

Innovative Industries' Position on Fair Pricing

Good morning. In the time allocated to me, I will try to cover our industry's viewpoint on "fair pricing".

Notwithstanding the very different views and experiences represented by this panel and in the room, I hope you will see that there is more that unites us than divides us.

I will try to convey three main messages:

- 1) We hear you, and we are sensitive to the debate about cost and pricing.
- 2) We are seeing great transformative new treatments reaching patients, and we are making progress through new partnerships in reaching many more patients also in LMICs, but
- 3) We need to do more and need to do better, and we can only do so if we agree to start a joint journey, not only on discussing the notion of Fair Pricing, but seeking solutions to make our medicines affordable and accessible in many more countries.

As we are having this discussion in South Africa, I am compelled to look back to the HIV/AIDS crisis twenty years ago. If there was ever a moment in recent history when many pharma companies were tested, it was then. Tragically, precious time was wasted in making the first breakthrough antiretroviral treatments available to patients in this country. The infamous lawsuit was nominally about IP – actually not about patents but about legislation allowing parallel imports and generic substitution - but really it was about "fair access", about access and affordability. And this will be my main message to you: the "fair pricing" we all want is in the end about "fair access" for all. I was as part of the industry team that facilitated, with the help of Kofi Annan, a then-revolutionary settlement between the South African

government and the pharma companies, a settlement only made possible because both sides agreed on the shared objective of patient access to innovative medicines. Today as I represent the global interests of the innovative biopharmaceutical industry, I can assure you that there has been a sea change over the past 20 years.

Today, our member companies ARE acutely aware of the real concerns around the costs and prices of medicines. Together with millions of colleagues in biopharma companies around the world, I am also convinced that **innovation is meaningless if people cannot access it. And unlikely to happen in the future without the continued incentives to invest.**

The inescapable truth is that we, all of us here today, have a shared responsibility to find ways for many more patients to have **access** to **today's** medicines **and** for future patients to benefit from new, yet to be developed medicines.

“Fair pricing” of medicines is a powerful and important concept. Pricing clearly matters. However, stating that “price is the main barrier to accessing many new and effective medicines”, as announced in the media release for this forum, may garner attention but does not quite do justice to the multiple barriers to access medicines.

Access depends on so much more, not least **strengthening local healthcare systems, educating and training health care workers, strengthening supply chains, tackling waste and inefficiencies, corruption and falsified medicines, mobilizing domestic resources, achieving Universal Health Care Coverage.** In short, **using pricing concerns as a surrogate for talking about inadequate access falls far short of addressing the complexity of the challenges we have to tackle together. I do not want to fudge the affordability question at all, but we risk failure**

of achieving equitable access if we lose sight of the fact that pricing is just ONE part in a much larger system.

Let me start by setting out our industry's position on pricing.

WHO defines a “fair price” as “one that is affordable for health systems and patients and, at the same time, provides sufficient market incentive for industry to invest in innovation and the production of medicines.” I agree with the WHO here, **affordability - for health systems and patients - is inextricably linked to incentives for businesses to invest in innovation and production.**

Our judgments may differ on what is the right balance. Where we can agree is that the solution lies in **balancing the needs to incentivize research into future breakthrough therapies and, at the same time, making sure medicines are affordable for health systems, but most importantly to patients and their families and leaving no one behind.**

More dialogue is certainly required on how to find the right **balance between access to medical progress, the proper incentives for innovation, and the need for sustainable budgets.** Here today **I want to emphasize industry's willingness to explore new avenues of innovative reimbursement models such as paying for performance (outcomes), risk sharing, or even paying in variable annuities, as well as engaging in dialogue on how to make these medicines more affordable and accessible in LMICs.**

I see achieving “fair pricing and fair access” as a constant process of adjustment that takes into account:

1. **Fostering innovation**, i.e. rewarding medicines with an added therapeutic benefit, to stimulate research &

development which will benefit future generations and address unmet health needs;

2. **Affordability and access to care and innovation** for today's patients;
3. **Sustainable budgets for health systems**, of which medicines are one element.

We are making progress across the board. Just last week, the WHO announced that **healthy** life expectancy at birth has increased by nearly 5 years since the turn of the millennium¹. Sanitation and new, innovative medicines and vaccines are the two key drivers of this progress.

We have seen deaths from cancer fall by 20%. Two thirds of those diagnosed with cancer remain alive for at least five years after diagnosis/treatment. In just the last few years, people living with Hepatitis C can now be cured through a 12-week course of medicines. Moreover, millions of children in LMICs are living beyond their 5th birthday thanks to immunization. More than half of the new medicines approved by the FDA benefitted from accelerated review because of the "breakthrough" therapeutic value they bring for patients. And let me reassure you, there is a rich diverse medicine pipeline of over 7,000 medicines in development.

Today's innovative medicines are tomorrow's generics and biosimilars. Without one, you will no longer benefit from the other. We have lower cost options for treating conditions like heart disease and depression thanks to past innovation. The generics and biosimilars we use today create "head-room" in budgets for innovative treatments. Furthermore, the continuous upgrading of treatment regimens via new additional medicines create fierce innovator-to-innovator competition within

¹ **Healthy** life expectancy at birth - the number of years one can expect to live in full health-increased from 58.5 years in 2000 to 63.3 years in 2016.

therapeutic classes. To ignore this dynamic, is to turn our backs on the hope to find solutions for still fatal cancers or Alzheimer's where despite failure rates of clinical trials of 99.7% over the last 15 years, we have nevertheless more than 100 compounds in clinical trials. This is the long-term, true value of innovation.

Fostering innovation by acknowledging added therapeutic value, through a value-based pricing approach to incentivize industry to continue investing in high risk of pharmaceutical R&D is fundamental to sustainable innovation.

On my **second point on affordability**: the biggest challenge we face is where people have to pay for their health-care "out of pocket". At least half of the world's population cannot obtain essential health services².

However, the challenge of access goes beyond affordability. For most major diseases, there are generic treatments available. Yet, a report, launched yesterday by Center for Disease Dynamics, Economics & Policy (CDDEP), found that more people lack access to antibiotics than die from antimicrobial resistance. One of the reasons for this is that far too often the health system cannot provide quality medicines for those who need them, even if they are cheap.

We have found that even when \$1 per month treatments for chronic diseases are available far too many people cannot access them. Just last week a WHO / World Bank report also underscores the need to prioritize primary health care. It highlighted the issue of cardiovascular diseases that are the No. 1 cause of death globally³: The report also asked, "why is something as simple as controlling blood pressure just not happening on the scale needed to prevent premature death?"

² According to a 2017 report from the World Bank and World Health Organization

³ [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds))

These few examples are what Universal Health Coverage (UHC) and the health SDGs more broadly have set in their sights to tackle. The WHO General Program of Work (GPW 13) clearly shows the way ahead. It also provides a blueprint for building collaboration and partnership with the private sector. Creating UHC and mobilizing domestic resources is an important component of improving affordability and access. We all, public, private, and civil society, have key roles to play here.

In our experience, the most helpful way to assess the affordability of medicines to health systems is to take into account both the spending involved and the cost to society represented by disease. This means accepting that medicines can and do make a real contribution to reducing other healthcare costs as well as lost productivity. Think of a vaccine that prevents cancer (e.g., human papillomavirus/HPV) or a drug that eliminates the need for a liver transplant (e.g., the new hepatitis treatments) – both reduce pressure on health systems. They reduce the need for hospitalisation, cure previously chronic conditions, and avoid losing productive life years. They are cost-effective and cost saving in addition to life saving.

Although I am deeply aware of the debate on the price and cost of innovative medicines is truly global, I want to focus here on affordability and access in LMICs. In countries with often fragile health systems, compounded by investing a lower percentage of their national budgets on healthcare overall, assessing affordability has clearly very different implications to more mature markets.

For many LMICs, strengthening healthcare systems still requires considerable investment in reliable healthcare infrastructures and supply chains and training skilled healthcare staff to effectively diagnose and treat.

In addition, governments and pharmaceutical companies must continue to partner to find solutions for access and affordability appropriate to each national context. These initiatives must focus on health and economic outcomes where the unique set of national circumstances can be fully taken into account, rather than a myopic focus on cost containment. The goal should be to improve the quality of care, reduce overall expenditures, increase productivity and fiscal capacity. Accordingly, any review process regarding costs and benefits of individual medicines should adopt a societal perspective. The incentive-based model underlying the pharmaceutical lifecycle is essential in enabling innovators to pave the way for generics.

What can industry do? **DRAFT**

I will now outline what I think we as **industry can do to achieve “fair pricing”**. And where we see opportunities for better engagement with governments, patients and civil society.

As somebody who strongly believes in paying for the added therapeutic value of an innovative medicine, I’d like to state something, which is often forgotten in the global pricing discussion: **advocating value-based pricing by definition means advocating for some form of differential or tiered pricing**. For several years now, many companies have been applying differentiated pricing solutions across LMIC to take into account the specific country contexts. We are keen to hear from participants about how this could be done more effectively. Furthermore, many pharma companies have patient assistance and other programs to ensure patients have access to medicines independent of their economic status. Our industry is involved with over 250 health partnerships, many of which focus on access and health systems strengthening.

The lesson learnt from that South African turning point two decades ago was for governments, the research-based and

generic industries to work together. The experience showed that differential pricing could work when done in partnership with governments, donors and industry. As a result of the settlement reached, we now have “4th generation” treatments for HIV because a model was found that enabled industry-led innovation to continue. It mobilized stakeholders in support of partnerships that increased access to diagnosis and treatment in the LMICs – for AIDS, of course, but also for diseases such as malaria and TB with the Global Fund and for vaccines with GAVI. Nobody can deny that partnerships have had a huge impact on improving lives and preventing disease of many million people in LMICs.

Similarly, the **London Declaration on Neglected Tropical Diseases of 2012**, a partnership between industry, the Gates Foundation and WHO, has made a decade-long commitment to donating drugs, 14 billion dosages altogether, until diseases such as Chagas or River Blindness are entirely eliminated. As a result, the mass drug administration programs not only ensure people get access to treatment but also build capacity, training millions of health workers and community volunteers.

Today, the biopharma industry as a whole is spearheading new types of collaboration with initiatives such as Access Accelerated. Two dozen global biopharmaceutical companies are working together to set up partnerships with the World Bank for health systems strengthening or individual programs involving civil society, multilaterals and NGOs. The goal is very tangible. It is to drive on-the-ground implementation and action plans to address NCDs in LMIC. The City Cancer Challenge is exemplary in aiming at improved cancer care in cities such as Asuncion, Cali, Kumasi, Kigali, Porto Alegre, Tbilisi, and Yangon. This novel approach means that governments or city mayors do not waste scarce resources dealing with multiple companies towards achieving their health SDGs. We are also working to explore what other approaches industry could usefully take forward to enhance access.

Let's face it; all the individual and collective industry efforts to improve access to medicines will not be truly game changing on their own. **What we need is the right conditions, which allow scaling up of such initiatives, and ensuring that the medicines reach the patients for whom they were destined.** We need to do more and do better to tackle access hurdles and make innovative medicines more affordable in LMICs. From multiple discussions with industry colleagues, I know that there is a willingness to leave our comfort zones and engage in dialogue to find new solutions.

What would be our ask from governments?

The single most important thing is a clear process to meet UHC, organizing and funding a system where patients no longer risk to be impoverished because of out of pocket payments. Understanding where efficiencies can be achieved in regulatory processes, improving disease awareness, education, diagnosis and treatment, building necessary infrastructure; understanding how supply chain systems can be strengthened to ensure timely and effective delivery of care to patients are also important parts of achieving UHC.

Governments could also consider more general budgeting approaches that include the cost of disease and the benefit a medicine confers. WHO Afro has recently made a powerful investment case for investing in immunization. The World Bank Human Capital Development Index shows that investing in health is about investing in creating wealth.

How can WHO support the process?

The WHO has a privileged role as a convener for collaboration and information sharing between stakeholders in health systems. The WHO plays a key role in fostering engagement

and collaboration between governments, industry and civil society in contributing to better health systems.

Let me conclude with the following short remarks:

I am acutely aware that much more needs to be done to reach ALL patients, regardless of economic circumstances. I do not believe that a debate on transparency of prices and R&D costs – as promoted by some in the audience today – will help to reach this objective. Investment in health infrastructure, service delivery and prevention must be part of the dialogue.

I believe we have a commitment, and a responsibility to get medicines and vaccines to the people who need them. That is why biopharma companies are actively exploring better ways to price our medicines based more on patient outcomes and societal value.

Over the coming days, biopharma company representatives here will share with you their different approaches – how they are working with governments, insurers, and doctors to create sustainable solutions with the aim that no patient will ever go without our medicines because they cannot afford it. I invite you to engage with them – both in the sessions and outside – as we are here together in this convention centre.

The industry is rightfully being challenged. Do I think we always get it right? No. However, I believe we are raising our game. We are finding new and better ways of showing the therapeutic value of medicines to society; we are making progress in reaching more patients, including in LMICs. So, let us work together here to listen and learn about the good that is already happening and discover even more new ways to meet the challenges we all share for the benefit of patients today **and** tomorrow. Last, but not least, let us not lose sight of the toll and debilitating costs of non-treatment.