operating models of the mRNA Technology Transfer (TT) Programme and the Health Technology Access Programme (HTAP).

The mRNA TT Programme aims to build sustainable regional production of mRNA-based health products, preparing for future pandemics and ensuring sustainability in-between global health emergencies³. In 2024, the mRNA TT Programme was integrated into the HTAP, a WHO initiative that promotes global equitable access to health products and health security by expanding regional innovation and manufacturing capacity through selection of priority technologies, and mobilization of partners to support their development, transfer and sustainable production to make them available for communities that need them⁴.

To strengthen implementation, optimize use of resources, and maximize meaningful results, mRNA TT Programme and HTAP will be supported by the cross-cutting work areas that contribute to access to safe, effective and quality-assured health products and technologies, specifically: regulatory systems and local production ecosystem strengthening, manufacturing support, and the access 'ecosystem', i.e. intellectual property (IP) management; pricing policies and market assessment; WHO Model List of Essential Medicines (EML); WHO Model List of Essential Diagnostics (EDL); WHO List of Priority Medical Devices for management of cardiovascular diseases and diabetes, and controlled medicines.

Overall, this project will contribute to implementation of the Access Roadmap for WHO Action 2025-2030⁵, contributing to the operationalization of the WHO 14th General Programme of Work (GPW14) 2025 - 2028 (refer to Figure 1).

Figure 1. Access to quality-assured health products and technologies within the GPW14.

IMPACT	More people, everywhere, attain the highest possible standard of health and well-being
OVERARCHING GOAL	To promote, provide and protect health and well-being for all people everywhere
STRATEGIC OBJECTIVE	Advance PHC approach and essential health system capacities for UHC
JOINT OUTCOME	3.2 Health and care workforce, health financing and access to quality-assured health products substantially improved
GPW14 OUTPUT	3.2.3 WHO supports countries to implement measures for better access to, and use of, safe, effective and quality-assured health products

³ [https://www.who.int/initiatives/mrna-technology-transfer-\(mrna-tt\)-programme](https://www.who.int/initiatives/mrna-technology-transfer-(mrna-tt)-programme)

⁴ <https://www.who.int/initiatives/who-health-technology-access-programme>

⁵ <https://www.who.int/publications/i/item/9789240112049>

Objectives

Building on the concrete gains achieved from the previous collaboration, this project aims to achieve two specific objectives to progress from the established foundational efforts of mRNA TT Programme and HTAP towards geographic diversification of sustainable production to accelerate global equitable access to health products and technologies:

- ▶ Specific Objective 1: Strengthen established production capabilities to guarantee long-term sustainability and to deliver health products and technologies for pandemic preparedness and response; and
- ▶ Specific Objective 2: Enable sustainable regional production ecosystems capable of delivering innovative health products and technologies to respond to other public health priorities, including those essential for prevention, diagnosis, treatment, monitoring, rehabilitation, and palliative care.

Relevance

In the context of the lessons learned from the COVID-19 Pandemic and the evolving needs for health products and technologies, the project adopts a “fit for purpose” approach towards contributing to the achievement of UHC, aligning with Belgium’s reaffirmed commitment to the 2030 Agenda. This project builds on previous collaboration that consolidates the strengths of proven operating models from the mRNA TT Programme and the HTAP. Through the integration of cross-cutting work areas, it enables aligned and systematic efforts across the components and stakeholders of the regional production ecosystem. This approach facilitates effective progress towards geographically diversified, sustainable manufacturing to address unmet health products and technology needs in LMICs and bridge the global health technology access gap.

The implementation of the proposed project contributes to broader goals like pandemic preparedness and health systems resilience. It is closely aligned with the principles of the Pandemic Agreement, particularly in regulatory systems strengthening, sustainable and geographically diversified local production, and technology transfer. These core areas contribute to equitable and timely access to medicines and health products, which is a key priority area for Belgium.

The scope of this project, including stakeholder engagements, complements with WHO’s efforts to contribute to the EU Global Gateway and implementation of Team Europe’s Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (‘MAV+’) in the African region. The European Commission, along with Belgium, Germany and Spain are providing support to WHO in this domain.

Additionally, the objectives of the project resonates with the European Commission’s new Multiannual Financial Framework (MFF) for 2028 – 2034, particularly on boosting EU’s competitiveness, which supports investment from research to market to global production for Europe to secure supply chains and scale-up innovation - the project aims to enable sustainable regional production ecosystems capable of delivering innovative health products and technologies that will contribute to generate revenues that will sustain the investments in pandemic preparedness and broader public health priorities outside of emergencies.

mRNA Technology Transfer Programme Phase 2.0

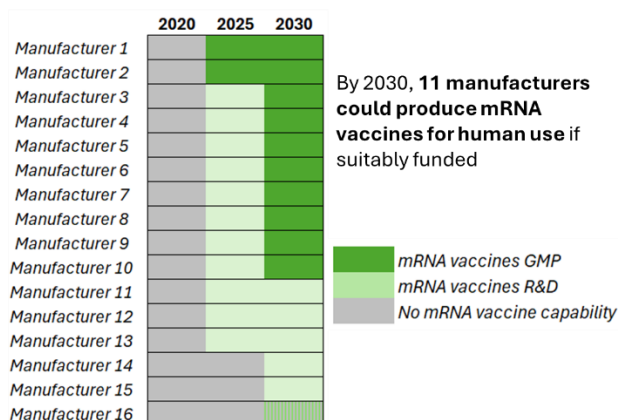
In June 2021, a groundbreaking initiative, the mRNA TT programme co-led by WHO and the [Medicines Patent Pool](#) (MPP) was launched with a main focus on technology platform development using COVID-19 as proof of concept, technology transfer, training, and platform implementation, laying the foundation for regional development and manufacturing. To date, this initiative has been able to deliver pivotal milestones, which demonstrated that the mRNA technology platform works and is ready for broader application towards building sustainable health products manufacturing ecosystems in LMICs, specifically:

- ▶ Afrigen being able to successfully develop its own COVID-19 mRNA vaccine technology;
- ▶ First technology transfer completed in September 2024, to Biovac, with additional Programme Partners such as Torlak Institute, Sinergium, and Bio-E3 (out of the 14) also receiving technology transfer training in 2024, and other 8 in 2025;
- ▶ Capacity to produce safe and effective mRNA health products has been increased, in countries with no prior foundation of skills, equipment, technology and know-how; and
- ▶ Notable innovation has been facilitated, such as the synthesis of new lipids, which are used to make mRNA-based products.

Building on these foundational concrete gains from Phase 1, the mRNA TT Programme now enters its second phase - Phase 2.0. In June 2025, the mRNA TT Programme Phase 2.0 was launched⁶ with the global health leaders on the sidelines of the G20 Summit. It was underscored by the WHO Director-General that “the mRNA Technology Transfer Programme is delivering on its promise to build capabilities in low- and middle-income countries”. This Phase will focus on supporting sustainable, commercially viable Good Manufacturing Practices (GMP)-grade mRNA production capacity and associated pandemic response capability in LMICs.

Phase 2.0 aims to realize the vision of the Programme for the period 2026 – 2030. In this phase, the focus is to ensure real world impact, moving from “can manufacture” to “can deliver”. The overarching goal is to support manufacturers in LMICs to become independently viable, GMP-compliant producers with competitive portfolios, capable of addressing regional public health needs, including epidemic and pandemic response, while contributing to global health security and integrating effectively into national health systems. Refer to figure 2 for the overview of the expected outcome by 2030.

Figure 2. Overview of the mRNA TT Programme outcome by 2030.



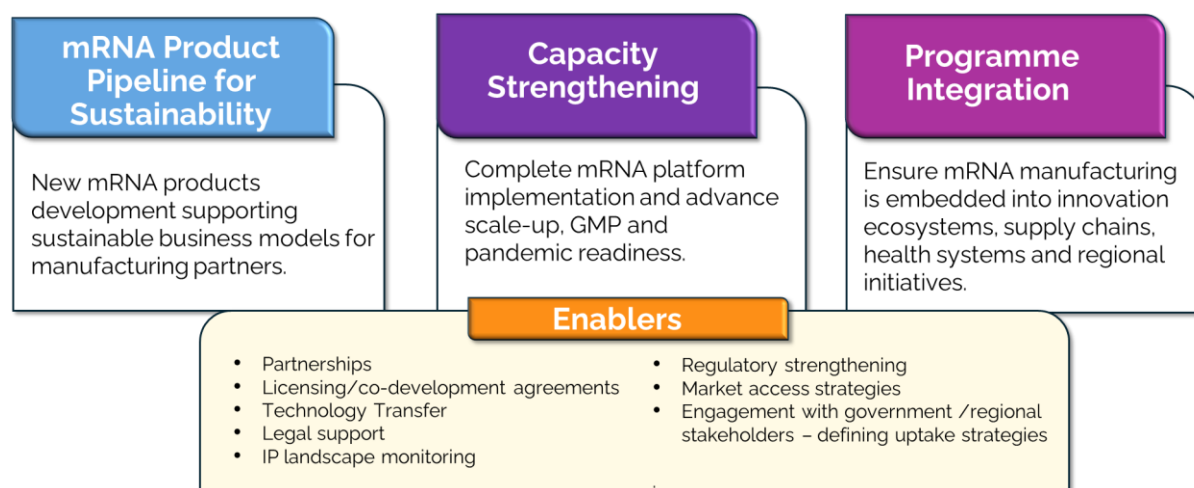
⁶ [mRNA Technology Transfer Programme's Phase 2.0 discussed with partners on the sidelines of G20 Summit](#)

To translate into real world impact, the Programme Partners will now move from technology acquisition to developing economic case for long-term, flexible, and commercially viable manufacturing. This will enable production of mRNA vaccines and therapeutics during interpandemic periods and ensure its availability for rapid response in future health emergencies. Phase 2.0 will also expand its focus to include the following health products:

- ▶ mRNA vaccines – for pandemic and priority diseases (e.g., influenza, TB, HIV, malaria, dengue, leishmaniasis);
- ▶ mRNA therapeutics – such as oncology and monoclonal antibody (mAb) treatments; and
- ▶ Biologicals beyond mRNA – including near-term commercial products to support facility viability.

The vision of the Programme will be operationalized through three interdependent strategic pillars (refer to Figure 3). These pillars will be supported by robust enabling mechanisms, including business case development, regulatory preparedness, intellectual property (IP) and freedom-to-operate (FTO) strategy, and early engagement with technology holders.

Figure 3. Snapshot of the mRNA TT Programme Phase 2.0 strategic pillars.



Pillar 1: mRNA Product Pipeline for Sustainability – focuses on having strategic, sustainability-oriented product pipeline to ensure that product development is anchored in both regional health needs and commercial feasibility. It positions manufacturers in LMICs to transition from donor dependency to sustainable, investment-ready biomanufacturing capacity. The product pipeline is supported through two complementary channels: (1) Programme R&D Activities, by a network of consortia supported directly by the Programme, including funding for development activities up to the completion of Phase I/II clinical trials; and (2) In-Licensing and Co-Development of External Candidates, sourced from academic institutions, biotech firms, and public research entities.

Furthermore, mRNA candidates are evaluated and prioritised using a structured three-dimensional framework, which will inform robust business cases, helping manufacturers define priority products, forecast volumes, assess return on investment, and navigate IP landscapes:

- (1) Probability of Technical and Regulatory Success (PTRS): to assess scientific and clinical

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- feasibility, development stage, and regulatory pathway readiness;
 - (2) Probability of Policy Development and Procurement (PPDP): to evaluate alignment with LMIC disease burden, policy priorities, and likelihood of pooled or national procurement; and
 - (3) Probability of Population Acceptance and Uptake (PPAU): to consider end-user perceptions and product's acceptance and uptake.

In parallel, the Programme supports evaluation and integration of next-generation mRNA technologies to enhance cost-efficiency, thermostability, and pandemic preparedness. **WHO and MPP will facilitate technical guidance, engagement with funders, and collaboration with technology developers to support shared development and procurement of enabling technologies.**

Pillar 2: Capacity Strengthening – focuses on strengthening Programme Partners' technical, regulatory, and organisational capabilities to produce and supply quality-assured mRNA products at scale to fully operationalise the sustainability pipeline and integrate next-generation innovations. The targeted areas of support include: (1) Complete Platform Implementation - ensuring all partners adopt and operationalize the mRNA platform; (2) Advance Industrial Scale-Up - supporting process optimization, facility upgrades, GMP compliance, and workforce development; (3) Strengthen Regulatory Capabilities - facilitating early engagement with regulatory authorities and providing technical guidance for product registration and compliance; (4) Mitigate IP Risks - conducting FTO assessments and access to legal expertise to support technology transfer and partnerships; (5) Leverage Coordinated Resources - promoting shared use of workforce, infrastructure, and expertise; (6) Develop and Test Pandemic Response Plans - developing and testing integrated pandemic preparedness and response plans through scenario-based simulations.

While implementation is led by manufacturing partners, **MPP and WHO provide technical guidance, coordination, and access to expert resources to ensure partners meet milestones, regulatory obligations, and contribute meaningfully to regional and global health security.**

Pillar 3: Programme Integration – focuses on ensuring sustained investments in mRNA manufacturing capacity by embedding each Programme Partner's contribution within regional and global health ecosystems, promoting long-term self-reliance and maximizing public health impact. This underpins that regionally developed mRNA manufacturing capabilities are not only technically functional but also aligned with broader public health systems, policy frameworks, and market dynamics. Key areas of support include: strengthening supply chain self-reliance; aligning pipeline with regional mechanisms; fostering collaboration & coordination among network partners, R&D initiatives, public health agencies, and the private sector; leveraging regulatory strengthening; promoting market access and uptake and; documenting lessons learned and adapting models to promote evidence-based guidance for other novel technologies requested by WHO Member States, promoting continuous learning and scalability.

Cross-cutting Enablers - to aid the delivery of sustainable, impactful results, Phase 2.0 will be supported by eight cross-cutting enablers that strengthen capacity, drive innovation, and ensure equitable access to locally produced mRNA vaccines and therapeutics. These enablers create a supportive ecosystem that links technical capabilities with regulatory readiness, political commitment, and market engagement specifically: partnerships, licensing and co-development agreements, technology transfer, legal support, IP landscape monitoring, regulatory strengthening, market access strategies and engagement with governments and regional stakeholders.

In the implementation of Phase 2.0, WHO and MPP will continue to work with the South African Consortium, composed of Afrigen, Biovac, the South African Medical Research Council (SAMRC), and the Department of Science and Innovation and Programme Partners in Argentina, Bangladesh, Brazil, India, Indonesia, Egypt, Kenya, Nigeria, Pakistan, Senegal, Serbia, Tunisia, Ukraine, and Vietnam.

Health Technology Access Programme (HTAP)

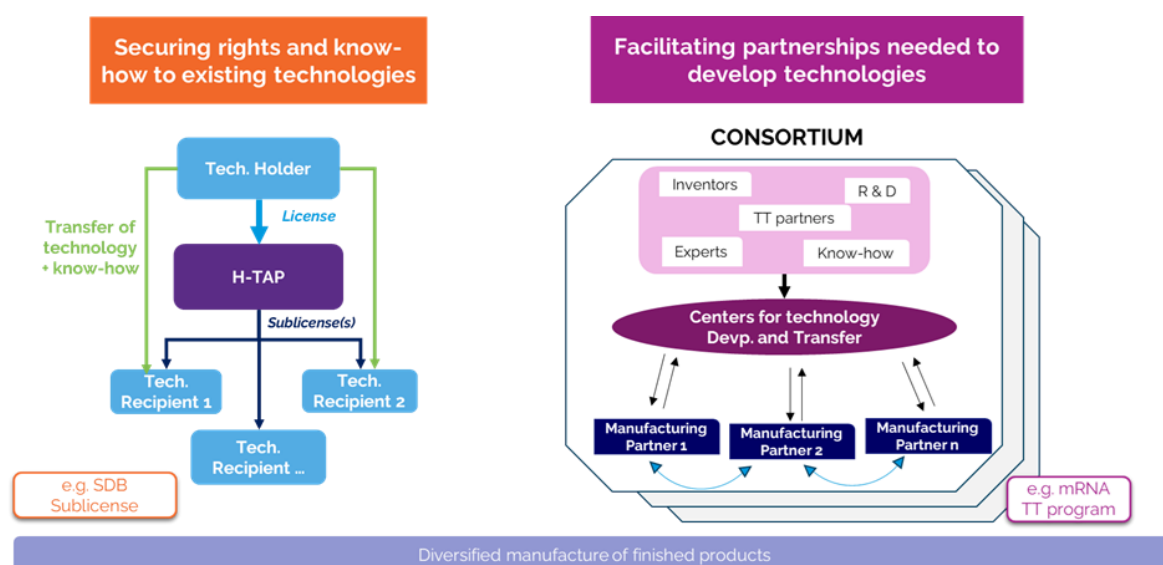
Launched⁷ in January 2024 as the successor to the COVID-19 Technology Access Pool (C-TAP), HTAP fully integrates with the mRNA TT Programme and has strengthened and expanded its operating model from one based on securing rights and supporting the geo-diversified transfer of technologies (C-TAP model) to one that includes the longer-term goal of strengthening health product manufacturing from end to end. Its mission is to bridge the health technology access gap by providing an evidence-driven mechanism for selecting, securing and facilitating the geo-diversified transfer of technology and know-how, while helping build product development capacity in LMICs through health technology consortia platform, informed by the experience of the mRNA TT Programme.

HTAP's long-term goal is to boost local innovation, development and manufacturing capabilities by fulfilling the role of multilateral mechanism – working in collaboration with other organizations – to promote and facilitate the transfer of technology to increase access to innovative health products and technologies for both pandemic preparedness and public health priorities outside of emergencies.

HTAP adopts a nuanced approach to know-how sharing and technology transfer through two complementary modalities (refer to Figure 4):

- ▶ Securing rights and know-how to existing (market-authorized) technologies and supporting their translation into diversified, sustainable production by sublicensed manufacturers; and
- ▶ Facilitating partnerships through a network of interconnected health technology development consortia to support LMICs in developing and producing the health technologies and finished products they need.

Figure 4. HTAP operating models for facilitating partnerships for technology development and production scale-up.



⁷ <https://www.who.int/news/item/31-01-2024-who-introduces-the-health-technology-access-pool>

HTAP's initial focus is on diagnostics and mRNA (as part of the mRNA TT programme) and will consider other innovative technologies based on public health needs and their business case.

To date, notable progress has been achieved, serving as foundation to its strategic implementation aimed at advancing regional innovation and manufacturing capacity, which include:

- ▶ Finalized HTAP strategic plan, articulating how HTAP works across the full technology value chain;
- ▶ Facilitated license agreement and technology transfer with SD Biosensor (SDB)⁸ (in partnership with MPP), a prototype for HTAP's select, secure and transfer operating model;
- ▶ Secured first sublicense agreement with Codix Bio⁹ to facilitate the technology transfer of rapid diagnostic tests (RDTs) from SDB;
- ▶ Provision of technical assistance (in partnership with MPP) to facilitate the implementation of the RDT technology transfer at Codix Bio; and
- ▶ Established partnerships with public R&D Institutes, and strengthened engagements with key stakeholders, enabling coordinated and unified approach to facilitate geo-diversified manufacturing.

Leveraging on these foundational achievements, HTAP will strengthen its commitment to: build product development capacity for diagnostics in underserved regions and provide support on the technology transfer and successful production of sublicensed RDTs; select and license new technologies for geo-diversified production; select, sub-license and support new manufacturers in the transfer and scale-up of technology; expand the network of R&D organizations contributing to the facilitation of technology transfer and know-how sharing; implement the HTAP strategy and expand partnerships required to realize its full potential.

Additionally, the HTAP Secretariat will put in place the necessary elements to reach optimal effectiveness and monitor its progress, in coordination with relevant WHO programmes and external partners such as the: development of performance evaluation framework; development of guidance on incentives and access terms in funding agreements, to help governments adopt packages that support sharing health technologies; foster essential partnerships to translate licensed technologies into supplied products with a market demand, alongside with the creation of a network of IP holders interested in technology transfer agreements, and a downstream network of manufacturers capable of absorbing and producing these technologies and; based on the maturity of supported technologies, initiate discussions on expanding R&D consortia beyond mRNA to include biologics and diagnostics, empowering countries to build capacity across the value chain.

Cross-cutting work areas enabling mRNA TT Programme and HTAP

Regulatory systems strengthening

Strengthening regulatory systems and processes in resource-constrained regions catalyses local manufacturing of health products, thereby promoting equity, access and self-reliance and improving

⁸ <https://www.who.int/news/item/31-01-2024-who-and-mpp-announce-technology-transfer-license-to-enable-greater-patient-access-to-multiple-essential-diagnostics>

⁹ <https://www.who.int/news/item/09-05-2025-who-and-medicines-patent-pool-announce-sublicensing-agreement-for-rapid-diagnostic-test-technology>

quality for better health outcomes.

A well-functioning regulatory system plays a critical role in ensuring the quality of health products, throughout their lifecycle. Through a robust regulatory system, the availability for a needed health product to reach the population is accelerated while ensuring its quality from development to post-market use. This begins with thorough understanding of product development, continued assessment of data (pre and post market) to support the safety, quality and efficacy/performance and the accompanying product information, continuing through monitoring and surveillance of the products when in use in the real world.

Guided by the WHA67.20 resolution on regulatory systems strengthening for health products, tangible progress was made on the efforts to strengthen regulatory systems, contributing to the key milestones achieved by Phase 1 of the mRNA TT Programme. Designated by the African Union (AU) as priority countries for the establishment of mRNA production and technology transfer, Senegal and Rwanda achieved Maturity Level (ML3)¹⁰ in medicines and vaccines (non-producing) regulations for their national regulatory agencies (NRAs). Furthermore, the capacities of regulators and GMP inspectors from South African Health Products Regulatory Authority (SAHPRA) were strengthened in the context of Quality Management System (QMS), Registration and Marketing Authorization (MA) and Vigilance (PVL), promoting harmonization and fostering regulatory collaboration and reliance mechanisms.

Complementing these efforts, it is important to highlight that the effective technical support through the financial contribution from the European Union has been provided to the AU and the secretariat of African Medicines Agency (AMA) in advancing its operational framework, including governance structures, regulatory guidelines, and stakeholder engagement mechanisms. These efforts have reinforced regulatory efficiency through the harmonization of internationally recognized and science-based standards, and implementation of reliance activities. These are essential in the mRNA technology transfer programme and HTAP, which fundamental intent is to ensure that developed and transferred health products and technologies can be effectively utilized across multiple national markets.

Building on these notable achievements, the continued work on strengthening regulatory systems to support Phase 2.0 of the mRNA TT Programme and HTAP will focus on enhancing global regulatory ecosystem that benefits all countries, particularly LMICs. This effort is closely aligned with the overarching strategic priorities outlined in the Department of Regulation and Prequalification's Strategic Action Plan 2025–2028¹¹, including: strengthening country and regional regulatory systems in line with the drive towards UHC and increasing regulatory preparedness for public health emergencies. Support for the Programme will concentrate on the following areas: (1) maintaining ML3 for Egypt, Senegal, South Africa and other relevant African countries to ensure continued regulatory performance and sustainability; (2) advancing regulatory capacity towards ML4, with the aim of achieving WHO Listed Authorities (WLA) status and; (3) expansion of benchmarking scope to include vaccine-producing countries, medical devices (including in vitro diagnostics), and blood and blood products, thereby broadening regulatory oversight and preparedness across critical health product categories.

¹⁰ [Senegal and Rwanda achieve WHO Maturity Level 3 in medicines regulation](#)

¹¹ <https://iris.who.int/server/api/core/bitstreams/8a13806c-efc0-4840-a9ee-1626ae1b818a/content>

Manufacturing Support

WHO provides manufacturing support to Member States in strengthening sustainable local production of quality-assured health products through a holistic, ecosystem-wide approach across the value chain. This work area promotes supply security through diversified and sustainably developed national and regional manufacturing capacities. In collaboration with governments, partners, and stakeholders manufacturing support is facilitated through political commitment through strategies, policies and partnerships; country-level support and technology transfer; capacity building for manufacturers, regulators and other stakeholders and; technical assistance on Prequalification (PQ) processes.

In Phase 1 of the mRNA TT Programme, the efforts on providing manufacturing support complemented with the key activity areas of the Programme. The selected countries for the ecosystem assessments and published case studies ¹² of local production ecosystems for pharmaceuticals, vaccines, and biologicals align with the countries of the Programme Partners. The assessments helped countries identify key gaps and provided recommendations to guide targeted strategies for building conducive ecosystems and supporting efforts to attract investment and strengthen sustainable local production capacities. Additionally, the establishment and successfully convened World Local Production Forums provided an effective platform for coordination, partnerships, and strategic engagements of countries with industry associations, financial institutions, civil society and international partners on critical topics about sustainable local production including regulatory systems, licensing and technology transfer, financing, vaccines and innovation.

Drawing on this progress, the manufacturing support work area will enhance its complementarity with the mRNA TT Programme Phase 2.0, aligned with its pillars, through, for example: conducting holistic ecosystem assessments, particularly in countries hosting mRNA technology Programme Partners; delivering technical support and capacity building activities to address identified gaps in the ecosystem assessments; and providing specialized technical assistance to the mRNA technology Programme Partners to meet international regulatory norms and standards and achieve WHO Prequalification (PQ) or Emergency Use Listing (EUL).

The Access “Ecosystem”

WHO’s constitutional mandate and impartial, evidence-based processes enable the development of robust and transparent international standards for a broad range of medicines, vaccines, biotherapeutic products, blood products, medical devices, including in vitro diagnostics, and cell and gene therapy products. These standards provide foundation for national regulation, particularly in addressing global health priorities and the needs of LMICs.

Norms, standards and guidance for the development and delivery of health products and technologies are essential for achieving impactful outcomes in the mRNA TT Programme Phase 2.0 and HTAP. They ensure quality control across the health product and technology ecosystem. WHO’s work in this area contributes to consistently produced and distributed health products and technologies according to international quality standards and better regulatory oversight, fostering greater collaboration, convergence and harmonization amongst national and regional regulatory authorities.

¹² <https://www.who.int/news/item/08-05-2024-who-publishes-six-country-case-studies-on-local-production-ecosystems-for-pharmaceuticals--vaccines--and-biologicals>

Pricing policies and market assessments

Guided by the WHA72.8 resolution on improving market transparency for medicines, vaccines, and other health products, WHO's work in this area focuses on providing pricing policy guidance and supporting greater market transparency. These efforts aim to optimize market efficiency, maximize population health outcomes, and reduce inequities due to access barriers, including wasteful spending and high out-of-pocket expenditure. In addition, WHO provides leadership in convening the biennial Fair Pricing Forums, participated by WHO Member States and relevant stakeholders to share experiences and address problems pertaining to affordability and market transparency of health products. The primary goal is to help Member States and stakeholders better understand existing approaches and emerging policies to improve market transparency and affordability of essential medicines and health products.

Leveraging the outcomes of the Fair Pricing Forums, improving transparency of pricing and market efficiency for health products continue to be policy priority. The forums have underscored the importance of collaboration and regional cooperation in sharing policy experiences and foster efficient markets (e.g. improved competition via the introduction of quality-assured generics and biosimilar medicines and therapeutic alternatives). The forums have also highlighted the importance of aligning incentives to facilitate fair pricing throughout the innovation cycle, as well as the need for greater transparency and accountability to make informed decisions and negotiate for fairer prices across the supply chain. To support supply reliability, geographic diversity in manufacturing has been recognized as critical.

The efforts on pricing policies and market assessments will support mRNA TT Programme Phase 2.0 and HTAP by informing the development of market strategies and any structural policy reforms. This area of work will address the need for frameworks and analytics to facilitate patient access to quality-assured health products of public health importance while incentivising commercial interest and sustaining financial viability of market participants across the supply and distribution chains. Overall, this area of work will contribute to evidence-informed, legitimate and transparent processes for assessing and prioritizing quality-assured health products and innovative technologies according to public health needs. It will enable countries to select and prioritize and allocate resources according to specific national contexts in an efficient and sustainable manner.

Selection and Essential Medicines¹³ List

Since its inception, the WHO Model List of Essential Medicines¹⁴ has substantially evolved, reinforcing its relevance to all countries. It is recognized as a transformative tool in public health, supporting countries, including LMICs and high-income countries, to select medicines that address priority public health needs. Over time, the Model List has expanded to include more treatments for chronic and noncommunicable diseases, reflecting shifts in the global disease burden and the needs of aging populations. Notably, the inclusion of patented medicines on the Model List has increased from

¹³ Essential medicines are those that satisfy the priority health care needs of the population and Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.

¹⁴ <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>

17/319 (5%) in 2003 to 82/502 (16%) in 2023.

In April 2025, the repository of National Essential Medicines Lists (nEMLs)¹⁵ was launched, marking a major milestone in global health-care collaboration. It provides centralized access to a comprehensive repository of national essential medicines lists, national formularies, and national standard treatment guidelines that guide public sector procurement and supply of medicines, inform reimbursement schemes, support medicine donations, and shape local medicine production.

Driving forward the momentum from these achievements, and given the increased global engagement in the EML, this work area will continue to strengthen on evidence-based selection of health products, underpinning the prioritization of health products and technologies, particularly in the context of mRNA TT Programme Phase 2.0 and HTAP.

Notably, 2027 will mark the 50th anniversary of the first mention of the concept of essential medicines by the WHA. This offers a timely opportunity to reaffirm and renew global political commitment to accelerate progress towards the 2030 Agenda for Sustainable Development, with a focus on enhancing efforts to ensure access to safe, effective, quality-assured essential medicines and other health products and technologies. This also presents a valuable opportunity to update the EML procedure, including consideration of local production as a potential factor in recommending medicines.

Essential Diagnostics List

The WHA76 in May 2023 adopted a new resolution, recognizing the importance of access to diagnostics (WHA76.5) to strengthen global diagnostics capacities¹⁶. Diagnostic services are essential for the prevention, diagnosis, case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities. Around 70% of clinical decisions rely on diagnostic test results, however, only 3–5% of healthcare funding is allocated to diagnostic services. In many countries, clinicians and health care providers lack access to essential diagnostic tools needed to support patients.

In October 2023, WHO published the new list of Essential Diagnostic List (EDL 4)¹⁷, an evidence-based tool intended to support national in vitro diagnostics (IVD) policy development and to improve access to IVD testing and clinical laboratory services. It also provides recommendations for prioritizing IVDs across different levels of the healthcare system. Additionally, it is regularly updated to remain relevant and aligned with innovation and emerging technologies. EDL 5 is expected to launch before the end of 2025. Following the adoption of resolution WHA76.5, Member States are encouraged to consider the establishment of national diagnostics strategies as part of their national health plans, and to consider the development of national essential diagnostics lists, adapting the WHO model list of essential in vitro diagnostics.

To improve access to diagnostics across clinical services, including those for UHC and emergency preparedness and response, the Global Diagnostics Coalition was officially launched in May 2025. The Coalition serves as a platform and/or convening network to advance advocacy efforts aimed at strengthening diagnostics capacity. It brings together diverse and relevant stakeholders to promote

¹⁵ [WHO unveils global repository for National Essential Medicines Lists \(nEMLs\)](#)

¹⁶ [Strengthening diagnostics capacity](#)

¹⁷ <https://iris.who.int/bitstream/handle/10665/373322/9789240081093-eng.pdf>

harmonizing efforts, foster convergence, and drive a coordinated agenda on diagnostics. These efforts support the implementation of resolutions and initiatives such as the WHA76.5 and WHA78.13 (on Strengthening Medical Imaging capacity).

Advancing progress, this work area will have increased emphasis on collecting country-level data along with EDL to effectively consolidate identified gaps and needs and to inform policy strengthening, including evidence-based prioritization of health products and technologies, particularly in the context of mRNA TT Programme Phase 2.0 and HTAP.

List of Priority Medical Devices cardiovascular diseases and diabetes

Medical devices play a critical role in preventing, diagnosing, and treating diseases and injuries, as well as supporting rehabilitation. Without them, many routine and life-saving medical procedures would not be possible. Today, there are an estimated 2 million different kinds of medical devices on the world market, categorized into more than 7,000 generic devices groups.

Following the release of the WHO List of Priority Medical Devices¹⁸ for management of cardiovascular diseases and diabetes in 2021, which supports policymakers and healthcare providers in prioritizing the selection and procurement of essential technologies for these conditions, 92 countries have taken action to initiate a national priority medical devices list (including in vitro diagnostics).

In line with resolution WHA60.29 (2017), WHO established the Medical Devices Information System (MeDeVIS) in 2024, the first global open access clearing house for medical devices information. MeDeVIS offers standardized terms, codes and definitions of medical devices that are freely accessible by all stakeholders. By addressing the fragmentation caused by multiple existing nomenclature systems, MeDeVIS helps reduce duplication of efforts and mitigates the challenges these inconsistencies pose for the procurement, management, and effective use of medical devices across health systems.

Reinforcing progress, this work area will have increased focus on country level data collection to better understand the specific gaps and needs and to inform policy strengthening, including evidence-based prioritization of health products and technologies, particularly in the context of mRNA TT Programme Phase 2.0 and HTAP.

Controlled medicines

The WHA69 in May 2016 considered a report on the public health dimension of the world drug problem including in the context of the special session of the United Nations General Assembly on the world drug problem, held in April 2016, highlighting the need for a comprehensive package of drug control measures, shifting the focus from international drug policy responses towards public health measures that require a multisectoral and coordinated implementation to address the entire public health continuum.

The global burden of health-related suffering from serious life-threatening and life-limiting illnesses is expected to almost double by 2060, requiring far greater access to appropriate palliative care, including access to controlled medicines. WHO's work in this area is guided by international law and

¹⁸ <https://www.who.int/news/item/30-06-2021-who-launches-list-of-priority-medical-devices-for-management-of-cardiovascular-diseases-and-diabetes>

WHO is one of the four treaty bodies to the international drug control conventions. Ensuring access to controlled medicines for legitimate medical use as a part of a balanced national medicine policy is an essential element of WHO's strategies and action plans. The WHO Expert Committee on Drug Dependence (ECDD) provides recommendations to the Commission on Narcotic Drugs for subsequent decision on scheduling under the conventions. The ECDD highlights the merits of a medicine on the ground of benefits associated with its use and works in close coordination with the WHO Expert Committee on Selection and Use of Essential Medicines.

In September 2025, WHO published the full edition of the revised guideline on balanced national controlled medicines policies to ensure medical access and safety¹⁹. Taking the next steps, WHO will scale-up efforts to disseminate the revised WHO Guideline and promote their uptake through targeted communication and capacity-building. This will also include strengthening the WHO surveillance system for timely evidence-based information to support the prioritization and critical review of new narcotic drugs, and new psychotropic substances to determine their need to be placed under international control. Additionally, the revision of the pain management section of the WHO Model List of Essential Medicines will be facilitated through comprehensive review and update.

Proposed budget

The Government of Belgium has made a provisional commitment to provide € 8 million over four years from December 2025 to November 2029 to WHO, to fund activities to advance geographically diversified and sustainable manufacturing towards accelerating global equitable access to health products and health technologies.

Table 1. Overview of the budget allocation by year for 4 years

Proposed overall budget (€), including programme support cost (13%)					
Areas of Work	Y1 December 2025 - November 2026	Y2 December 2026 - November 2027	Y3 December 2027 - November 2028	Y4 December 2028 - November 2029	TOTAL
TOTAL Budget	2,000,000	2,000,000	2,000,000	2,000,000	8,000,000

The proposed budget allocation for the duration of the project is presented in Table 1. Details of the budget allocation for the various areas of work and activity outputs will be subject to annual discussions between the Government of Belgium and WHO, taking full account of the priorities of the Belgian Government and WHO. Subject to progress across the various areas of work and in line with the priorities of the Belgian Government, adjustments to the planned allocation of funds may be considered and mutually agreed upon during the annual discussions. Table 2 provides the proposed budget allocation by area of work by year.

¹⁹ <https://www.who.int/news/item/19-09-2025-who-publishes-full-guideline-report-to-help-countries-ensure-safe-equitable-access-to-controlled-medicines>

Table 2. Proposed budget allocation by area of work by year

Areas of Work	Proposed funding allocation (€), including programme support cost (13%) from December 2025 to November 2029 (indicative)				
	Y1	Y2	Y3	Y4	TOTAL
	December 2025 - November 2026	December 2026 - November 2027	December 2027 - November 2028	December 2028 - November 2029	
mRNA Technology Transfer	884,956	884,956	884,956	884,956	3,539,823
HTAP	353,982	353,982	353,982	353,982	1,415,929
Regulation	123,894	123,894	123,894	123,894	495,575
Manufacturing Support	106,195	106,195	106,195	106,195	424,779
Access "Ecosystem" - Fair pricing and other access to health products work streams, e.g. EML, EDL, MDD controlled medicines	300,885	300,885	300,885	300,885	1,203,540
TOTAL	1,769,912	1,769,912	1,769,912	1,769,912	7,079,646
<i>Programme Support Cost (13%)</i>	<i>230,088</i>	<i>230,088</i>	<i>230,088</i>	<i>230,088</i>	<i>920,354</i>
GRAND TOTAL	2,000,000	2,000,000	2,000,000	2,000,000	8,000,000

Reporting

It is proposed that in addition to annual technical reports, based on relevant extracts from WHO corporate Results Reports, and highlighting Belgian's support to activities to advance geographically diversified and sustainable manufacturing towards accelerating global equitable access to health products and health technologies, WHO will provide:

- yearly certified financial statements of income and expenditure
- yearly plans of activities supported with Belgian funds
- technical updates on activity implementation to be provided at in-person or virtual meetings