

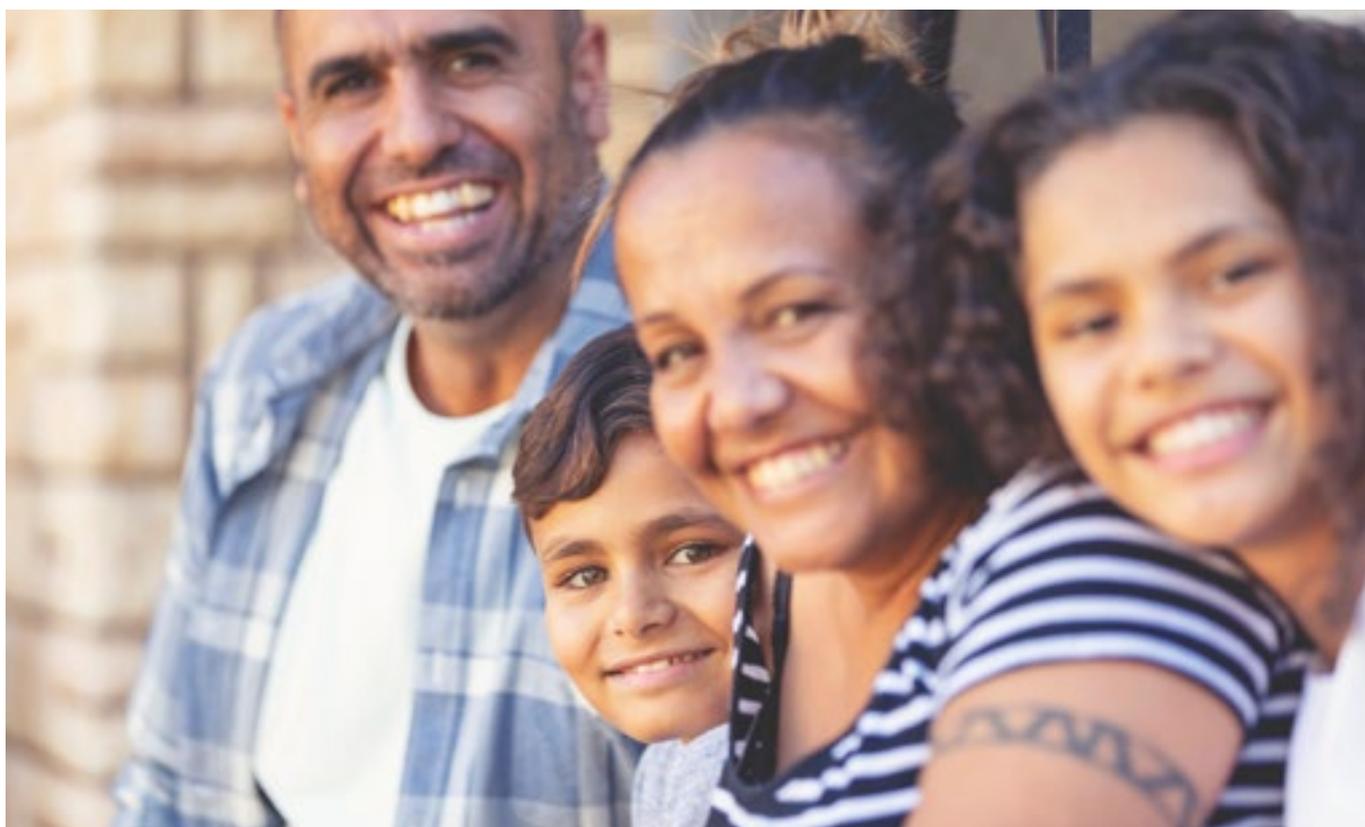


**WORLD
HEART
FEDERATION**

**IMPROVING
ACCESS
TO ESSENTIAL
MEDICINES
FOR CIRCULATORY DISEASES**

A CALL TO ACTION





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EXECUTIVE SUMMARY

Only **9%** 
reduction in the burden of CVD mortality²
 in low- and middle-income countries

 
2 billion
lack access to essential medicines

Up to **60%** 
 in low- and middle-income countries cannot afford cardiovascular medicines⁷

Together, heart disease, stroke and diabetes caused more than 
20 million
 annual deaths

We are at a crossroads in the prevention and control of cardiovascular diseases (CVDs) and other circulatory diseases. In almost three decades, between 1990 and 2017, high-income countries have reduced the burden of CVD-induced mortality, as expressed in Disability Adjusted Life Years, by 30 percent¹. Part of this success lies in ensuring access to affordable and quality essential medicines for CVD.

By contrast, low- and middle-income countries (LMICs) have achieved only a 9 percent reduction.² Not surprisingly, an estimated two billion people, almost one third of the world's population, lack access to essential medicines. Of those, approximately 50 percent are in Africa and Asia.³

What is more, on average, only 38 percent of essential medicines are available in the public health systems in low- and middle-income countries.⁴ Medicines account for up to a quarter of the global health expenditure, with LMICs allocating between 20-60 percent of health expenditure on medicines.⁵ To put these figures further into context, 70 percent of the global population resides in 105 low- and middle-income countries; the latter shoulder most of the global burden of disease.⁶

As staggering as these statistics are, they can obscure gaps in access to essential medicines for cardiovascular and other circulatory diseases. One of the largest epidemiological studies globally, the Prospective Urban Rural Epidemiology (PURE) study, showed that 25 percent of households in upper middle-income countries (MICs), 33 percent in lower-MICs, and up to 60 percent of households in low-middle income countries (LICs) cannot afford cardiovascular medicines.⁷

Access to essential medicines for CVD is not high on the global health agenda, despite circulatory diseases* being the number one killer and cause of disability worldwide, as well as the cause of debilitating health costs. Together, heart disease, stroke and diabetes caused more than 20 million annual deaths and accounted for almost half a billion disability-adjusted life years (DALYs) in 2016.⁸ Of those, cardiovascular diseases alone claim 17.9 million lives every year, cost the world USD\$ 957 billion in 2015 in productivity losses and treatments, and are set to cost approximately USD\$ 1,044 billion to manage globally by 2030.⁹

* defined here as diseases that affect the circulatory system



Beyond the costs, ensuring access to essential, safe and quality medicines is a cornerstone of strong health systems and of progress towards achieving universal health coverage (UHC).

Achieving it globally has been enshrined in the **Sustainable Development Goals (SDG) framework**, in particular in target 3.8 to “achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.”¹⁰ Given the impact of access to medicines on the health of populations and individuals, achieving it has an impact on other SDGs, including SDG 3, target 3.4 to “reduce by one third premature mortality from non-communicable diseases,” SDG 1 to “end poverty in all its forms,” SDG 4 to “ensure inclusive and equitable quality of education and promote lifelong learning,” SDG 5 to “achieve gender equality and empower all women and girls,” SDG 8 to “promote sustained, inclusive and sustainable economic growth, full and productive,” and SDG 10 to “reduce inequality within and among countries”.¹¹

The World Heart Federation (WHF) and its members believe in a world where heart health is a fundamental human right for everyone and a crucial element of global health justice. Global health justice¹² cannot be achieved without access to essential medicines for circulatory diseases.

We acknowledge that ensuring access to safe, effective and quality essential medicines is a complex and multidimensional undertaking. It depends on the strength and financing of health systems, the running of supply chains, the appropriateness of the selection, prescribing and use of drugs, and on the quality of medicines, to name just a few key factors. Common denominators, however, are the overall policymaking and policy strategies that underpin the process of getting the right

medicines to those who need it the most. Political commitments underpinned by investments in national health systems are key to ensuring access to essential medicines. Governments are still the primary coordinators of resources and systems in countries and exert significant influence at regional and global levels.

Therefore, this position paper puts forward a four-pronged approach aimed at national governments to improve and expand access to essential medicines for CVDs. Together, the recommendations under the 4 pillars aim to drive action and make progress towards achieving access to safe, effective, quality and affordable essential medicines for heart health by:

1. **Streamlining access to essential medicines in health, regulatory and surveillance systems;**
2. **Investing in and building the capacity of health care professionals;**
3. **Rethinking health financing through win-win-win taxation;**
4. **Harness innovations for access to essential medicines.**

While we look at Ministers of Health, Finance, Education and Labour to take forward the recommendations, we acknowledge the role of national and international civil society, academia, and the private sector in supporting and initiating access programmes and initiatives. In addition, while we acknowledge that ensuring access to medicines relies on transparent supply chains and procurement practices, on sound research and development, on the enforcement of anti-graft legislation, and on calibrating pricing policies, these aspects are beyond both the scope of this paper.

Moreover, we recognize that ensuring access to essential medicines must be complemented by access to health technologies. Without technologies, health systems cannot provide the right screening, diagnosis, rehabilitation and palliative care that are needed

to improve health outcomes and quality of life.

However, for all the reasons highlighted so far, we have chosen to make access to essential medicines for cardiovascular and circulatory diseases the focus of this position paper.

Therefore, the four pillars are grounded in evidence and are globally relevant but take into account regional or national differences, align with WHF’s mission and areas of expertise, and provide value for money. Moreover, the recommendations build on the World Health Organization’s (WHO) draft “Roadmap for Access 2019-2030. Comprehensive Support for Access to Medicines and Vaccines,” WHO’s General Programme of Work 2019-2023 and the Lancet Commission Report on Access to Medicines 2017.

Leading up to the recommendations, Section 1 of the paper takes stock of access to medicines in general and to essential medicines for cardiovascular diseases in particular, and Section 2 highlights challenges and opportunities in ensuring access and brings the stories of patients, programmes and initiatives alongside the scientific and policy literature.

Target 3.4 SDG 3

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to reduce by one third premature mortality from non-communicable diseases



Target 3.8 SDG 3



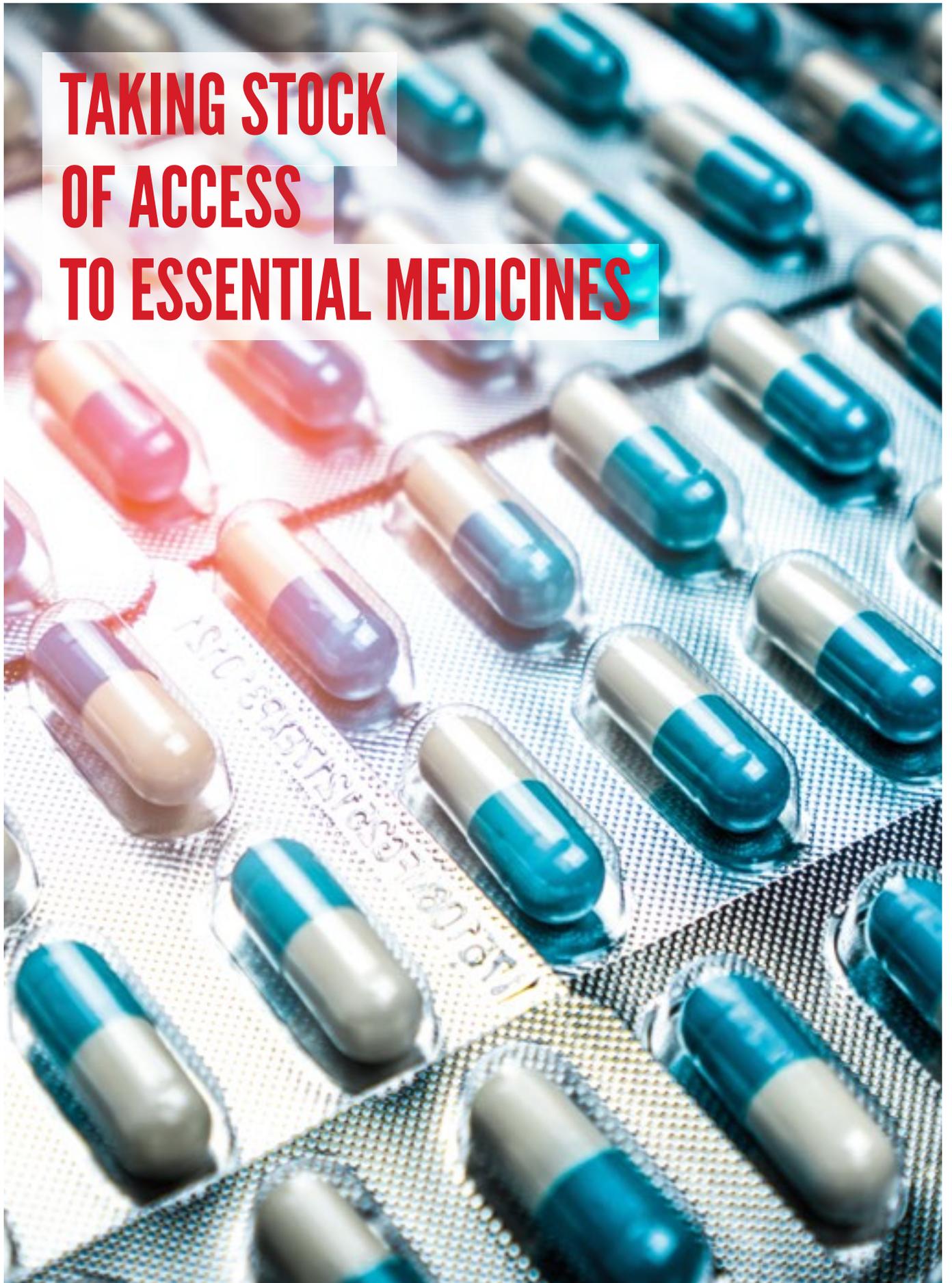
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achieve universal health coverage (...) including access to safe, effective, quality and affordable essential medicines



TAKING STOCK OF ACCESS TO ESSENTIAL MEDICINES

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1. TAKING STOCK OF ACCESS TO ESSENTIAL MEDICINES

From the 1958 Nairobi Conference on the Rational Use of Drugs to the 2017 Lancet Commission on Essential Medicines Policies and the Sustainable Development Goal 3.8 (access to safe, effective, quality and affordable essential medicines and vaccines for all), the policy and academic consensus is clear: access to essential medicines is crucial for a healthy population and is a cornerstone of achieving universal health coverage (UHC).

Given the impact of access to medicines on the health of populations and individuals, achieving it has an impact on other SDGs, including SDG 3.4 to “reduce by one third premature mortality from non-communicable

diseases,” SDG 1 to “end poverty in all its forms,” SDG 4 to “ensure inclusive and equitable quality of education and promote lifelong learning,” SDG 5 to “achieve gender equality and empower all women and girls,” SDG 8 to “promote sustained, inclusive and sustainable economic growth, full and productive,” and SDG 10 to “reduce inequality within and among countries.”¹³

Nevertheless, staggering statistics highlight the gap between policy ideals and the reality on the ground. An estimated two billion people, almost one third of the population globally, lack access to essential medicines. Of those, approximately 50 percent are in Africa and Asia.¹⁴ Moreover, on average, only 38 percent of essential medicines are available in the public health systems in low- and middle-income countries (LMICs).¹⁵ Even against this background of medicine scarcity, the World Health Organization (WHO) suggests

that up to 90 percent of health facilities in some countries cannot provide a “complete ‘basket’ of essential medicines for treating non-communicable diseases (NCDs).”¹⁶

DEFINING ACCESS

Essential medicines are “those medicines that respond to the priority health needs of a specific population.”* Ensuring access to medicines means “the reliable and consistent availability of appropriate essential, quality medicines at health facilities, the rational prescribing and dispensing of such medicines, and ensuring that they are affordable.”**

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BACKGROUND

*Maryam Bigdeli, David Peters and Anita Wagner eds, “Medicines in Health Systems. Advancing Access, Affordability and Appropriate Use,” Alliance for Health Policy and Systems Research and World Health Organization, 2014, 11.

**World Health Organization, Report by the Director General, “Addressing the Global Shortage of, and Access to Medicines and Vaccines,” Executive Board 142nd session, EB142/13, 12 January 2018, 2.

'WHO'S WHO' OF ESSENTIAL MEDICINES

The minimum list of CVD medicines and technologies, as defined in WHO's Global Action Plan on Non-communicable Diseases (NCDs), includes at least aspirin, statin, an angiotensin-converting enzyme inhibitor, a thiazide diuretic, a long-acting calcium channel blocker, metformin, insulin, a bronchodilator and a steroid inhalant.*

WHO's Global Action Plan for NCDs targets for access to medicines are:

- "At least 50 percent of eligible people receive drug therapy and counselling to prevent heart attacks and strokes;
- An 80 percent availability of the affordable basic technologies and essential medicines, including generics, required to treat major non-communicable diseases in both public and private facilities;
- A 25 percent relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure, according to national circumstances." **

Even considering this low availability, medicines account for up to a quarter of the global health expenditure, with LMICs allocating between 20-60 percent of health expenditure on medicines.¹⁷

More worrying still, for the majority of the population in low- and middle-income countries, purchasing drugs is the second largest type of expenditure after food.¹⁸ Even when medicines are accessible, available and affordable, questions about their safety and quality may arise, with an estimated 10 percent of medicines in LMICs believed to be substandard or falsified.¹⁹

Global cost of CVD is estimated to reach

USD\$ 1.4 billion



in 2030

WHY ACCESS TO CARDIOVASCULAR DISEASES MEDICINES MATTERS

With non-communicable diseases on the rise nationally and globally, there is an even stronger case to make for providing access to essential medicines. In 2016, NCDs claimed 41 million lives, the equivalent of 71 percent of the 57 million deaths registered worldwide that year. Of the four main NCDs — cardiovascular diseases, cancer, chronic respiratory diseases, and diabetes — heart diseases accounted for 17.9 million deaths and were particularly devastating in low- and middle-income countries,²⁰ where approximately 80 percent of all CVD deaths are occurring.²¹ Moreover, the Global Burden of

Disease (GBD) 2015 found a 12.5 percent increase in the global burden of mortality attributable to CVD in the past decade.²²

Diseases that affect the circulatory system, such as CVDs and related comorbidities, are not only the world's number one cause of death, but also of disability. Indeed, the global burden of CVD, diabetes and kidney diseases, expressed in disability-adjusted years (DALYs), amounted to almost half a billion years in 2016.²³ Circulatory diseases carry a hefty price tag as well. The global cost of CVD is estimated to reach USD\$ 1.4 billion in 2030 in both direct healthcare expenditure and losses to productivity because of disability or premature death.²⁴

However, circulatory diseases need not be synonymous with global death, disability and financial losses.

Approximately 75 percent of CVD is attributable to modifiable risk factors such as high blood pressure, diabetes, high cholesterol and obesity, tobacco use, alcohol consumption, physical activity and unhealthy diet.²⁵ Moreover, an estimated 20 percent of deaths occur in individuals who had been diagnosed with cardiovascular diseases, which highlights the need for access to safe and effective essential medicines for CVD.²⁶

Indeed, the management of CVD relies on medicines. For example, medication to control hypertension is key, especially considering that an estimated 62 percent of deaths caused by cerebrovascular conditions and 49 percent of those caused by ischemic heart disease may have been preventable with an appropriate control of blood pressure.²⁷



A GLIMPSE INTO THE REAL WORLD: IMPACT OF LACK OF ACCESS TO ESSENTIAL MEDICINES

BREAKING THE GENERATIONAL HOLD OF CHAGAS DISEASE THROUGH TREATMENT

Francisca is 40 and lives in the United States (US) but she is originally from Brazil.

Her second son was born prematurely and was very sick but the doctors in the US did not know why. Francisca's uncle, who is a doctor in Brazil, told her she should ask about Chagas Disease. They tested her tiny,

newborn son and the test came back positive, so he successively received the treatment and is now a healthy young boy. Francisca did not know at the time but the treatment for Chagas Disease has few side effects for babies and worked very well at curing the disease for life. She also wanted to take the treatment for Chagas but she couldn't find a doctor to treat her because she did not

have health insurance. Eventually she found a doctor who worked with many Chagas patients and who helped her access the treatment called benznidazole. This was very important for Francisca because she may want to have another child one day and getting treatment would greatly reduce the risk of having another baby born with the disease.³⁸

GIVING A CHILD WITH RHEUMATIC HEART DISEASE A SECOND CHANCE

Lilian is the mother of a young girl and lives in a village in Western Kenya.

One day, she saw a poster at the community health clinic in the next village which said she should come to the clinic if her child had fever, as it could be malaria. She also saw a sign which said that a sore throat can damage the heart. In only a matter of days, Lilian's little girl developed a sore throat. But Lilian could not make the trip to the village because she had to work in the field.

Over the next months the child suffered on and off from a fever and also aches and pain in the joints. Then she started to have difficulty breathing and she could only watch the other children play

and did not eat much. In the end, Lilian had no choice but to make the trip to the clinic. Once there, she waited in the queue all day until the nurse listened her child with a stethoscope and said there was something wrong with her heart. The nurse told Lilian that her child needed the penicillin medication but that she did not have it at the clinic; it was only available in a city 100 km away.

Lilian realized that it would cost too much for her and her little girl to travel to the city by bus and that she would have to wait for several days for a doctor to see them at a public hospital. In any case, Lilian would not be able to travel for long because her other child needed care and her husband works all day every day.

Lilian's daughter deteriorated further and stayed in bed all the time. Lilian went back to see the nurse in the community health clinic but was told there was nothing they could do for her daughter because there was something wrong with her heart, and that she needed to take the penicillin to stop it from getting worse. Eventually Lilian took a bumpy, 5-hour long bus ride to the city, where she waited all day at the clinic with all the other people needing to see the one doctor.

The doctor prescribed penicillin once a month for 5 years to stop the progression of the rheumatic heart disease Lilian's daughter had developed from her sore throat many months before. Luckily, the hospital had it in stock and Lilian's daughter was able to

receive the first 2 months supply of the medication. However, Lilian's daughter will need to take the medication for at least 5 years. This will mean many long trips back to the city, which will take up much of Lilian's time and the household's income and leave the family struggling to meet their basic needs at the end of each month.

But at least her daughter has been given a chance to reach adulthood. The long course of medication, the cost involved, and the damage already done to the heart could have been avoided if she had received the correct diagnosis and treatment for her sore throat.

LIVING WITH HYPERTENSION IN A REMOTE VILLAGE

Maria worked hard all her short life. She had been living off the land, as generations before her, and had not given much thought to doctors and hospitals. She did not have one near her anyways, nor did she have the money for regular check-ups. After six months of suffering with unbearable headaches, frequent dizzy spells, fatigue and chest pain, she begged a neighbor to

drive her to the nearest village with a community health center.

There she was told that she had high blood pressure and that she was at risk of stroke or heart disease if she did not start taking medication. Maria was given a prescription but only had the money for a couple of weeks of treatment. After the first week, she started feeling better and

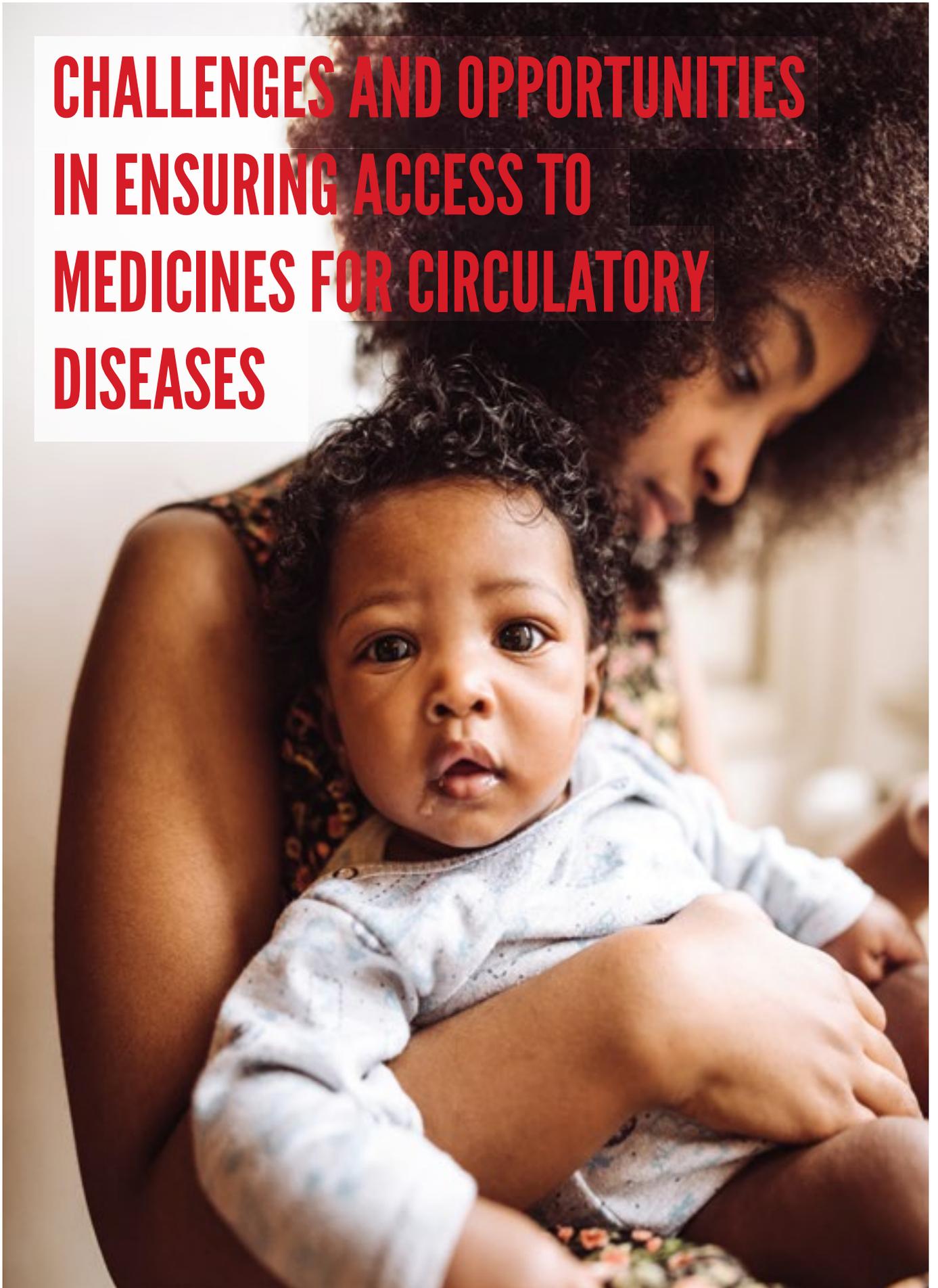
thought it was safe to stop taking the medications.

Even if she wanted to continue the treatment, she did not have the money and could not afford to travel to the community health center. Not even a year later, Maria had a stroke caused by her uncontrolled high blood pressure, an outcome that could have been entirely

preventable had she been near a health center and could afford medication to keep her hypertension in check.



CHALLENGES AND OPPORTUNITIES IN ENSURING ACCESS TO MEDICINES FOR CIRCULATORY DISEASES



2. CHALLENGES AND OPPORTUNITIES IN ENSURING ACCESS TO MEDICINES FOR CIRCULATORY DISEASES

Challenges abound in ensuring access to essential medicines in general and to CVD and other circulatory diseases drugs in particular. As mentioned in the introduction, this position paper focuses on those challenges that are within the purview of governments to address but acknowledges the importance of multi-sectoral and multi-partnership approaches.

Therefore, this section highlights health governance and financing, surveillance systems, workforce capacity, gaps in innovation uptake, and low health awareness and education as key pain points and showcases case studies of initiatives trying to address some of these challenges.

Insufficient or inappropriate public financing for health, especially for CVDs and other NCDs, stands out as the main barrier to ensuring a basket of essential medicines. Households in low- and middle-income countries are forced to make difficult choices about whom gets treatment for which disease and for how long, and often face catastrophic expenditure when confronted with health emergencies or long-term treatment for chronic diseases. Indeed, WHO estimates that low-income households in developing countries spend up to 10 percent of their total income on medicines,³⁹ compared to the 3.5 percent that poorer households in high-income countries spend on medicines.

These statistics are striking, but they could also become a footnote of history, especially for cardiovascular diseases, provided that the right investments are made in healthcare. Indeed, providing WHO's "best buys" — namely "a multi-drug regime for individuals

at high risk of CVD plus measures to prevent cervical cancer" — is estimated to cost only USD\$ 2.5 dollars per person a year in upper-middle income countries,⁴⁰ less than USD\$ 1.5 dollars in middle-income countries and USD\$ 1 dollar per person in low-income countries. These figures put in context why health investments are smart investments.

WHO estimated that USD\$ 1 put towards the Best Buys will generate a return of at least USD\$ 7, reduce premature mortality by 15%, prevent 17 million case of ischemic heart disease and stroke, save 8.2 million lives in LMICS and bring USD\$ 350 billion in economic growth — all by 2030.⁴¹

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NOVEL ORAL ANTICOAGULANTS (NOACs)

Novel oral anticoagulants (NOACs) are blood thinners used to reduce the risk of stroke in people with non-valvular atrial fibrillation (NVAF) – a common heart rhythm disturbance. They are also used by people who have previously suffered venous thromboembolism to reduce the risk of recurrence.

In both cases, NOACs are now preferred in the United States and Europe over an older class of anticoagulants – vitamin K antagonists – of which the most widely used

example is warfarin. The number of people with NVAF are on the rise in low- and middle-income countries and is estimated to reach 17.8 million by 2020, and at least 6 million cases of venous thromboembolism annually.

One of the most important advantages of NOACs over warfarin is that they do not require regular monitoring, due to significantly more stable and predictable pharmacokinetics and pharmacodynamics. This may be particularly important in resource limited settings, where access to regular monitoring (which is required with warfarin) can be limited. In addition, NOACs likely

confer a lower risk of bleeding, have fewer interactions with other medications and fewer dietary restrictions.

Nevertheless, the use of NOACs in LMICS has generally remained very limited. Low availability and unaffordable prices are reported as being major barriers to their wider use. With the inclusion of NOACs in the World Health Organization's Model List of Essential Medicines (WHO EML) in 2019, there is a real opportunity to scale up their use. Licensing the NOACs to the Medicines Patent Pool (MPP) could contribute to making such medicines available sooner at affordable prices in LMICS.

The MPP is a public health organization that negotiates intellectual property licensing agreements with patent holders to allow generic manufacture and supply of patented medicines in LMICS. MPP licensing for the NOACs could potentially contribute to increasing their availability and improving affordability in LMICS. Given the lower monitoring requirements of NOACs over alternatives, this could enable more people in need to access anticoagulation therapy, therefore reducing the risk of strokes and other sometimes fatal complications in LMICS.

A TALE OF TWO PUBLIC-PRIVATE PARTNERSHIP PROGRAMMES FOR ACCESS TO NCD MEDICINES IN KENYA

In Kenya, 27 percent of deaths among adults aged between 30 and 70 years old are caused by non-communicable diseases, making access to essential medicines for NCDs a critical issue. This is also considering that many of the patients end up paying for the medicines out-of-pocket.

Against this background, Novartis launched its Access programme in the country to provide a basket of NCD medicines – including for CVD, type 2 diabetes, respiratory illnesses and breast cancer – at the price of USD\$ 1 per treatment per month. 15 months after the launch of the programme, its impact was evaluated in eight counties in

Kenya, looking specifically at the “availability and price of portfolio medicines at health, irrespective of brand, and availability of medicines at patient households.”⁴² The evaluation indicated that Novartis Access had little impact on the availability and cost of medicines for chronic diseases in health facilities and at household level. This may suggest that lowering prices is not enough and that other factors, including awareness around access programmes, extension to private sector facilities and navigating the complexities of the health system – may equally influence access to medicines.

Similarly, Novo Nordisk implemented its Base of the Pyramid (BOP) project, a public-private partnership designed to increase access to

diabetes care for individuals living on low-incomes in LMICS in 28 of Kenya's 47 counties, and capped the price of a insulin viable at USD\$ 5. An 2019 evaluation showed that the project was successful in ensuring a “stable and affordable insulin supply,” especially compared with the unpredictable supply in counties in which the BOP project was not implemented.

However, as with the Novartis Access program, Novo Nordisk's BOP project revealed that reduced cost is not the only factor in ensuring access to medicines. Many benefiting from BOP still fell short of access to the comprehensive care they needed, including medicines, because of the high costs of medical follow-up and travel to health facilities.⁴³

In Kenya



27%

of deaths among adults aged between 30-70 are caused by non-communicable diseases

Making the right investments for access to medicines depends on **good leadership, strong regulation and appropriate governance for health**. The reality in many countries, however, is contrary to these aspirations. Fragmentation in decision-making, work in silos, regulations lacking monitoring and enforcement, lack of transparency, corruption and inappropriate alignment between health needs and policies are just a few of the issues plaguing health systems and hampering concrete actions to ensure a consistent basket of essential medicines. Particularly concerning is the issue of substandard and falsified medicines, whose global prevalence is estimated at 13.6 percent and regional prevalence at 18.7 in Africa and 13.7 in Asia respectively.⁴⁴

HARNESSING DIGITAL SOLUTIONS AGAINST FALSIFIED MEDICINES

Across the world, entrepreneurs working at the nexus of health and technology are creating innovative products to fight fake or substandard medicines. In Nigeria, for example, a company called RxAll is using artificial intelligence and a portable nanoscanner to test the quality of drugs and protect patients from life-harming substandard medicines. Once the drug is scanned, the information is cross-referenced with data in the company's cloud database, and its quality and authenticity is verified. The founder of RxAll was inspired in his fight against falsified medicines by his own near-death experience; in 2004, RxAll's founder spent 21 days in a coma caused by a fake drug.⁴⁵

Even when efforts are made to improve governance, policies and regulations at national levels, gaps persist in **monitoring and evaluating** how those are implemented on the ground and how access to essential medicines and health outcomes is, thus, impacted. In the cardiovascular field, for example, what is also lacking is a clear understanding of the real burden of access to medicines and of surveillance systems around the continuum of care. This is because, in many LMICs for example, primary healthcare facilities “do not have room for cardiovascular diseases and only have few blood pressure-measuring devices. If monitoring access to diagnosis is not possible, it becomes difficult to monitor access to medicines.”⁴⁶

MAKING HYPERTENSION AND DIABETES DRUGS AVAILABLE AND AFFORDABLE IN BRAZIL

With non-communicable diseases on the rise in Brazil, the government established the Farmacia Popular programme in 2004 to address the insufficient stock of medicines in the public sector and the high prices in the private sector. One of the milestones of the programme came in 2014, when it started providing for free diabetes and hypertension medicines to patients who went to public or private pharmacies affiliated to the programme.⁴⁷ Going beyond public sector pharmacies to include private retail pharmacies, Farmacia Popular had built an impressive network of 25,200 private-sector pharmacies and 558 public sector ones by 2013, albeit the majority of them in more prosperous regions of the country, and had reached more than six million people with medication for diabetes and more than 14 million people with medicines for hypertension for 80 percent of the period of the treatment.⁴⁸

Another systemic challenge in ensuring access to essential medicines for circulatory diseases is the **level of education and health awareness**. For example, when examining the association between education, wealth and risk of cardiovascular diseases in 20 low-income, middle-income and high-income countries, the PURE study found that individuals with low levels of education had higher rates of cardiovascular events and encountered more barriers to accessing healthcare, especially in low-income countries.⁴⁹

Beyond the PURE study, there is mounting evidence that low levels of education and health literacy correlate with adverse health outcomes, increased mortality rates, and challenges in navigating health systems and interacting with health professionals at all levels.⁵⁰

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Under-staffed, under-funded and in many settings under-trained and under-valued, the **health workforce** is key to ensuring good health, but it is in crisis. Indeed, a shortage of 18 million health workers, the majority in low- and middle-income countries, is estimated until 2030.⁵¹

Addressing this will require not only considerable investments in recruiting new health workers⁵² but also a shift in the way health professionals at all levels are trained and in how their competencies are mapped, evaluated and thought through for the best health outcomes and optimal access to essential medicines.

Among the challenges linking the health workforce with access to medicines is the appropriate dispensing of and advice for the use of essential medicines, which remains difficult in many low-income settings. Moreover, some low-income countries face rates of absenteeism of between 35 to 68 percent among public sector health workers.⁵³ With challenges come opportunities, however. For example, WHO is developing a Global Competency Framework for Universal Health Coverage that will map the key competencies required for health workers to make UHC possible in their countries and to meet both the changing educational needs and the epidemiological shifts.⁵³

COMMUNITY-LED PROJECT AGAINST HYPERTENSION IN NIGERIA (CLUB-MEDS)

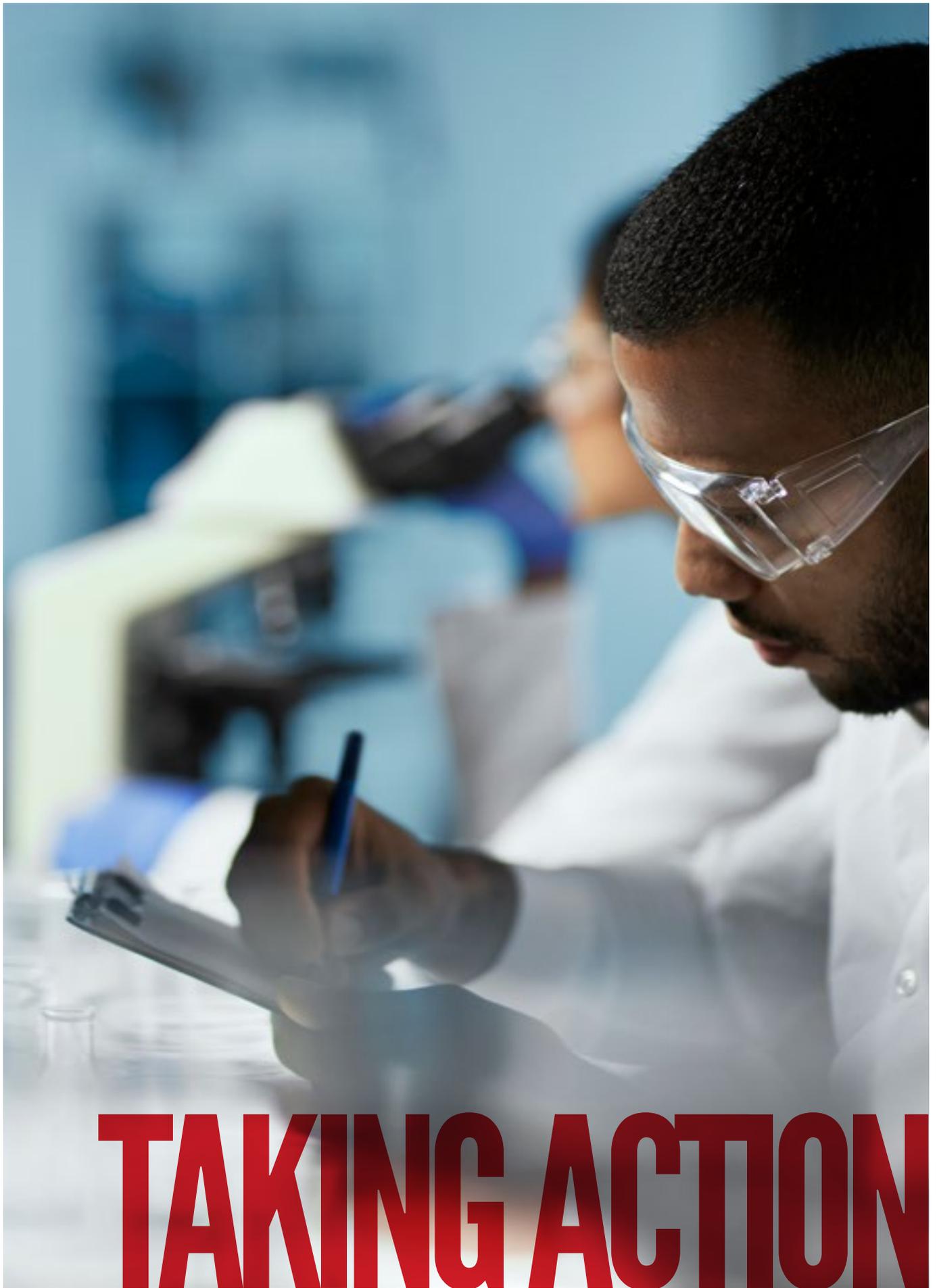
Nigeria is facing one of the highest prevalence rates of hypertension in the world, with much of it uncontrolled because of “low motivation and social support to medication adherence, long distance to healthcare facilities, long waiting time and under-dispensing of drugs.”*

The CLUB MEDS pilot project is tackling hypertension with community groups such as adherence clubs, supported by community health workers and facility nurses. The adherence clubs are centered around role-model patients who receive training to:

- 1) support and educate the group about adherence;
- 2) collect and deliver BP medication refills, conduct BP measurements; and
- 3) screen for alert signs during the monthly club sessions.

104 people with hypertension have been recruited from urban and rural sites and nine role-model patients trained to lead the nine adherence clubs. Seven of the clubs are run in urban sites and two in rural areas and each club brings together a maximum of 13 patients. Their meetings are currently ongoing; data on adherence and control of blood pressure will be collected at six months.





TAKING ACTION

3. TAKING ACTION

The World Heart Federation (WHF) and its members believe in a world where heart health is a fundamental human right for everyone and a crucial element of global health justice. Global health justice cannot be achieved without access to essential medicines for circulatory diseases.

We acknowledge that ensuring access to safe, effective and quality essential medicines is a complex and multidimensional undertaking. It depends on the strength and financing of health systems, the running of supply chains, the appropriateness of the selection, prescribing and use of drugs, and on the quality of medicines to name just a few key factors. Common denominators, however, are the overall policymaking and policy strategies that underpin the process of getting the right medicines to those who need it the most. Political commitments underpinned by investments in national health systems are key to ensuring access to essential medicines. Governments are still the primary coordinators of resources and systems in countries and exert significant influence at regional and global levels.

Therefore, this position paper puts forward a four-pronged approach aimed at national governments to improve and expand access to essential medicines for circulatory diseases. Together, the recommendations under the four pillars aim to drive action and make progress towards achieving access to safe,

effective, quality and affordable essential medicines for heart health by:

1. Streamlining access to essential medicines in health, regulatory and surveillance systems;
2. Investing in and building the capacity of health care professionals;
3. Rethinking health financing through win-win-win taxation;
4. Harnessing health technologies.

While we look at Ministers of Health, Finance, Education and Labour to take forward the recommendations, we acknowledge the role of national and international civil society, academia, and the private sector in supporting and initiating access programmes and initiatives. In addition, while we acknowledge that ensuring access to medicines relies on transparent supply chains and procurement practices, on sound research and development, on the enforcement of anti-graft legislation, and on calibrating pricing policies, these aspects are beyond both the scope of this paper.

Moreover, we recognize that ensuring access to essential medicines must be complemented by access to health technologies. Without technologies, health systems cannot provide the right screening, diagnosis, rehabilitation and palliative care that are needed to improve health outcomes and quality of life. However, for all the reasons highlighted so far, we have chosen to make access to essential medicines for cardiovascular diseases the focus of this position paper.

Therefore, the four pillars are grounded in evidence and are globally relevant but take into account regional or national differences, align with WHF's mission and areas of expertise, and provide value for money. Moreover, the recommendations build on the World Health Organization's (WHO) draft "Roadmap for Access 2019-2030. Comprehensive Support for Access to Medicines and Vaccines," WHO's General Programme of Work 2019-2023 and the Lancet Commission Report on Access to Medicines 2017.



RECOMMENDATION 1

STREAMLINE ACCESS TO ESSENTIAL MEDICINES IN HEALTH, REGULATORY AND SURVEILLANCE SYSTEMS

The World Health Organization highlights six components of a well-functioning health system: leadership & governance, health information systems, health financing, human resources for health, essential medical products and technologies, and service delivery.⁵⁴ Turning these around, we argue that four of these components — leadership & governance, health information systems, health financing, human resources for health — are central to ensuring equitable access to essential medicines in general and essential medicines for CVD in particular. While financing and human resources will be explored in subsequent recommendations, **we start by urging governments to strengthen their national health, regulatory and information systems as a pathway to ensuring or to improving access to essential medicines.**

Improved health governance is not a lofty ideal but a pragmatic approach to address pressing health issues impacting access to essential medicines. This is because medicines account for up to 60 percent of health expenditure in some countries,⁵⁵ meaning that a transparent, well-governed and well-regulated health system is more likely to prevent waste and ensure access to essential medicines. Each national health system deals with its own unique set of challenges. As a global actor connected to its 200 plus national and regional members, WHF cannot be prescriptive in its recommendations and understands that what works in a country may not be relevant in another or across different geographies of the same state. What we are recommending, however, is a health system approach that calls for governments to examine bottlenecks to access to medicines throughout their countries' health infrastructure and across "the interconnections between system components."⁵⁶

Building on the evidence base from WHO and the Alliance for Health Policy and Systems Research, **we advocate for "access to medicines and their appropriate use as an explicit focus in health systems strengthening**

and efforts towards universal health coverage."⁵⁷

Regarding regulation, we understand that National Medicines Regulatory Authorities are the first line of defense against substandard, fake or falsified health products, including essential medicines for cardiovascular diseases. Similar to national health systems, in-country regulatory agencies and systems have strengths and weaknesses unique to their context and history. Across many contexts, however, they are understaffed and under-resourced. Not surprisingly, an estimated 70 percent of national regulatory agencies globally cannot meet their core mandate.

Therefore, WHF calls on national governments to:

- **Submit health products, including essential medicines for CVD, to WHO's pre-qualification program, and harness the potential of the national Essential Medicines List for CVD;**
- **Work with WHO to assess the strength of their regulatory systems through the Global Benchmarking Tool;**
- **Report progress in their countries against the indicators of WHO's Global Monitoring Framework on NCDs;**

- **Increase uptake and utilization of WHO's technical guidelines and standards to regulate for safe and quality essential medicines.**⁵⁹

The road to strong health governance and regulatory systems for access to essential medicines is long but having a good surveillance and information system in place can act as a map to track and assess progress. This is particularly important for CVD, as we are lacking a comprehensive picture of access to essential medicines to prevent and treat heart diseases. We acknowledge that making any recommendations about surveillance and information systems means factoring in the contradictory realities of either limited infrastructure in place or a proliferation of competing, fragmented and inefficient surveillance systems nationally, regionally and globally.

Therefore, **we recommend governments to assess the extent to which their current information and surveillance systems give them an accurate picture of access to essential medicines, especially for CVD and NCDs, and to build, improve or revamp their information infrastructure accordingly. We also strongly encourage national governments to work as much as possible with WHO**

within the frameworks of the Health Data Collaborative, the WHO-Health Action International (HAI) Regional Collaboration for Action on Essential Medicines in Africa, the Service Availability and Readiness Assessment (SARA), the Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, and the shortages notification systems.⁶⁰



RECOMMENDATION 2

INVEST IN & BUILD CAPACITY OF FRONTLINE HEALTH WORKERS FOR IMPROVED ACCESS TO ESSENTIAL MEDICINES

Frontline health care professionals — i.e., community health workers, nurses or physicians — are the first to initiate diagnosis and treatment, dispense medicines and make referrals. As such, their role is key in ensuring rational dispensing and improving adherence to treatment.

In remote, rural or low-income areas, where health facilities are scarce, frontline health workers covering large areas may be the only link that people living there have with the health system. And in many settings, lack of access to a health worker translates

into lack of access to essential medicines. For these reasons, it is crucial to invest in the health workforce as a key pathway to improving access to medicines.

We urge governments — and in particular Ministers of Health, Finance, Education and Labour — to:

- Make appropriate investments in recruiting, retaining, incentivizing and training health workers and ensure their equitable distribution across their countries and health systems, and ⁶¹ especially in low-income, remote and rural settings;
- Support task shifting and empower “non-specialized workers to prescribe priority interventions,” especially in under-served, remote or rural areas; ⁶²
- Include learning modules and skills building relevant to access to essential medicines in the education curricula of health care professionals, including in rural and under-served areas;
- Incorporate lifelong learning and training for health workers on access to essential medicines, appropriate dispensing, rational use and adherence to treatment;
- Streamline access to essential medicines in national

guidelines on the prevention, management and treatment of cardiovascular diseases and other non-communicable diseases, and disseminate them to health workers at all levels;

- Support the recommendations of the High-Level Commission on Health Employment and Economic Growth and of the World Health Organization’s Global Strategy on Human Resources for Health 2030.



RECOMMENDATION 3

RETHINK HEALTH FINANCING FOR ACCESS TO ESSENTIAL MEDICINES THROUGH WIN-WIN-WIN TAXATION

Providing WHO's best buys, namely a basket of medicines for those at risk of CVD and a prevention package for cervical cancer, is estimated to cost only USD\$ 2.5 dollars per person a year in upper-middle income countries, less than USD\$ 1.5 dollars in middle-income countries and USD\$ 1 dollar per person in low-income countries.⁶³

- Alcohol consumption leads to an estimated 3 million deaths every year, representing 5 percent of deaths worldwide;
- Overweight, obesity and diabetes combined kill an estimated 6.1 million people every year. Unhealthy diets, rich in processed foods and added sugars, contribute significantly to obesity and diabetes.⁶⁵

Unhealthy commodities do not only significantly impact people's health but also cause substantial economic losses to countries. Estimates show that smoking cost the global economy USD\$ 1.4 trillion in 2012, including expenditure associated with smoking-induced diseases and productivity losses; similarly, alcohol consumption generated losses equivalent to one percent of the GDP in middle- and high-income countries in 2009.⁶⁶

The Task Force on Fiscal Policy for Health found that a 50-percent increase in excise taxes on tobacco, alcohol and sugar-sweetened beverages by all countries would save 50 million people from premature deaths over the next 50 years and add USD\$ 20 trillion in additional revenues.⁶⁷ Even a smaller, 20-percent increase of excise taxes by all countries on the three categories of unhealthy products would save 21 million people from a premature death and add USD\$ 11 trillion in revenues over a period of 50 years. These scenarios would significantly benefit low- and middle-income countries, where most lives would be saved.⁶⁸

Evidence from The Lancet Taskforce on NCDs and Economics and the Task Force on Fiscal

Policy for Health suggests that raising excise taxes on unhealthy commodities benefit the young and low-income consumers the most. This is because low-income households tend to have the highest consumption of tobacco and sugary drinks and shoulder the heaviest burden of health and economic consequences.⁷⁰

Mounting evidence from the Philippines and Mexico, which have implemented successful excise tax

policies on tobacco and sugar-sweetened beverages respectively, shows that taxation can have win-win-win outcomes for the health of populations, both in terms of preventing NCDs and reducing the consumption of unhealthy commodities, and for a country's revenue streams. The Philippines, for example, used the tax revenues to "almost triple the health coverage of low-income citizens and subsidize the insurance coverage of senior citizens."⁷¹

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Harnessing the potential of fiscal policies is a field ripe with opportunities, especially since the World Bank estimates that only 50 percent of developing countries are successful in raising taxes that are equivalent to 15 percent of their gross domestic product, and that a combination of effective fiscal policies and investments in health could reduce the health financing gap from USD\$ 176 billion to between USD\$ 114 and 122 billion by 2030.⁶⁴

The World Heart Federation urges Governments to raise excise taxes on unhealthy products such as tobacco, alcohol and sugar-sweetened beverages and use those revenues to increase access to essential medicines for CVD and other NCDs, strengthen health and regulatory systems, and recruit, retain and train health workers at all levels.

Taxing unhealthy commodities makes sense from a health perspective, considering that:

- Consumption of or exposure to tobacco accounts for 13 percent of annual global deaths (8 million people);

EFFECTIVE FISCAL POLICIES AND INVESTMENTS IN HEALTH COULD REDUCE THE HEALTH FINANCING GAP FROM

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RECOMMENDATION 4

HARNESS INNOVATIONS FOR ACCESS TO ESSENTIAL MEDICINES

Across the world, technologies are harnessed to track and improve supply chains, assist consumers and regulatory agencies in assessing the quality and safety of medicines, deliver diagnosis, and follow-up with patients to ensure adherence to treatment and the appropriate use of medicines.

From mHealth to digital initiatives and, in recent years, artificial intelligence being

used to shape processes along the R&D and supply chain continuum, governments can no longer ignore the power and challenges of health technologies for access to essential medicines.

We strongly support the harnessing of evidence-based digital and mHealth solutions to:

- **Provide lifelong learning to healthcare professionals on access to essential medicines, rational use and adherence to treatment for circulatory diseases;**
- **Raise awareness among consumers and patients on the use and quality of**

essential medicines for circulatory diseases;

- **Identify, prevent and address shortages of essential medicines for and circulatory diseases;**
- **Test and monitor the quality of essential medicines.**

When considering the recommendations above, Governments are encouraged to also consider the ethical implications, evidence-base and appropriateness of health technologies and digital solutions for each setting.

MAPPING OF WHF'S RECOMMENDATIONS IN RELATION TO WHO'S ROADMAP ON ACCESS TO MEDICINES AND VACCINES

World Heart Federation recommendations

Streamline access to essential medicines in health, regulatory and surveillance systems

Invest in & build capacity of health workers for improved access to essential medicines

Rethink health financing for access to essential medicines through win-win-win taxation

Harness innovations for access to essential medicines for CVD

WHO's Roadmap on Access to Medicines and Vaccines

Regulatory systems strengthening

Assessment of the quality, safety and efficacy/performance of health products through prequalification

Market surveillance of quality, safety and performance

Appropriate prescribing, dispensing and rational use

Improving equitable access

Improving equitable access

ABOUT THE WORLD HEART FEDERATION

WHF is the only CVD non-governmental organization (NGO) in official relations with the World Health Organization (WHO), and a member of the NCD Alliance.

WHF works at the international and national levels through our own activities and those

of our 200 plus members. Together, we are working to end needless deaths from exposure to tobacco and other risk factors, lack of access to treatment, and neglected conditions like rheumatic heart disease which kills hundreds of thousands of children each year.

Across 100 countries, we are acting now to build global

commitment to address cardiovascular health at the policy level, generate and exchange ideas, share best practice, advance scientific knowledge and promote knowledge transfer to tackle CVD. We are at the heart of driving the CVD agenda and advocating for better heart health — enabling people to live longer, better and more heart-healthy lives, wherever and wherever they are.

ABOUT THE GLOBAL SUMMIT ON CIRCULATORY HEALTH

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The Global Summit is an invitation-only event for leaders who are shaping the future of circulatory health. It aims to create a space where speakers and participants with diverse experiences — from governments, international organizations, academia, and the private sector — can network, debate and place critical issues of circulatory health in a wider global health context while staying hungry for more ideas, conversations and exchanges.

The objectives of the Summit are to:

1. **Convene** and mobilize advocates in circulatory health
2. **Coordinate** stakeholders and policymakers around shared goals
3. **Campaign** for circulatory health with a collective voice and a clear message

4. **Catalyze** action for circulatory health through civil society and policy engagement

These objectives lead directly to the intended outcomes of the Summit, namely to:

- Foster greater **connectedness** between participants
- Issue a **collective call to action** in light of the urgent need
- Discuss **concrete next steps** for programme implementation

ONE SUMMIT, THREE CONTINENTS AND COUNTING...

The first Global Summit, held in 2016 in Mexico City, resulted in the first Declaration on Circulatory Health — the Mexico Declaration — signed by 29 leading global organizations, including the World Health Organization.

Following the second Summit, held in 2017 in Singapore, the Global Coalition for Circulatory

Health was launched as the only network of international, regional and national organizations advocating for increased prevention, control and treatment of all circulatory diseases.

The 3rd Global Summit explored the theme of Access to Essential Medicines and Technologies by bringing together influencers and leaders from circulatory health and policymaking to propose concrete Calls to Action to drive action on cardiovascular diseases.

The 4th Global Summit (Paris, 29-30 August 2019) explores the issue of Innovations in Circulatory Care and Technologies.

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IMPROVING ACCESS

IMPROVING ACCESS TO ESSENTIAL MEDICINES FOR CIRCULATORY DISEASES: A CALL TO ACTION



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