



# ACHIEVING A HEALTHIER AND SUSTAINABLE FUTURE FOR ALL

Policy Perspectives on Universal  
Health Coverage from the Innovative  
Biopharmaceutical Industry

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## 01 Introduction

This publication builds on our industry's eight guiding principles on universal health coverage (UHC), developed in 2014, including our views on the key ingredients required for achieving UHC, and reaffirms our commitment to play our part. But before we can pave the way forward, we must first address why it is now more critical than ever to rise to this challenge.

Significant global health gains have been achieved in recent years: life expectancy has increased in many parts of the world; six million fewer children under the age of five years died in 2016 than in 1990; polio is on the verge of being eradicated; and 21 million people living with HIV are now receiving treatment. Despite this progress, people everywhere continue to face a complex mix of interconnected threats to their health and well-being—from poverty and inequality to conflict and climate change. Furthermore, the growing burden of disease continues to challenge the global community in finding and implementing adequate, ethical, and sustainable solutions to reach UHC.<sup>1</sup> We still have a way to go in fulfilling the vision of the World Health Organization (WHO) of a world in which all people attain the highest possible standard of health and well-being.<sup>2</sup>

Nevertheless, when it comes to health, we cannot afford to shy away from a challenge. We, the global community, have set ambitious and unifying goals that require us to come together as partners, to raise the bar and seek tools to speed up development for the benefit of all. The United Nations (UN) General Assembly passed a resolution in 2012 committing all Member States to work to attain UHC. The 2030 Agenda for Sustainable Development, adopted by all UN Member States in 2015, provides a shared blueprint for achieving peace and prosperity for people and our planet through the realization of 17 Sustainable Development Goals (SDGs) by 2030. With respect

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to health, SDG3 calls on all stakeholders to “Ensure healthy lives and promote well-being for all at all ages” and target 3.8 in particular identifies as a priority to “Achieve UHC, including financial risk protection, access to safe quality essential health-care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all” by 2030. The WHO embedded SDG3 into its own strategic work plan—the 13th general programme of work (GPW 13)—and committed in the first of its three interconnected priorities to achieving UHC for 1 billion persons by 2023, in addition to addressing health emergencies and promoting healthier populations.

The goal is clear: now, more than ever, we need to focus our attention on UHC. Heads of State and Government convene at the first-ever UN High-Level Meeting (UNHLM) on UHC in New York in September 2019 to reinforce their commitments to achieving UHC and agree to the framework for this coordinated effort. This UNHLM is a defining moment in affirming the world’s dedication and the actions needed.

With the goals set before us and the platform to commit to them, success can only be achieved if we invest the required will, resources, and expertise to achieve them. No single organization or sector can achieve UHC on its own. This endeavor will require pooling a diversity of resources, knowledge, and experience, and establishing meaningful partnerships among stakeholders. All must work together, with open minds, and agree on how to collaborate in the best interest of patients, people, and the planet.

This publication builds upon the Innovative Biopharmaceutical Industry Perspectives on UHC: Proposed Policy Principles (2014).



## 02 Why Universal Health Coverage?

At its core, UHC is about all people accessing the quality and effective essential healthcare they need without experiencing financial hardship as a result.<sup>3</sup> At its foundation, it starts with upholding quality primary healthcare (PHC).

At the UN Sustainable Development Summit in New York in 2015, all countries agreed to achieve SDG3 to “**ensure healthy lives and promote well-being for all**”. Nine targets on health were also agreed to under this broad goal, including target 3.8 as follows: **Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all.**

With health as a cornerstone of many other development targets, achieving target 3.8 on UHC will underpin success on the majority of the other nine targets.<sup>4</sup> A number of leading international bodies tackling health issues (including the WHO and the World Bank) and national governments are therefore promoting UHC as the most important immediate goal for global health.

**UHC improves population health outcomes**, including child and maternal mortality rates.<sup>5</sup> Think about the impact on the family and community of a young mother who dies in childbirth because she lacks access to healthcare. Consider the burden carried by an adult suffering from a chronic non-communicable disease (NCD), such as diabetes or hypertension, when a large percentage of NCDs are preventable.<sup>6</sup> Even mature, well-resourced health systems will be stretched to the breaking point if current NCD trends continue. Tackling NCDs early through prevention and

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promotion, especially in view of aging populations in many countries, and improving access to—and affordability of—quality health services improves health overall.

UHC, through health systems strengthening, also supports global health security by preventing outbreaks through high immunization coverage or by providing “early warning” through rapid access of all patients to healthcare. Conversely, investing in global health security also supports UHC. By avoiding health crises resources are not diverted to crises such as influenza pandemics or Ebola, preventing patients from accessing regular healthcare services.

**UHC strengthens healthcare and health systems governance.** The pursuit of UHC requires all stakeholders—industry, governments, healthcare professionals and providers, patients, and civil society—to support good governance, including responsive and inclusive regulatory and legal systems that are relevant for access to quality and effective essential healthcare. Well-governed systems ensure appropriate selection of medicines and health products for coverage under UHC, for primary care and beyond. In addition, they enable appropriate, managed interaction with the private sector to supply quality products, while avoiding corruption. They also ensure appropriate prescribing and use of medicines that improve the quality of care and health outcomes as well as reduce waste and inefficiency in the system. With high standards of ethical conduct—by the innovative biopharmaceutical industry and all stakeholders in the healthcare ecosystem—in the pursuit of UHC we can achieve healthcare and health systems that are better governed, higher quality, and more effective.

**UHC generates benefits to societies far beyond the health sector.** Whole communities and entire nations thrive when people are healthy. Healthy citizens can go to school, take care of their families, contribute to their economies, and achieve their full human potential. Health improvements drove a quarter of full income growth<sup>7</sup> in low-income and middle-income countries between 2000 and 2011. Two hundred and sixty seven eminent economists from 44 countries signed The Economists’ Declaration on Universal Health Coverage in 2015, which concluded that the economic returns on investing in UHC were more than 10 times the costs.<sup>8</sup>

**“The link between health and economic growth is clear. When people aren’t sick in bed or the hospital, they can go to work. But the wider impact of these investments is not always obvious. For example, over the past two decades, every dollar spent on essential medicines in Africa has generated US\$20 more in social and economic benefits. Every vaccine is a shot of adrenaline into the heart of the African economy.”<sup>9</sup>**

Paul Kagame | President of Rwanda  
& Bill Gates | Co-chair of the Bill & Melinda Gates Foundation

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**UHC increases social solidarity.** UHC, if properly implemented and driven by quality PHC, will have a disproportionately positive impact on vulnerable and marginalized groups such as women and children, people living with mental health issues, transgender populations, and those living in remote, rural communities. As a result, it is also a means to reduce inequalities within societies and contribute to building peace and security. As such, UHC can deliver substantial political benefits to states.

**“The Chinese government has clearly stated its objective of achieving a “harmonious society” as a national priority... this clearly demonstrates the Chinese government’s keen attention to the question of the people’s standard of living, which includes healthcare. It also demonstrates the government’s strategic commitment to...providing equal access for all the people to basic public services.”<sup>10</sup>**

Chen Zhu | Minister of Health (2007–2013), China

**UHC and a healthier population pave the way for all countries—no matter the level of development—to achieve the SDGs.** All 17 SDGs are inter-connected and mutually reinforcing. Besides contributing to SDG3 (“ensure healthy lives and promote well-being for all at all ages”), UHC also promotes:<sup>11</sup>



#### **POVERTY ALLEVIATION (SDG1)**

As it prevents people from being driven into poverty from high and potentially catastrophic and impoverishing out-of-pocket (OOP) health payments



#### **IMPROVED NUTRITION (SDG2)**

As people receive proper health information and advice to mitigate both malnutrition and overnutrition



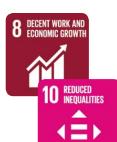
#### **EDUCATION (SDG4)**

As strong health systems ensure that children are healthy enough to attend school and complete their education



#### **GENDER EQUALITY (SDG5)**

Through ensuring that all people receive necessary health services, including the most vulnerable members of the population—often women and children



#### **ECONOMIC GROWTH AND JOB CREATION (SDG8) & THE REDUCTION OF INEQUALITY WITHIN AND AMONG COUNTRIES (SDG10)**

Because people are healthy enough to obtain jobs and consistently contribute to their countries’ economies



#### **PEACEFUL AND INCLUSIVE SOCIETIES (SDG16)**

As healthy populations help build effective, accountable and inclusive institutions at all levels and, in turn, peaceful and inclusive societies support healthy populations



#### **PARTNERSHIP (SDG17)**

Given the transformative power, scale, and expertise of various stakeholders, such as the private sector, those who have most contact with and need of health systems, and civil society, to name but a few



**US\$500 billion**

in estimated yearly costs from pandemic influenza

**6.0–8.5%**

of a country's GDP could be negatively impacted by 2030

**US\$1 trillion**

in costs globally could be accrued from Tuberculosis by 2030

**US\$3 trillion**

of losses in GDP per year worldwide could be caused by AMR

**The cost of inaction is well documented.** There is a greater sense of urgency when one considers how our societies are threatened by increasing health burdens related to chronic diseases, disaster risks, pandemic threats, antimicrobial resistance (AMR), the predicted impacts of climate change, and other environmental risks such as air pollution. These risks, especially when compounded, have the potential to impact people's health and well-being in a number of ways.<sup>12</sup> Globally, one in three adults lives with multiple chronic conditions, a figure that is predicted to rise dramatically by 2030.<sup>13</sup> The proportion of the world's population over 60 years of age will nearly double between 2015 and 2050.<sup>14</sup> Climate change and urbanization pose increased risk in the spread of infectious disease. Rising temperatures are expected to result in changes to the distribution of disease vectors like mosquitoes, putting more people at risk from diseases such as malaria and dengue fever.<sup>15</sup>

Without decisive and concerted action toward achieving UHC, economies will suffer.

- **Non-communicable diseases** (NCDs) such as cardiovascular diseases, cancers, diabetes, and chronic lung diseases could negatively impact a country's gross domestic product (GDP) by 6.0–8.5% by 2030.<sup>16</sup> By comparison, the United States experienced 8.5% of GDP loss in the first year of the Great Depression<sup>17</sup> (1929) and 4.3% of GDP loss throughout the entire Great Recession<sup>18</sup> (2007–2009).
- **Ebola virus** caused Liberia's economy to decline 8% from 2013 to 2014.<sup>19</sup>
- **Antimicrobial resistance** (AMR) in the form of drug-resistant superbugs could soon cause over US\$3 trillion in GDP loss per year worldwide.<sup>20</sup> By comparison, the estimated global cost of corruption is at least US\$2.6 trillion.<sup>21</sup>
- **Tuberculosis** (TB) could cost the global economy almost US\$1 trillion by 2030.<sup>22</sup>
- **Pandemic influenza** is estimated to have a yearly cost of US\$500 billion.<sup>23</sup>



## 03 Key Components to Achieving UHC

**UHC is an investment in the foundation of a healthier, more sustainable future for all.** The innovative biopharmaceutical industry stands together with the global health community to support all countries in accelerating efforts to achieve UHC. We encourage considering UHC as a foundational package of benefits that should not limit the adoption of other benefits.

UHC is a journey unique to each country's needs and priorities. Each country must deploy necessary resources to achieve them. There is no one-size-fits-all approach. Each country must prioritize which health services to cover, clearly defining beneficiary population groups, how to pay for those services, and how to ensure effective and efficient delivery in consultation with stakeholders.

Regardless of a country's unique needs, no single organization or sector can achieve UHC on its own; we are committed to playing our part.

From the perspective of the innovative biopharmaceutical industry there are three key components to achieving UHC, which are all elements of SDG Target 3.8. We are committed to playing our part in support of each:

- 03.1 UPHOLD QUALITY PHC:** to support “access to quality essential healthcare services”
- 03.2 INVEST MORE, AND INVEST BETTER IN HEALTH:** to support “financial risk protection”
- 03.3 IMPROVE:** “access to safe, effective, quality and affordable essential medicines and vaccines”

**Moving together begins with building a culture of trust.** This is why our industry prioritizes ethics and business integrity in all of our relationships, establishing a foundation that is based on the core values of care, fairness, respect, and honesty that aligns with society's expectations, with patients at the core of everything we do. Over the past decade, our industry has seen rapid worldwide adoption and implementation of industry codes of conduct. These codes have enabled the formation of national "consensus framework" agreements that now span five continents, bringing together diverse healthcare ecosystems—industry, government, patients, and healthcare professionals and providers—for the first time.



**IFPMA Ethos > Building a culture of trust**  
[https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA\\_Code\\_of\\_Practice\\_2019.pdf](https://www.ifpma.org/wp-content/uploads/2018/09/IFPMA_Code_of_Practice_2019.pdf)

We are ready and keen to collaborate to help achieve UHC so people, communities, and economies reach their full potential. As noted in the UN General Assembly Resolution on Sustainable Development in 2015, private business activity, investment, and innovation are major drivers of productivity, inclusive economic growth, and job creation. We believe these can be major drivers of UHC, too. We embrace SDG 17—"Revitalize the global partnership for sustainable development"—to unlock the transformative power, scale, and expertise of the private sector to contribute to achieving UHC and are committed to translating this goal into action. As part of the UHC 2030 movement, we are also committed to the "Key Asks" developed ahead of the UN High-Level meeting on UHC, which calls on all actors of the UHC movement to:

- Commit to achieve UHC for healthy lives and well-being for all at all stages, as a social contract
- Pursue equity in access to quality health services with financial protection
- Create a strong, enabling regulatory and legal environment responsive to people's needs
- Build quality health systems that people and communities trust
- Sustain public financing and harmonise health investments
- Establish multi-stakeholder mechanisms for engaging the whole of society for a healthier world



## 03.1 Uphold Quality Primary Healthcare

Together, Primary Health Care (PHC) and resilient health systems form the cornerstone of UHC. They are what enable UHC to be inclusive, to ensure it leaves no one behind. PHC is the package of essential health services—ranging from promotion and prevention to treatment, rehabilitation, and palliative care. A person receives these services across their life course, often beginning before birth and continuing through illness, injury, work, childbirth, aging, and the end of life. PHC is the frontline of a resilient health system, one which is able to prepare for, withstand the stress of, and respond to the public health consequences of disasters and emergencies.

**"We are convinced that strengthening primary healthcare is the most inclusive, effective, and efficient approach to enhance people's physical and mental health, as well as social well-being, and that primary healthcare is a cornerstone of a sustainable health system for universal health coverage."**

Astana Declaration, 2018

The innovative biopharmaceutical industry is part of a diverse treatment and prevention ecosystem working alongside public and private providers, health professionals, hospitals and clinics, laboratory services, and health insurers. While governments must lead to make UHC a reality, we play an indispensable role in developing and delivering health innovations to support and strengthen PHC and contribute to building resilient health systems. The innovative biopharmaceutical industry also serves as an essential partner to strengthen healthcare and health

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systems governance, championing efforts that drive implementation of high-standard ethical business practices and foster an enabling environment for sound PHC.

## **Primary healthcare designed to be comprehensive and evidence-based**

PHC should be grounded in a holistic, evidence-based life-course approach to health and well-being, as opposed to specific disease silos or age groups. Comprehensive PHC ensures continuity of care, starting with primary prevention at the public level and including treatment at the individual level, combined with higher levels of care if needed. Above all, PHC should provide choices, empowering people to live and age well. These PHC elements should be built on clear legal frameworks established by governments at the national level to ensure quality, safety, and financial risk protection.

Resilient health systems integrate multi-sectoral, people-centered disease prevention and health promotion strategies, building on immunization as a core pillar and ensuring a focus on NCD risk factors. Investment in NCD prevention and control can yield more than 8.2 million lives saved and more than US\$350 billion in economic growth by 2030 in low- and lower-income countries.<sup>24</sup> When investments are focused on young people, the foundation of tomorrow's healthy and prosperous societies, the value created can be even greater.<sup>25</sup> Public health measures that address the upstream determinants of health are also necessary to PHC working well. Finally, access to evidence-based health information and affordable health services and products, including for those paying out-of-pocket (OOP), are critical.

## **The staple products of primary healthcare: quality medicines and vaccines**

The innovative biopharmaceutical industry invests in and drives advances in research, development, and manufacturing capabilities so that safe, effective medicines and vaccines remain available as essential treatment interventions and tools for prevention. We develop new therapies, improve existing products, and work hand-in-hand with governments, civil society, and academia to ensure high-quality medicines and vaccines are delivered efficiently, effectively, and ethically, so that no one is left behind.

The impact is undeniable. One study found that new medicines accounted for 73% of the increase in life expectancy across 30 countries during the 2000s.<sup>26</sup> Medicines like antiretroviral therapies are a key example, transforming HIV from an untreatable and almost-always-fatal illness into a manageable, chronic condition. Life expectancy in turn drives income growth.

The industry also contributes research, development, and manufacturing capabilities so that vaccines remain the safest, most effective, and cost-efficient medical technology ever developed.<sup>27</sup> Immunization saves the lives of between 2 and 3 million children per year, and has tremendous positive social and economic impacts,<sup>28</sup> yet its benefits are often not fully realized. Immunization routinely reaches more households than any other health service and provides a platform for reaching families and communities with integrated health services. The diversity of stakeholders involved in immunization, including industry, must continue to promote the benefits of vaccines,

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challenge misinformation and vaccine hesitancy, and restore and protect vaccine confidence. Implementing policies that support immunization across the life course offers a cost-effective and sustainable way to improve population health and promote healthy aging, leading to wider socio-economic benefits.<sup>29</sup> Vaccine delivery through national immunization programs helps build epidemic and pandemic response capacity while reducing disease for all people, including the poorest, most vulnerable, and those that cannot receive vaccines individually. Vaccines can also play a vital role in the prevention of NCDs like cervical and liver cancers and the fight against AMR, reducing primary and secondary infections and reliance on and inappropriate use of antibiotics.<sup>30</sup>

**“Immunization is the only intervention that brings the majority of children and their families into contact with primary health services five or more times during the first year of a child’s life”<sup>31</sup>**

The Gavi Alliance

### **Protecting the integrity of medical products and services from manufacture to supply**

Tackling falsified and sub-standard medicines and vaccines remain critical components of a resilient health system.<sup>32,33</sup> As creators of medicines and vaccines, the industry has a fundamental responsibility to maintain compliance with the highest standards of quality and safety for our products. To meet this responsibility, we comply with regulatory frameworks for quality manufacturing, work with many regulatory stakeholders, provide input and expertise, and develop new packaging and tracking technologies so that healthy communities, patients, and caregivers can trust the medicines and vaccines they need. Quality medicines, including innovative medicines and their generics and biosimilars, and vaccines must be procured safely and remain in adequate stock at the local and PHC levels. Ensuring quality also helps to address AMR, since antimalarials and antibiotics are the most commonly reported falsified or sub-standard medical products.<sup>34</sup>

Governments—in partnership with industry and other stakeholders, such as civil society and people living with and affected by health conditions—must create an evolving and a responsible regulatory and legal system that sets an ethical framework, supports innovations, and promotes responsiveness, inclusiveness, and accountability of all stakeholders. This system must adapt to changing needs and comply with medical and public health ethics in a period of rapid technological evolution and medical innovation.

**“8.6 million people in low- and middle-income countries die from causes amenable to healthcare; of these, 5 million are people who have used the health system but received poor-quality healthcare. This is five times higher than all global deaths from HIV or AIDS and over three times higher than all deaths from diabetes.”<sup>35</sup>**

Kruk et al. | The Lancet, 2018



## Resilient health systems equipped to ensure quality, disease surveillance, and response

Resilient health systems focus on improving the quality of products and services, and improving the sustainability and efficiency of their procurement and delivery. To ensure that this is captured in health system design and planning, PHC should be measured by the quality of its performance, its ability to reach the most vulnerable, and the capacity of its institutions, financing, and operations, including healthcare professionals and caregivers.

**"Universal health coverage and health emergencies are cousins—two sides of the same coin. Strengthening health systems is the best way to safeguard against health crises. Outbreaks are inevitable, but epidemics are not."<sup>36</sup>**

Dr Tedros Adhanom Ghebreyesus | Director-General, World Health Organization

Health systems strengthening should include developing sound legal frameworks to ensure public trust; building information systems to monitor performance, assess quality, and align incentives to outcomes; improving early-warning mechanisms for disease outbreaks and natural disasters; and developing processes for systematic reduction and containment of national and global health risks, both upstream and downstream. Establishing high-performing and resilient routine immunization programs is one of the most effective ways of building emergency preparedness and response capabilities and should be prioritized.

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## **The intangible products of resilient health systems: empowering people, patients, and caregivers**

Beyond medicines and vaccines, the innovative biopharmaceutical industry also collects, organizes, and shares knowledge through websites, social media, and teams of advocates so that people, patients, and caregivers can acquire the information they need to demand and access comprehensive, quality PHC services. People and healthcare professionals should be informed and consulted to ensure that resilient health systems are providing options, especially for PHC, that correspond with their needs. In this way, we help to build resilient health systems to enable all people, without discrimination due to race, gender, age, socioeconomic status, or location, to have the ability to choose the right care to best suit them. An important part of the work of industry includes sharing information on the latest scientific advances so that healthcare professionals can provide the best options of care.

Mobile health technology is also helping empower patients and extend PHC. With almost seven billion mobile phone subscriptions globally, digital technologies hold great potential to help achieve UHC.<sup>37</sup> For example, SMS notifications are helping patients with medication or treatment adherence and providing information to clinicians that may impact their treatment decisions. Mobile and wearable devices are collecting important information from patients that can support telehealth and remote care in rural areas. Innovative biopharmaceutical companies are leveraging digital tools and digital therapeutics to provide care management and treatment support at home, such as helping diabetics to measure and manage blood glucose levels. For young, marginalized, stigmatized, or otherwise hard-to-reach populations, digital technology offers an opportunity to virtually shrink distances and share information to address health concerns, while remaining mindful that this must be done with respect for privacy and security.

## **Championing the role of healthcare professionals**

A resilient health system with well-trained and well-equipped health professionals is foundational to achieving UHC. It starts with ensuring that young people are knowledgeable and encouraged to enter health-related careers, and is sustained by providing health professionals with opportunities to improve their education and strengthen their skills, and by equipping them with the resources they need to deliver quality care, both in routine settings and emergency situations. The industry also has a fundamental responsibility to collaborate with healthcare professionals so that interactions adhere to the highest levels of ethical conduct and integrity.

The world is projected to face a shortfall of 18 million health workers needed to deliver and sustain UHC by 2030. More than half of that shortfall will be driven by nurses and midwives.<sup>38</sup> There also remain a high number of unpaid, unrecognized caregivers worldwide, who are disproportionately women. Health systems should be equipped to recognize, recruit, educate, train, develop, and retain PHC professionals, especially community health workers and nursing professionals who can also perform immunization services. Task shifting or training other relevant health professionals such as pharmacists, dentists, hygienists, community health workers, and educators in prevention, vaccination, and treatment can help provide a wider pool of caregivers and increase access to services for patients.

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Digital health technologies are empowering clinicians to tailor care to each patient. PHC professionals are using digital health technologies to aid in diagnosis and treatment. Clinicians who may not have specialized training to make important diagnoses are being aided by decision support tools that bring the research and knowledge to their fingertips. Software that incorporates artificial intelligence is emerging to support healthcare decisions and provide a high level of care for patients in rural or underserved areas. For example, PHC professionals are benefiting from simple digital health tools, such as SMS notifications made available in partnership with innovative biopharmaceutical and technology companies, to help boost immunization rates and provide a means for clinics and hospitals to report on medicine shortages, including providing status updates on when products will be available and their alternatives.<sup>39</sup>

## NURSING AND MIDWIFERY: The Key to the Rapid and Cost-Effective Expansion of High-Quality UHC

The World Innovation Summit for Health (WISH) Nursing breaks down the arguments for investing in nursing and midwifery in their 2018 report:<sup>40,41</sup>

### 1. RAPID EXPANSION

Enable nurse and midwives to work to their full potential through the creation of more nurse-led clinics, more specialist nurses, and more midwifery services.

### 2. COST-EFFECTIVE EXPANSION

There is enormous potential for nurses to expand their scope of practice through task-sharing. One study cited in the report estimates that advanced practice nurses can complete approximately 70% of a general practitioner's workload.

### 3. HIGH QUALITY EXPANSION

The report cites studies that show physicians and nurses generally achieve equivalent health outcomes for long-term NCDs management; and in fact, nurses often score higher for patient satisfaction and for treatment adherence. Nurses also often provide more health promotion and disease prevention advice.



## 03.2 Invest More, Invest Better in Health

**“Universal health coverage is ultimately a political choice. It is the responsibility of every country and national government to pursue it.”<sup>42</sup>**

**Dr Tedros Adhanom Ghebreyesus** | Director-General, World Health Organization

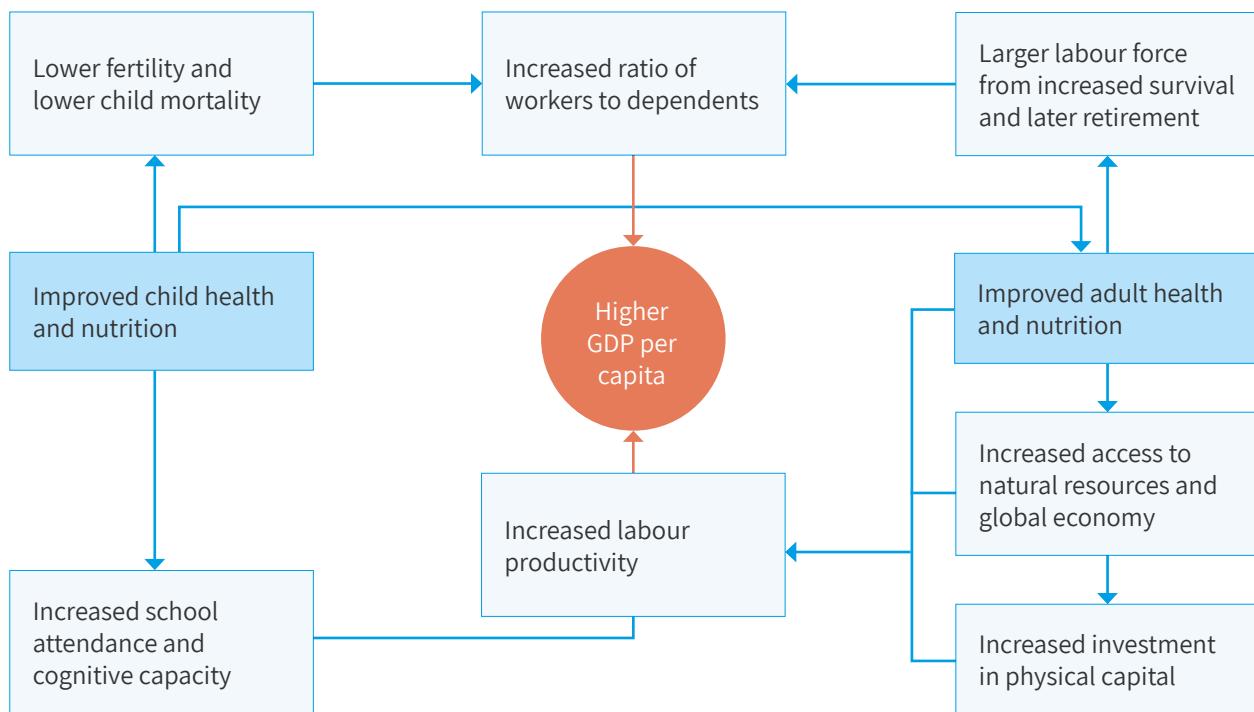
For UHC to become a reality, sufficient, sustained, equitable, and innovative funding is required and new partnerships are needed to reduce high and potentially catastrophic and impoverishing OOP health payments. We must work together to ensure that more resources are invested, but also that they are invested better and more efficiently.

### **Health is the wisest investment a country can make**

Investing in health not only saves lives, it is also a critical investment in the wider economy. This is because ill health impairs productivity, hinders job prospects, and adversely affects human capital development. Evidence shows that investment in prevention can be cost-effective, provide value for money, and give returns on investment in both the short and longer terms.<sup>43</sup>

According to a Lancet Commission study<sup>44</sup> improved health leads to increased personal and national income through five main channels: (1) productivity; (2) education; (3) investment; (4) access to natural resources; and (5) demographics.

**Figure 1:** Links between health and GDP per person



**Figure 1:** Improved health leads to increased personal and national income through five main channels. | **Productivity:** healthier workers are more productive and have lower rates of absenteeism. | **Education:** healthier children are more likely to attend school and improved education increases income growth. | **Investment:** increased life expectancy is an incentive to save for retirement which can boost investment and economic growth. | **Access to natural resources:** control of endemic diseases can increase human access to land or other natural resources. | **Demographics:** improvements in health can lead to an increase in working age people, though the benefit is temporary. Taken from a Lancet Commission study “Global health 2035: a world converging within a generation.”<sup>45</sup>

The WHO has shown that every US\$1 invested in the WHO Best Buys—a set of cost-effective interventions for the prevention and control of NCDs—will yield a return of at least US\$7 by 2030.<sup>46</sup> By investing an additional US\$1.27 per person, per year and implementing just some of the recommended WHO Best Buy’s in low- and lower-middle-income countries between now and 2030, 8.2 million lives could be saved and US\$350 billion could be generated in economic output as a result of reduced expenditure on healthcare, increased workforce participation resulting in boosted GDP, and more resources to invest in health.<sup>47</sup> If countries were to implement the full set of WHO cost-effective interventions, the returns on investment would far outweigh any perceived initial costs.<sup>48,49</sup> Investments in the health and well-being of youth are some of the best that can be made, resulting in an approximately 10-fold economic benefit.<sup>50</sup> Included in the WHO Best Buys are fiscal measures, such as taxation, which can serve as a powerful lever to reduce risks from exposure to or consumption of unhealthy products. Subsidies can also be used to promote health (e.g., subsidies for healthy school lunches) or harm health (e.g., subsidies for products that generate air pollution).

Achieving the SDGs and specifically UHC require a long-term approach. Rapidly aging populations, resurgence of vaccine-preventable diseases, and increased incidence of NCDs globally will slow economic growth and strain social security systems. These systems will also require reform to ensure sustainability and reflect demographic changes.

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## **Reduce out of pocket payments and reduce catastrophic expenditures and impoverishment**

According to the WHO, OOP spending on health causes approximately 100 million people to fall below the poverty line every year.<sup>51</sup> Up to 90% of expenditures on medicines in low- and middle-income countries are OOP.<sup>52</sup> In Global Finance Facility (GFF) eligible countries, a group of 67 low- and lower-middle-income countries with high disease burden, close to half of domestic expenditure comes from OOP payments, which is the most regressive form of health spending and further impoverishes those least able to afford care. Additionally, over 60 per cent of people living with NCDs have experienced catastrophic health expenditure.<sup>53</sup>

## **Public financing is essential**

Despite the proven importance of public funds for making progress towards UHC, evidence published by the WHO suggests that domestic public financing has declined in some low- and middle-income countries in recent years.<sup>54</sup> Public financing is essential for countries to make sustainable progress towards UHC. Achievement of UHC may require domestic fiscal reform to increase the total resources available and to reduce the share from OOP expenditures. Governments should ensure prioritization of (and enhancement of budget allocations to) health, including disease prevention, in national budgets by setting appropriate financing targets for quality investments which minimize OOP by patients and healthy people (e.g., ideally at least 5% of GDP on public health spending according to the World Bank). Financing should be consistent with national development strategies, help ensure efficient and equitable allocation of resources to PHC, and recognize the value of prioritizing prevention and resilient health systems. Using the latest data available, the WHO estimates that public spending on health as a percent of gross domestic product in low, lower-middle, upper-middle, and high income countries as 1.5%, 2.3%, 3.7%, and 6.1% respectively.<sup>55,56</sup>

## **Private sector engagement**

While public financing is essential, this does not mean that governments have to deliver all health services themselves. There are many good examples of countries achieving UHC by using public funding to deliver services through both public and private health providers. Multi-sectoral collaborations in the provision of health services have a very long history in OECD countries.<sup>57</sup> A combination of effective government regulation and hybrid of private and public healthcare service provision can support equitable access to healthcare across a range of socioeconomic groups and ensure efficient use of funds to facilitate the provision of sustainable high-quality care.<sup>58</sup> Private healthcare providers play an increasingly important role in the health systems of many low-income and middle-income countries with governments deliberately promoting private providers, acknowledging their role in increasingly pluralistic health systems.<sup>59</sup>

The private sector is not homogenous; it includes a wide range of industries, organizations and stakeholders. In some countries, many patients would not have the healthcare they have access to today if the private sector was not present. Removing or restricting engagement with the private sector would not benefit the end goal of reaching populations with UHC. Instead, we need to

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ensure complementary private and public sector services and manage these appropriately to have the best impact for patients and governments.

## **Partnerships will be critical**

While UHC is primarily the responsibility of governments, structured and meaningful multi-sectoral partnerships are required. It will be important that we move together and foster stronger alignment among global health actors and development partners to support progress, including coordination of financing mechanisms.

The innovative biopharmaceutical industry operates in and adapts to a range of financing systems through our companies and our associations in nearly every country. This includes multi-payer, single-payer, and hybrid systems, as well as public and private health insurance programs. As a result, we have significant experience to share with governments on sustainable financing models to meet their unique needs. We are ready and keen to collaborate to ensure sustainable financing for UHC so people, communities, and economies reach their full potential. When we move together, we can achieve more than we can if operating in silos.

## **Whole-of-government, whole-of-society approach is necessary**

It is not ministries of health alone who must buy in to the notion that health is an essential driver of economic growth and a necessary condition for achieving the SDGs—heads of state and ministries of finance, education, economy, and others must also support this principle. A whole-of-government, whole-of-society approach is required to ensure real prioritization of health in national budgets. This approach also helps to move away from siloed health spending budgets. Dialogue between Ministers of Health, Ministers of Finance, Ministers of Trade and Economy, parliamentarians, and other stakeholders will be required to mobilize and manage domestic resources to reduce waste, make health spending more efficient, and shield patients from the strains of OOP payments. Policies should also be assessed for unintended and potentially negative impacts on health, such as subsidies for unhealthy products.

## **Diverse approaches to financing UHC will be required**

There is no one-size-fits-all health financing solution. How countries can raise public financing for UHC will depend on their economic and political circumstances, while also balancing their available resources with other, conflicting policy priorities. UHC can be financed with a range or mix of models. Public and private funding mechanisms can coexist and serve as complementary means to achieving UHC. The model selected will be tailored to each country's social, cultural, and political framework, but must ultimately be sustainable to deliver long-term benefits. For example, in some countries employers include health benefits as part of their overall benefit package to employees. Many low-income countries with weak economies will undoubtedly need catalytic external aid funding in the short term, to reach funding levels compatible with achieving UHC.

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## A Range or Mix of Options to Finance UHC

### PUBLIC OR GOVERNMENT FINANCING

Includes social health insurance funded by various forms of taxation and mandated private health insurance.<sup>60</sup> These mechanisms are facilitated by fighting tax evasion and corruption. A single-payer system implies that one organization—typically the government—collects and pools revenues and purchases health services for the entire population, meaning no other insurers are envisioned as part of the system.<sup>61</sup> According to the WHO, regardless of country income, a larger share of public spending on health is tied to a smaller gap in access to services between income groups.<sup>62</sup>

### PRIVATE FINANCING

Includes voluntary health insurance (e.g. universal/long-term healthcare insurance, partial/limited/micro insurance) and private health savings accounts. Many UHC systems incorporate private health insurance and are therefore considered multi-payer systems. Even with public insurance some individuals choose to purchase complementary private health insurance to cover out-of-pocket (OOP) expenses. Some individuals choose to purchase supplementary health insurance to gain access to benefits excluded by the public insurance plan. Indeed, the purchase of substitute private health insurance—insurance that fully substitutes for the public insurance program—is deliberately encouraged by some governments through tax incentives and penalties.<sup>63</sup> These complementary financing options are often better suited to high resource settings.

### OUT-OF-POCKET PAYMENTS

Are defined as direct payments made by individuals to healthcare providers at the time of service use. OOP payments are part of the health financing landscape in all countries relying on user fees and co-payments to mobilize revenue, rationalize the use of health services, contain health system costs or improve health system efficiency and quality.<sup>64</sup> Without decisive and concerted action toward achieving UHC, OOP spending outside of high-income countries<sup>65</sup> is projected to remain substantial, which increases the risk of catastrophic expenditures and impoverishment.

### DEVELOPMENT ASSISTANCE FOR HEALTH

Remains a significant part of the financing landscape. Despite decisive and concerted action toward achieving UHC, many low-income countries are expected to remain dependent on development assistance from government and non-government sources.<sup>66</sup> Synergies should be explored between existing resources and infrastructure for global health and as domestic resources rise in low and lower-middle income countries a growing portion of healthcare should be financed by domestic sources.

## **Innovative approaches to health financing will help us achieve UHC**

In a world of limited resources, there is clear appetite for new funding models, especially ones that generate sustainable income. There is also clear interest in multi-sectoral partnerships. If properly designed and managed, these can offer a way for governments, development actors and the private sector to pool resources and work together for efficiency. Where necessary, the private sector can work with governments and other stakeholders to develop and enable innovative health financing mechanisms such as health impact bonds to complement domestic resources. As called for in the Addis Ababa Action Agenda and in subsequent high-level meetings and dialogues, we must enhance our sustainable financing strategies and seize the potential of new financial innovations and technologies, including digital technologies.

## **Case Studies:**

### **CLOSING SOCIETY'S PROTECTION GAPS<sup>67</sup>**

China faces a sharp increase in cancer rates in the coming years. However, most oncology treatments are not covered by government-provided healthcare and only 6% of the Chinese population has a health insurance policy that covers the cost of cancer treatment. Through its worldwide contacts, Roche works with hospitals, laboratories and healthcare networks, providing local and global data on cancer treatment options and cost analysis to the insurance companies. This enables insurance companies to determine an appropriate pay-out for treatment and to launch affordable cancer insurance policies that cover the best available treatment, access to hospitals and doctors, and cancer education and support. As a result of this work, around 40 million oncology insurance policies have been sold in China. This is just one of many examples of how the innovative biopharmaceutical industry is contributing to the development of new, affordable health insurance products.

### **INVESTMENT STRATEGIES THAT GENERATE A MEASURABLE IMPACT ON HEALTH<sup>68</sup>**

Impact investments can provide funding to launch or expand programmes that promote health. They are particularly important as a sustainable funding model, because if they are successful they fully cover their own costs. The Utkrisht Impact Bond aims to improve the quality of maternal and newborn health services provided through private facilities. Through this multi-sectoral partnership, private capital from UBS Optimus Foundation<sup>69</sup> covers the initial costs to improve the quality of health services in private health facilities in Rajasthan, India and implementing partners will use that capital to improve the quality of care in facilities and help them become accredited. As outcome payers, USAID and Merck for Mothers (known as MSD for Mothers outside of the US and Canada) will pay back the investment only if certain targets to improve quality are met. This effort has the potential to reach up to 600,000 pregnant women and newborns with improved care during delivery. The pay-for-success approach ensures appropriate stewardship of U.S. taxpayer dollars, while unlocking both private capital and government resources for health.

## **USE OF FINANCIAL TECHNOLOGY TO HELP FAMILIES SAVE FOR HEALTH EXPENSES<sup>70</sup>**

Pfizer Foundation has an investment partnership with M-TIBA, a health financial technology platform based in Kenya that provides Africans without health insurance an innovative way to save money towards their health expenses. Using a mobile phone application, M-TIBA users save and send money that can only be spent on services at qualified, licensed healthcare providers that have been approved. The application provides monetary incentives for saving a certain amount of money each month, and has therefore dramatically increased the resources its users allocate toward health spending on an annualized basis. Approximately \$6.7 million USD has already been paid in medical expenses through this application. Furthermore, the M-TIBA provider accreditation process is a market-oriented process that provides a robust check against counterfeit medicines.

## **INCREASING COVERAGE OF INNOVATIVE MEDICINES BY PRIVATE HEALTH INSURANCE**

Johnson and Johnson is working to increase coverage of innovative medicines and advanced surgeries by private health insurance in Indonesia. The private health insurance sector, although small, is growing at double digits as companies establish large pools of members through corporate insurance benefits for employees. In addition, private health insurance is growing as insurance companies better understand adverse risk selection, costs, and patient pathways.

## **Fund health services and technologies based on evidence and increased efficiencies**

Investing more is important. But we must also work together to invest better, which is why strengthening public financial management is required. Increasing public resources for health—or more precisely, expanding “fiscal space” for health—can be accomplished by increasing annual allocation of health budgets as well as by increasing the efficiency with which those funds are used. Efficiency improvements in the health sector, even in small amounts, can yield considerable cost savings and even facilitate the expansion of services for the community. Minimizing waste, corruption and other forms of inefficiency—estimated to be between 20-40% of total health spending by the World Health Report 2010<sup>71</sup>—means that health systems can achieve better outcomes if the funds are used more efficiently. Decisions to fund health services and technologies should be based on sound evidence of the value they deliver and ensure sustainability across the health system. We encourage the use of a sound monitoring strategy, such as the WHO Health Systems Framework, that enables decision-makers to accurately track health progress and performance, evaluate impact, and ensure accountability at national and global levels.

## **Funding for UHC is a political choice**

The innovative biopharmaceutical industry believes that UHC is an investment in the foundation of a healthier, more sustainable future for all. But without the leadership and political will of governments, achieving UHC is not possible. This includes leadership and political will by national governments to ensure sufficient, sustained, and innovative funding and partnerships to finance UHC. Countries should seek to achieve UHC early in their development process. For example, Japan started a stepwise expansion of social groups covered by health insurance beginning in the

1920s.<sup>72</sup> UHC requires us to revolutionize the way we see investments in health—not as a cost to society, but as a genuine investment in our human capital, as the drivers of economic development and growth.



Source: [www.who.int/health\\_financing/topics/sustainable-financing-for-uhc/en/](http://www.who.int/health_financing/topics/sustainable-financing-for-uhc/en/)



### 03.3 Improve Access to Medicines and Vaccines

Medical innovation is not only a foundation of modern healthcare, but a critical element for achieving UHC. Access to safe, effective, quality, and affordable medicines and vaccines to prevent, manage or even cure disease fulfills the promise of innovative medical technologies as a key contributor to good health and well-being. For more than 40 years the World Health Organization's (WHO) Essential Medicines List (EML) has served as a helpful model list of the essential medicines that satisfy the priority healthcare needs of patients in various countries. Historically, the EML was largely focused on off-patent medicines: as of 2015, between 90% and 95% of medicines on the EML were generic.<sup>73</sup> Updates of the EML in recent years have added a number of innovative medicines. In fact, the EML has gradually expanded in scope in response to medical innovation, unmet medical needs, and increasing societal expectations, with more treatments added in areas such as cancer, hepatitis C, cardiovascular disease and a range of vaccines. Such expansion reflects the increased value provided by innovation brought about by investments of the biopharmaceutical industry, academia as well as public and private research agencies. The inclusion of innovative medicines on the EML can enable improved population health only when combined with broader healthcare system investments to support efficient and effective access, delivery and uptake (i.e., devising innovative financing and payment methods, improving health workforce balance and quality, improving service delivery infrastructure and accessibility, etc.). Thus, UHC through health system strengthening and sustainable financing are necessary conditions for improving access to medicines and vaccines.

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## **Making medicines and vaccines more available, accessible and affordable**

As recognized in SDG target 3.8, ensuring that safe, effective, quality and affordable essential medicines and vaccines reach those who need them is fundamental in achieving UHC and improving health outcomes. The innovative biopharmaceutical industry works in diverse health, regulatory and payment systems to make medicines and vaccines more available, accessible and affordable. This starts by working with stakeholders across the supply chain to ensure the efficient delivery of products, as well as to prevent the diversion or entry of substandard and falsified products. This is especially important for low- and middle-income countries, where the WHO estimates that 1 in 10 medical products in circulation are substandard or falsified, potentially resulting in tens or hundreds of thousands of additional deaths from diseases such as pneumonia or malaria.<sup>74</sup>

Governments must also adopt science-based regulatory standards and enhance capacity in regulatory and health systems and supply chains to improve the availability of quality medicines and vaccines. For many medicines and vaccines, both global and national supply chains are fragmented and complex. A lack of visibility and accountability across these supply chains increases the chances of stockouts and of high quantities of poor-quality products reaching pharmacy shelves. Biopharmaceutical companies, together with non-governmental organizations, governments, and private logistics providers, are leveraging a number of measures to improve the effectiveness and efficiency of supply chains. For example, demand planning involves using consumption data or epidemiological patterns to make predictions so the right quantities of medicines are produced and delivered when people need it. Once a reliable demand forecast is available and products have been widely registered, individual companies also make efforts to maintain sufficient and reliable supply, so as to prevent shortages and stockouts. In a fragmented environment, the distribution chain can be long and intricate, involving multiple factories or production sources. All stakeholders have a strong role to play in managing these complexities.

Affordability is also crucial. Affordability for patients is most directly and effectively addressed through sustainable healthcare financing mechanisms that reduce OOP expenditures. Unfortunately, 80 percent of health products in lower-middle-income countries are paid OOP through private channels.<sup>75</sup> To address affordability to both health systems and patients, the biopharmaceutical industry is leveraging innovative arrangements to advance accessibility in developing countries, including through differential pricing, appropriate voluntary licensing agreements, and technology transfer arrangements that promote access while respecting intellectual property (IP) rights and the different economic and public health status between various countries. Defining affordability hinges on balancing the value of a medicine with willingness and ability to pay in the local context, with suppliers and buyers of medicines collaborating to find payment and access arrangements that are sustainable for all parties. As noted in a recent report by the Access to Medicines Foundation, these collaborative approaches to pricing and access are becoming increasingly prominent.<sup>76</sup>

However, these approaches are only viable if governments uphold their political commitment and proactive policies to combat diversion as well as against the use of international reference pricing to ensure that prices tailored for the developing world are not used as benchmarks for

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pharmaceutical products in developed countries.<sup>77</sup> Thought leaders should also recognize the uniqueness of national circumstances, priorities, and health system designs that governments must consider when they tailor suitable solutions to local needs.<sup>78</sup> Individual companies can include access programs as part of differential pricing models to address exceptional circumstances. Combining these approaches helps to create the conditions for equitable access to high-quality medicines and vaccines in both low and high-resource settings so that no one is left behind. IFPMA and its members individually are willing to engage constructively with governments and policymakers on sustainable approaches to pricing and pricing models to ensure affordability to health systems and patients.

However, addressing affordability alone does not ensure access, as evidenced by the unfortunate circumstances where even “cheap” generic medicines are often not reaching patients due to systemic barriers. To further address such barriers, the new Access Accelerated initiative, brings together over 20 biopharmaceutical companies, to reduce barriers to treatments for NCDs through innovative programs and partnerships in low and middle-income countries,<sup>79</sup> by catalyzing scale-up of new and existing company programs as well as undertaking pilot programs to improve the treatment of NCDs and strengthen health systems.

## Partnering with governments and others in creating medicines and vaccines

**“It’s true that government-funded basic science research shines a light on promising pathways to health advances. Philanthropy can help nurture the best ideas through discovery and development, and balance the risk-reward equation for private-sector partners. But industry has the skills, experience, and capacity necessary to turn discoveries into commercially viable products.”**

**Bill Gates** | Co-Chair of the Bill & Melinda Gates Foundation and Founder of Microsoft

Cumulatively, the innovative biopharmaceutical industry spends more on research and development (R&D) than any other industry—taking significant investment risks to advance society’s understanding of disease and to make new and improved treatments and prevention tools a possibility.<sup>80</sup> Governments and the innovative biopharmaceutical industry must work together, and often with other stakeholders in the research and healthcare ecosystems, to ensure the full value of modern medicine and vaccines translates into impact for patients and populations. Governments have the ability to put in place the overall policy frameworks at domestic and global levels in which innovation can flourish and prosper, and set clear health priorities that will advance UHC by ensuring access to safe, effective, quality, and affordable medicines and vaccines. Industry serves as an indispensable partner in this process by investing in the necessary research and development and scaling up production of high-quality medicines and vaccines. Industry also plays a critical role in enhancing healthcare outcomes and efficiencies by offering expertise so that health systems function efficiently.

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Research partnerships between the innovative biopharmaceutical industry, government, and academia are helping to advance the development and commercialization of new and improved products across all phases of the R&D cycle.<sup>81</sup> For example, a consortium of nine innovative biopharmaceutical companies and major academic organizations is working together through the Tuberculosis (TB) Drug Accelerator to speed up discovery and development of much-needed novel compounds against TB. The innovative biopharmaceutical industry is also working through the Global Health Innovative Technology (GHIT) Fund—a multi-stakeholder partnership with funders such as the Government of Japan, Gates Foundation, and Wellcome Trust—to catalyze innovation and product development for individuals suffering from neglected diseases. Such activity leverages innovative incentive and risk-sharing schemes, helping to focus the world’s greatest minds and innovation efforts in ways that support UHC objectives.

## **Developing innovations to improve health outcomes**

New and improved medicines and vaccines are helping to address medical needs and achieve better health outcomes for all. They play a vital role in a joint effort to empower physicians, nurses, and the broader health ecosystem to deliver on the promise of UHC. Over the course of 70 years, innovation in medicines and vaccines has helped increase average global life expectancy from 47 to 72 by preventing close to 30 diseases by vaccination,<sup>82</sup> by turning an almost-always-fatal illness like HIV/AIDS into what is now a manageable chronic condition,<sup>83</sup> by reducing the mortality rates for cancer,<sup>84</sup> and by curing diseases such as hepatitis C. These high-quality medicines and vaccines help bring the benefits of modern science to individuals and families and advance our common effort towards UHC.

Cutting-edge medical innovation also plays an indispensable role in developing solutions to critical emerging health challenges in low-resource settings, as well as addressing increasingly prominent issues such as healthy aging in high-resource settings. For instance, several newly developed Ebola vaccines have been rapidly integrated into efforts to address an outbreak that began in mid-2018 in the Democratic Republic of the Congo.<sup>85</sup> Researchers are also working to develop new treatments to address diseases such as dementia, which by 2060 is expected to double in burden in the United States<sup>86</sup> and impose societal costs 1.6 times higher in Japan compared to 2014.<sup>87</sup>

Digital technologies can potentially unleash new medicines when used by innovative biopharmaceutical companies in the R&D process. Artificial intelligence can spot tiny patterns in large genetic data sets, providing a starting point that could have otherwise been overlooked. Startups are seeking to harness artificial intelligence to suggest ways to make a new medicine, find new and innovative indications for existing medicines, or help researchers identify high-quality therapeutic targets that impact disease risk.<sup>88</sup>

## MEDICAL NEEDS AND THE INNOVATIVE BIOPHARMACEUTICAL INDUSTRY



**140,000**  
industry researchers

**74%**  
of medicines are in  
clinical development

**822**  
orphan drugs designated  
in the US alone

**3rd**  
largest funder of R&D  
for neglected diseases

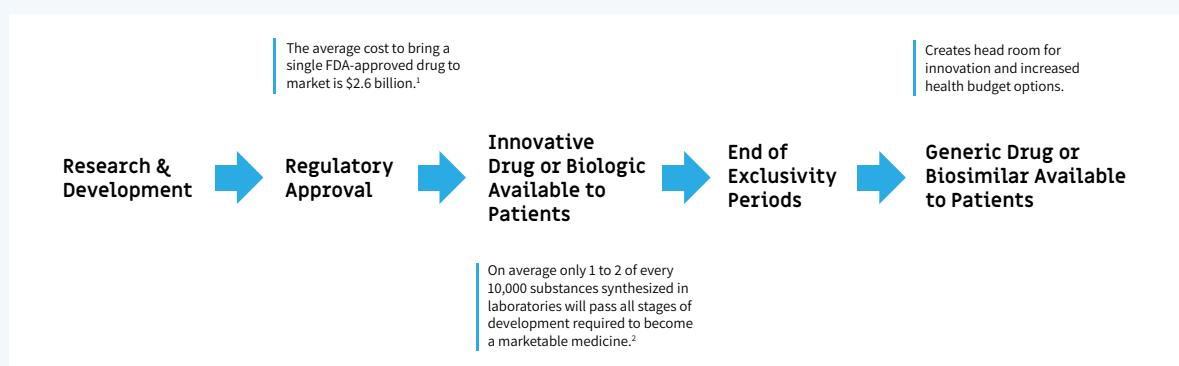
- **140,000** industry researchers are working on 7,000 new medicines.<sup>89</sup>
- **74%** of medicines in clinical development are potentially first-in-class medicines, meaning they use a new approach to fight a disease.
- **822** projects have been designated by the U.S. Food and Drug Administration as orphan drugs, which is critically important given 95% of the 7,000 identified rare diseases have no approved medicine.<sup>90</sup>
- Innovative biopharmaceutical industry is the **third largest funder of product R&D for neglected diseases**, after the U.S. National Institutes of Health and the Gates Foundation.<sup>91</sup>

### Medicines and vaccines promote efficiency and savings

More efficient treatments, cures, and preventive medicines are helping to improve society's returns on healthcare spending, generating significant cost savings in the process. Across 15 high-income countries, new medicines introduced to the market save at least 2.5 times as much in hospital spending as it costs to pay for those innovative drugs.<sup>92</sup> The WHO estimates the global yearly return on vaccination investments at 12-18%.<sup>93</sup> A recent analysis of the investment in childhood immunization in low- and middle-income countries between 2011 and 2020 identified that for every US\$1 spent on expanding access to vaccines, US\$16 would be returned in direct savings and US\$44 when taking into account the broader economic impact of illness.<sup>94</sup> Even in the United States, a country with an advanced economy and health infrastructure, US\$10 is saved for every US\$1 spent.<sup>95</sup> Through continued innovation, every dollar invested in health and UHC goes farther and provides greater value to individuals and economies.

## The Innovation Lifecycle: Increasing the affordability and choice of medicines and vaccines<sup>96</sup>

The creation of quality generic drugs and biosimilars is an important result of the IP-driven innovation ecosystem. A mix of innovative, quality generics and biosimilar treatments benefits governments and society alike by increasing the affordability and choice of medicines and vaccines and broadening access for all across different levels of development and geographies. By helping to achieve cost savings, quality generic drugs and biosimilars also enable governments and societies to prioritize investment in the next generation of innovative medicines and vaccines to address unmet needs.



1. Tufts Center for the Study of Drug Development “R&D Cost Study” 2016 <https://csdd.tufts.edu/csddnews/2018/7/12/press-release-julyaugust-2018-tufts-csdd-impact-report-just-released>

2. EFPIA “The pharmaceutical industry in figures” 2018 [https://efpia.eu/media/361960/efpia-pharmafigures2018\\_v07-hq.pdf](https://efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf)

What people most commonly think of as medicines—tablets or capsules—are usually “small molecule medicines” made from chemically-synthesized ingredients. After the expiration of relevant exclusivity periods for these medicines, quality generic versions can be made available, providing more competition and a range of choices for patients and providers. UHC is advanced by a diverse marketplace in which individuals can access breakthrough, innovative medicines and vaccines subject to exclusivity periods, as well as generic versions of time-tested products. For instance, the first innovative drugs such as statins to lower cholesterol and prevent cardiovascular disease were introduced in the 1980s. Today they have become the world’s most widely prescribed class of medicines, with a mix of generic versions saving health systems tens of billions of dollars annually.<sup>97</sup> While generics have helped to address affordability and create headroom for new innovation, there is still significant opportunity to improve health by addressing continuing challenges such as lack of diagnosis and non-adherence.

A growing field of biopharmaceutical innovation resides in “large molecule medicines” known as biologics. These innovative treatments are made from living cells and organisms and tend to be much more complex. Biosimilars make similar versions of treatments available after the exclusivity periods on an innovative biologic expire. Because they are derived from living cells, innovative biologics can never be exactly reproduced (whereas generic drugs are a copy of an innovative drug). A biosimilar version, however, can be produced that is highly similar to the innovative biologic in terms of quality, safety, and efficacy, and can be approved for use to treat the same illness or condition, in some cases

interchangeably with the innovative biologic, making more products available and providing more choices for patients. Quality, safety, and efficacy are essential attributes for any biologic, including biosimilars. Comparative studies of the biosimilar against the innovative biologic help to ensure these attributes are met and adhere to science-based standards as described by the WHO.

Evidence shows that IP rights play an important role in accelerating the launch of medicines and vaccines by giving originators the legal certainty to invest in obtaining regulatory approval, educating healthcare professionals, and strengthening healthcare infrastructure. These investments ultimately help create a viable market which quality generics and biosimilars will build on, leading to faster and greater access to medicines and vaccines.

## **Governments and the innovative biopharmaceutical industry partner to support innovation and UHC**

Innovation does not happen on its own. Governments can and do invest directly in innovation, particularly in basic research. But transforming initial research into new and improved innovative medicines and vaccines requires major investment and acceptance of significant risk. Biopharmaceuticals operate uniquely high-risk business models. When a biopharmaceutical company chooses to invest significant sums to advance a potential medicine in its portfolio, it may not know for over ten years whether the asset will be approved and it must wait even longer to know whether the product will be a commercial success.

The U.S. Food and Drug Authority (FDA) estimates the probability of a drug in development reaching the market at only 8%. Furthermore, approximately 70% of the cost of bringing a product to market arises after discovery of the compound (i.e. at the development stage). Recent data confirms that industry not only contributes the majority of global expenditure on pharmaceutical R&D (71%) but also performs 26% of basic pharmaceutical research. Many products which come to market also do not prove commercially successful. Governments must therefore create incentives to promote private sector investments in R&D and commercialization of innovative medicines and vaccines.

Governments can contribute to innovation by supporting a business environment that is non-discriminatory, rules-based, and clear.<sup>98</sup> Such an environment can promote investment in and expand availability of the latest medical innovations. Examples of policies that encourage long-term investment are avoiding unnecessary tariffs and taxes on biopharmaceutical products that distort markets; and in procurement, ensuring that purchasing procedures are transparent and fair, and provide an avenue for appealing decisions. To promote new and improved treatments and prevention measures, governments must value medicines and vaccines in ways that recognize the value of innovation based on clear and evidence-based criteria.<sup>99</sup> At the same time, governments

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play a central role in shaping an enabling policy environment where procurement models, regulation, and other initiatives facilitate individual suppliers to put in place differential pricing between countries in order to address affordability challenges.

**"Intellectual property exists to encourage innovation and creativity, which stimulate improvements in our quality of life, spur economic growth and address the radical challenges we confront such as climate change, clean energy, food security and health."**<sup>100</sup>

**Francis Gurry** | Director-General, World Intellectual Property Organization

Intellectual property protections, granted in the form of patents and data exclusivity, provide the market with crucial signals to generate investment and enable companies to re-invest in R&D. IP protection can also help to create certainty in the overall business climate to usher in future investments (including sectors beyond the innovative biopharmaceutical industry).<sup>101</sup> According to the OECD, a 1% increase in the protection of IP rights measured by the Patent Rights Index is associated with a 2.8% increase in the inflow of foreign direct investment.<sup>102</sup> Innovative medicines and biologics of today pave the way for the quality generics and biosimilars of tomorrow. When the exclusivity periods end, policies that ensure high-quality generics and biosimilars flourish play a crucial role in the affordability of a whole “basket” of medical products. Doing so leads to a wider and more affordable range of quality medical treatments that benefit all, contributing to UHC goals. Thus, we encourage policies to enhance competition in quality generic and biosimilar medicines in the off-patent market to create both budget headroom for financing innovation and increased affordability of well-established treatments.



## 04 Our Recommendations for Achieving UHC

The innovative biopharmaceutical industry stands together with the global health community to support all countries in accelerating efforts to achieve UHC.

UHC is a journey unique to each country's needs and priorities, and there is no one-size-fits-all approach. Each country must deploy necessary resources to achieve them and must prioritize which health services to cover, what beneficiary population groups to cover, how to pay for those services, and how to ensure effective and efficient delivery in consultation with stakeholders.

Regardless of a country's unique needs, no single organization or sector can achieve UHC on its own and in recognition of the need to move together towards achieving UHC, we are committed to playing our part.

**From our perspective, there are three key components to achieving UHC:**

- Uphold Quality Primary Healthcare
- Invest More, Invest Better in Health
- Improve Access to Medicines and Vaccines

# Uphold Quality Primary Healthcare (PHC)

Together, PHC and resilient health systems form the cornerstone of UHC. They are what enable UHC to be inclusive, to ensure no one is left behind. PHC is the package of essential health services—ranging from promotion and prevention to treatment, rehabilitation, and palliative care. A person receives these services across their life course, often beginning before birth and continuing through illness, injury, work, childbirth, aging, and the end of life. PHC is the frontline of a resilient health system, one which is able to prepare for, withstand the strain of, and respond to the public health consequences of disasters and emergencies. Therefore, we support policies that:

- **Create an evolving and responsible regulatory and legal system that sets an ethical framework, promotes responsiveness and inclusiveness of all stakeholders, and supports innovations.** This system must adapt to changing needs and comply with medical, public health, and business ethics in a period of rapid technological evolution and medical innovation.
- **Design PHC to be comprehensive, evidence-based, and grounded in a holistic, life-course approach.** Expand the package of benefits as more resources are available. Provide choices, empowering people to live and age well.
- **Improve quality, sustainability, and efficiency.** Avoid seeking only to lower costs, which can reduce the number of suppliers and result in a race to the bottom in quality, safety, and efficacy and increase the potential for supply disruptions.
- **Measure performance by the ability to reach the most vulnerable,** the capacity of institutions, financing, and operations.
- **Ensure systems integrate disease prevention and health promotion as a core strategy in PHC**—including well-equipped disease surveillance and response systems, health education, and screening; high performing and resilient routine immunization programs should be prioritized.
- **Foster integrated, multi-sectoral, people-centered approaches to reach every household with a basic package of PHC interventions and manage both infections and chronic conditions across the life course, leaving no one behind.** Countries should leverage the immunization touchpoints and roll out other interventions that will be part of a comprehensive PHC package to ensure that all those being reached also receive a core package of PHC services.
- **Recruit, educate, train, develop, and retain frontline health workers.** Seek support of other relevant health professionals. Improve health literacy amongst practitioners and the general public.
- **Promote innovation and harness a variety of technologies,** including digital technologies, to improve equitable access to health services, complement and enhance existing health service delivery models, and empower and enable people and communities to play an active role in their own health.

# Invest More, Invest Better in Health

UHC is an investment in the foundation of a healthier, more sustainable future for all. Achieving UHC can also drive economic growth, development, and wealth. For UHC to become a reality, sufficient, sustained, and innovative financing mechanisms are required and new partnerships are needed. We must work together to ensure that more resources are invested, but also that they are invested better and efficiently. Therefore, we support policies that:

- **Ensure prioritization of (and enhancement of budget allocations to) health**, including disease prevention, in national budgets by setting appropriate national financing targets for quality investments which minimize out-of-pocket payments by patients and healthy people.
- **Create fiscal space for health** by improving efficiency and effectiveness of existing health budgets, including by reducing waste and corruption.
- **Finance with a range or mix of models**. Select a model tailored to a country's social and political framework, but one that ultimately will be sustainable.
- **Develop and enable innovative health financing mechanisms** tailored to the unique needs of each country, such as health insurance products and impact bonds.
- **Employ a whole-of-government, whole-of-society approach**. Move away from siloed health spending. Promote dialogue and multi-sectoral partnerships approaches across government and with other stakeholders.
- **Engage employers to include elements of health** in employee benefit packages or other incentives.
- **Promote digital health technologies to improve health system efficiency** and invest in suitable data ecosystems, including data infrastructure and strategies for data use.

# Improve Access to Medicines and Vaccines

Medical innovation is not only a foundation of modern healthcare, but a critical element for achieving UHC. Access to safe, effective, quality, and affordable medicines and vaccines to prevent, manage or even cure disease fulfills the promise of innovative medical technologies as a key contributor to good health and well-being. Therefore, we support policies that:

- Enable medicines and vaccines to reach people by **increasing capacity in and harmonization between regulatory systems, strengthening supply chains, and improving health system infrastructure.**
- **Adopt regulatory standards that are consistent with scientific evidence** following best practices for safety, efficacy and quality standards to improve availability of innovative, generic and biosimilar medicines and vaccines.
- Implement **robust supply chains**, both to ensure efficient delivery of products and to prevent diversion or entry of substandard and falsified products.
- **Value new medicines and vaccines in ways that recognize and incentivize innovation and health outcomes**, taking into account willingness and ability to pay in the local context. Evaluate procurement and/or reimbursement of medicines and vaccines based on medical need and burden of disease, efficacy, available real-world evidence and infrastructural requirements.
- **Enhance competition in quality generic and biosimilar medicines** in the off-patent market to create both budget headroom for financing innovation and increased affordability of well-established treatments.
- **Ensure that procedures in procurement as well as reimbursement are predictable, transparent, provide mechanisms for appealing decisions, and respect appropriate commercial confidentiality.** Procurement criteria should not only focus on price but also on quality assurance and security of supply.
- **Remove tariffs and taxes** on medicines and vaccines.
- **Enable differential pricing, appropriate voluntary licensing agreements, and technology transfer arrangements that promote access to treatments** for patients in developing countries while respecting IP rights and the different economic and public health status between various countries.

Finally, policies should promote appropriate incentives, including the protection of intellectual property, to enable the development of breakthrough medicines and vaccines that are essential to address unmet medical needs. Together, UHC and innovation promotes continued global health progress and well-being for all.

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