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Sua Excelência

Sr. Presidente da Comissão de Saúde

António Maló de Abreu

Contacto-o por parte da Unitaid, uma organização global de saúde dedicada a salvar vidas ao introduzir novos medicamentos e diagnósticos para melhor prevenir, diagnosticar e tratar doenças como malária, HIV/AIDS, tuberculose (TB), cancro do colo do útero e hepatite C em países de baixo e médio rendimento. O nosso foco está em novos produtos que irão acelerar a equidade, acessibilidade, escala e impacto para responder às endemias e responder de maneira mais rápida e equitativa a pandemias (atual e futuras). Somos parte da Organização Mundial da Saúde, com um mandato específico relacionado à inovação e acesso.

Recentemente, a Unitaid aplicou sua experiência na introdução de novas ferramentas de saúde para auxiliar no avanço de novas terapias e diagnósticos para a pandemia de COVID-19, atuando como um membro-chave do Acelerador de Ferramentas de Acesso a Covid-19 (ACT-A) como co-organizador do Pilar de Tratamento e co-líderes do fluxo de trabalho de preparação para o mercado do Pilar de Diagnóstico.

No âmbito desta vertente de trabalho, a Unitaid e Portugal iniciaram uma colaboração, na qual Portugal anunciou uma contribuição EUR116.244,13, contribuição tal que foi fundamental para apoiar o acesso equitativo a novas ferramentas de saúde para enfrentar a fase aguda da pandemia de COVID-19, especialmente nos países de baixo e médio rendimento.

A Unitaid está empenhada em fortalecer as colaborações com Portugal e procura estabelecer uma parceria de longo prazo para apoiar as inovações globais em saúde fundamentais para o sucesso da resposta global à saúde. Neste sentido, gostaríamos de solicitar, para o dia 14 de setembro, uma apresentação sobre a Unitaid e da nova estratégia para o período de 2023 a 2027 que tem como objetivo introduzir 30 novos produtos de saúde até 2030 para acelerar o alcance das metas dos Objetivos de Desenvolvimento Sustentável (ODS) durante a sessão da comissão de saúde.

Em anexo, encontrará um documento sobre a Unitaid, bem como sobre a colaboração com Portugal e perspectivas para o futuro.

Estou à disposição para esclarecer o que for necessário.

Com os melhores cumprimentos,

Mauricio Cysne

Director, External Relations and Communications

ABOUT UNITAID

Unitaid is a global health organization dedicated to saving lives by pioneering the introduction of new medicines and diagnostics to better prevent, diagnose and treat diseases such as malaria, HIV/AIDS, tuberculosis (TB), cervical cancer, and Hepatitis C in low- and middle-income countries. Our **focus is on new products that will accelerate equity, affordability, scale and impact.**

Our work targets one of the biggest challenges in innovation: closing the gap between late-stage development of health products and their widespread adoption at scale. This is often a difficult process for low- and middle-income countries, which face economic and logistical barriers to accessing treatments for life-threatening diseases.

Since 2006, Unitaid has been a critical contributor to the effectiveness of global health institutions, including the Global Fund.

A joint initiative by Unitaid and the Global Fund analysed the potential impact of Unitaid-supported innovations on the Global Fund's Investment Case for the last Replenishment (2019) whilst an updated analysis is under development. The 2019 analysis yielded two key findings, highlighting the significant impact of partnership between the two agencies:

- Innovations supported by Unitaid and scaled by the Global Fund would reach over 100 million people each year (2020-2023)
- Without these innovative solutions, it would take an additional 3 years to reach the targets set in the investment case.

Today, twenty percent (20%) of the health products that are available on the Global Fund's online procurement platform (wambo.org) were introduced by Unitaid. These products are core to country proposals and national responses being financed through the Global Fund.

By 2030, innovative approaches supported by Unitaid, and scaled by the Global Fund and countries, has the potential to save an additional 2.2 million lives and achieve €4,7 billion in cost savings.

The estimated return on investment across Unitaid's portfolio is on average EUR 7 to EUR 20 for every EUR 1 invested.

Key essential medicines and tools that form the backbone of the global health response today would not exist if Unitaid had not been there, working behind the scenes, first to find them and then prove their worth.

COLLABORATION WITH PORTUGAL

The global community has set out an ambitious agenda to achieve Universal Health Coverage by 2030. This agenda is more urgent than ever due to the devastating COVID-19 pandemic, which has laid bare the gaps in health systems and supply chains that ultimately affect us all. ***Equitable, affordable and accelerated access to innovations in medicines and diagnostics will be vital to achieving SDG 3 targets and to any future agenda on health security.***

Unitaid shares key priorities with Portugal, notably a strong commitment to innovation, efficiency and equitable access to new medicines and tests in infectious disease control (HIV, TB, malaria and co-infections) for patients most in need, a focus on addressing antimicrobial resistance, women and girls and the supply-side barriers that also prevent uptake of innovative health tools, including supporting

local manufacturing. Recently, Unitaid has applied its expertise to assist in advancing new therapies and diagnostics for the COVID-19 pandemic, serving as a key member of the Access to Covid-19 Tools Accelerator (ACT-A) as co-convenors of the Therapeutics Partnership and co-leads of the market preparedness workstream in the Diagnostics Partnership. Under this workstream, Unitaid and Portugal started a collaboration, and Portugal's contribution of EUR EUR 116,244.13 was key to support equitable access to new health tools to address the acute phase of the COVID-19 pandemic.

Unitaid is committed to strengthening its engagement with Portugal and it is seeking to setting up a long term partnership to support global health innovations critical to the success of the global health response.

For the Unitaid Strategy period 2023 – 2026, a contribution from Portugal would 1) support national responses for HIV, TB and malaria and their coinfections and co-morbidities, especially in the context of the health gains lost due to the COVID-19 pandemic; 2) deliver health tools specifically for children and women, helping achieve global goals such as cervical cancer elimination; 3) and strengthen pandemic preparedness and response worldwide based on the lessons learned from the global COVID-19 response and the Access to COVID Tools Accelerator (ACT-A).

Production of medicines and diagnostics in Low-and-Middle Income Countries (LMICs) is a cornerstone of Unitaid's work and will remain a key objective for its next strategy. Unitaid is keen to collaborate with Portugal in this area recognizing that domestic manufacturing is essential for equitable access to affordable and reliable supplies of essential health products required in LMICs. Unitaid works across the three pillars that are required for a successful domestic manufacturing drive in any part of the world: 1) Technology transfer; 2) Procurement and supply systems; and 3) Regulatory strengthening. All of this happens within the context of several enablers like resolving patent issues, financing, enabling policy environment, as well as a vibrant research and capacity building network.

TRACK RECORD - EXAMPLES OF UNITAID'S WORK

- **Strawberry Syrup as a Tuberculosis Medicine for Children:** For decades, children have not received proper treatment or have been undertreated due to the lack of appropriate child formulations of lifesaving medicines for HIV/AIDS, tuberculosis and malaria. There is little incentive for companies to invest funds to develop child-friendly medicines due to small, disparate markets, reinforced by poor global estimates of demand. Unitaid funded the development of the first high-quality, affordable, properly dosed and good-tasting TB medicines using **strawberry syrup** flavoured treatments for children. **These formulations are now in more than 116 countries which account for 75% of the child TB burden and have changed TB treatment for the most vulnerable and helped save many children.**
- **New preventative treatment methods for cervical cancer for women in rural areas in Africa:** Self-screening for cervical cancer has been identified as one of the most impactful interventions to reach women in rural settings and to overcome access, religious and cultural barriers to seeking care in facilities. Unitaid has reached more than **a quarter of a million women with screening for cervical cancer** and importantly has played a critical role in introducing innovative, effective, treatment technologies and lowering the cost of screening and treatment.
- **New tools to address antimicrobial resistance in tuberculosis:** The spread of drug-resistant TB is a major threat to tuberculosis control. In 2018, less than 40% of the estimated 500,000 people with drug-resistant TB were diagnosed, only a quarter of them started treatment, and less than 14 percent were cured. Testing to see which medicine will work for a patient's

infection avoids putting them on ineffective treatment, poorer health outcomes and greater overall costs for health systems. Testing is a key component of the WHO End TB Strategy. Unitaid is investing US\$ 48 million to address drug-resistant TB including better treatments and prevention for drug-resistant TB in children, innovative adherence technologies, late stage development and deployment of next-generation genome sequencing for fast, accurate diagnosis of drug-resistant TB.

- **COVID-19 Therapeutics and Medical Oxygen:** Unitaid leads the Emergency Oxygen Task Force and co-leads the Therapeutics Pillar of the ACT Accelerator to ensure equitable access to new therapies to treat the COVID-19 pandemic in low-income countries. Unitaid supported more than 97 countries with technical assistance to address O2 bottlenecks during COVID-19 and signed MOUs with two of the largest gas companies to expand supply and reduce prices for low income countries. On therapeutics, together with the FIND and the Diagnostics Pillar, Unitaid has invested in 22 countries to generate data on how to roll out new oral antivirals and is working on supply bottlenecks on new antivirals, including those still in the pipeline. Unitaid also initiated the technology transfer to enable the local production of rapid tests across 3 continents, including the first ever in Africa. Moving forward, Unitaid under the ACT Accelerator is planning support to market interventions to stabilize oxygen supply and pilot sustainable oxygen deliver models across diseases. To ensure oxygen is available when people need it, parallel efforts are needed at both global and local levels.

UNITAID PIPELINE

Without investment in Unitaid's new Strategy, critical new tools such as those listed above will be significantly delayed or remain unavailable to LMICs, undermining the impact and efficiency of funds invested in the three diseases. It is for this reason that Unitaid is an essential partner in ensuring the effectiveness of the Global Fund, as this work drives the strategies and products available to countries.

- **Urgent action needed on emerging malaria drug resistance:** for the first time, partial resistance to artemisinin, the backbone of first line combination treatment has been detected in Africa. Artemisinin resistance increases the risk of the emergence of partner drug resistance, which can result in treatment failures. This has major implications in Africa where the malaria burden is highest (>90% of global cases) and drug use is heaviest. The occurrence of partner drug resistance could impede our ability to treat malaria and erode the effectiveness of current but also future combination drugs in the pipeline. WHO is urgently developing a strategy to respond to antimalarial drug resistance. There is urgent immediate need for multi-country implementation pilots of resistance management strategies targeting to consider a better use of existing tools and the role of new tools and strategies. Unitaid has the partnerships, track record and know-how to mount multi-country implementation pilots that support product adoption and demand creation, and supply-side market interventions that promote a healthy market to inform new standard of care for Africa. Without urgent action, the risk is that both the drugs we have and the one under development will be undermined by spreading drug resistance, at a time when climate change is shifting vector patterns, risking lives and decades of progress in malaria control.
- **New tools for Malaria Prevention** – many new tools available for malaria prevention (new insecticide nets, spacial repellents, partially effective vaccine targeted at high incidence areas) **but countries lack data on how best to choose and deploy these tools** with limited funds. There is an urgent need for country pilots to inform national strategies, which can then be supported by

Global Fund, domestic, or bilateral funding. Without this, malaria prevention strategies will not be optimal.

- **New tools for Post-partum hemorrhage** – one-third of women dying in childbirth are dying due to post-partum hemorrhage. In high income countries, including European countries, women would be treated with oxytocin, among other things. Oxytocin requires a cold chain which is often lacking in decentralized areas of poor countries, resulting in poor quality and ineffective oxytocin use and maternal death. There is a new drug available – carbocin – that does not require cold chain. However, two trials are needed to inform use in LMICs. First, if carbocin can be administered by intra-muscular injection vs intravenous (IV) infusion and remain equally effective. (Decentralized health settings do not often have capacity for IVs). And second, if carbocin can be used not only to prevent hemorrhage but to treat it. Without this information, countries are hesitant to register and deploy the drug and WHO cannot issue updated guidelines, as oxytocin would still be needed. In addition, there is fear that carbocin would be misadministered. Supply, early introduction and price interventions are also required. Compared to the current approximate 70,000 yearly maternal deaths from PPH worldwide¹, this intervention could result in an 11% reduction in worldwide post-partum related maternal mortality. Moreover, research shows that maternal mortality has a large follow-on impact on children, families and communities.

REQUEST FOR A PARLIAMENTARY HEARING

Unitaid would thank the opportunity to present the information on this briefing in a parliamentary hearing in the Portuguese Parliament to explore opportunities to strengthen the collaboration between Portugal and Unitaid, aiming at improving the global response to health treats.

¹ Say, L. *et al.* Global causes of maternal death: A WHO systematic analysis. *Lancet Glob. Heal.* **2**, 323–333 (2014).