

# **GLOBAL REVIEW**

A QUARTERLY UPDATE OF THE IFPW FOUNDATION

# GAVI Board Approves 2030 Strategy; World Leaders Pledge US\$1.2 Billion in Vaccines for Africa During Paris Summit

(Sources: An article by VenturesAfrica and a press release by France24)

The Board of Gavi, the Vaccine Alliance announced a series of decisions that provide a framework for an acceleration of global immunization – including approval of "Gavi 6.0", the Alliance's 2026-2030 strategy, which includes expansion of Gavi's vaccine portfolio and plans to support global health security and regional manufacturing through the African Vaccine Manufacturing Accelerator and a First Response Fund (for use in future pandemics.) The decisions were taken during a two-day meeting convened in Geneva from 6-7 June.

"Vaccines are one of the most impactful and cost-effective health and development interventions available today," said Professor José Manuel Barroso, Chair of the Gavi Board. "As we look to 2030 and progress against the *Sustainable Development Goals* amidst climate change and other challenges, the message is clear: the world must continue to invest in the transformative impact of vaccines and their ability to save lives and ensure our collective security."

Gavi's strategy for the period 2026-2030 will be the most ambitious in Gavi's history: seeking to protect more people, against more diseases, faster than ever before. This means a continued focus on Gavi's core mission to support vaccine introductions, expand existing programs, achieve equity through targeted efforts to reach and fully immunize missed "zero-dose" children and communities, scale up critical innovations and, shape markets to ensure the availability of affordable vaccines for lower-income countries.

The new strategy will also make the Gavi model increasingly responsive to the evolving global context – from climate change to the increasing threat of outbreaks, antimicrobial resistance, and fragility and conflict – to continue meeting countries' and communities' needs. Key elements to this approach include proposed adjustments to Gavi's co-financing, eligibility and transition approach to ensure the continued sustainability of immunization programs; deeper partnerships with global and regional organizations, civil society and communities; differentiated, flexible and tailored support for fragile and humanitarian contexts; streamlining Gavi's operating model; and enhanced support for climatesensitive and outbreak, epidemic and pandemic-prone diseases. The Alliance will immediately begin working on operational details, in preparation for implementation of the strategy beginning in 2026.

A critical part of each five years is the approval of a new *Vaccine Investment Strategy (VIS)*, which looks at the pipeline of promising vaccines and vaccine candidates and evaluates how best to expand the portfolio of vaccines Gavi offers. The Board approved the 2024 VIS, which will include future vaccination programs and learning agendas for tuberculosis (adolescent vaccines), group B streptococcus, and dengue fever, as well as global stockpiles and learning agendas for vaccines against mpox and hepatitis E.

The Board also approved a learning agenda on vaccination against (continued on Page 2)

#### Around the Globe...

- In a historic development, the **World Health Assembly** the annual meeting of the UN's 194 member countries agreed to a package of critical amendments to the *International Health Regulations* (2005) (IHR) and made concrete commitments to completing negotiations on a global pandemic agreement within a year, at the latest, and possibly in 2024. These critical actions have been taken to ensure comprehensive, robust systems are in place in all countries to protect the health and safety of all people everywhere from the risk of future outbreaks and pandemics. These decisions represent two important steps by countries, taken in tandem with one another on the final day of the *Seventy-seventh World Health Assembly*, to build on lessons learned from several global health emergencies, including the COVID-19 pandemic. The amendments to the Regulations will strengthen global preparedness, surveillance and responses to public health emergencies, including pandemics.
- The Novo Nordisk Foundation has teamed up with Wellcome and the Bill & Melinda Gates Foundation to support what the partners call "critical scientific R&D for global health" to advance solutions that are accessible and affordable to people in low- and middle-income countries. The three-year initiative, announced at the Novo Nordisk Foundation's global science summit in Denmark on 6 May, will see the organizations commit US\$100 million to the pact, with initial funding supporting solutions to address the health impacts of climate change, infectious disease and antimicrobial resistance (AMR). The cash will also be used to advance "greater understanding of the interplay between nutrition, immunity, disease and developmental outcomes."

# As AMR Looms Large, A Non-profit Collaborates with Pharma to Tackle This Global Challenge

(Source: An article by Amy Baxter for PharmaVoice)

Antimicrobial resistance is an ongoing challenge on a global scale that requires new and innovative solutions; however, the lack of ROI for antibiotic drug development has kept new drugs at bay in recent years. Only a few pharma companies have continued to keep antibiotics in their pipelines and without the market's high incentives, those that are tackling AMR are teaming with the federal government and nonprofits to help fund their efforts to tackle this persistent challenge.

From 2017 to 2022, only a dozen new antibiotics were approved by the U.S. Food and Drug Administration (FDA), according to the World Health Organization. Without much in the industry's development pipeline, the gap between R&D and unmet need is considered a "dead zone", said Erin Duff, chief of R&D at biopharmaceutical accelerator CARB-X.

"They can't make any money," Duffy said of pharmas working on antibiotics.

CARB-X - Combating Antibiotic Resistant Bacteria

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### GAVI Board (cont.)...

shigella, and, given the levels of coverage achieved, current epidemiology and country demand, recommended sunsetting the routine COVID-19 vaccination program at the end of 2025. Potential COVID-19 needs for a "worst-case scenario" after 2025 will be addressed through Gavi's emergency response mechanisms.

The Board approved the final structure of the *African Vaccine Manufacturing Accelerator (AMVA)*, which launched on 20 June. This includes the eligibility criteria designed to focus support on sustainable end-to-end vaccine manufacturing on the Continent. The Board also endorsed AVMA's governance mechanisms, which will involve the Gavi Board as well as partners including the AU, Africa CDC, UNICEF, WHO, manufacturers, and donors. The finalization of AVMA sends an immediate signal to investors regarding Gavi's long-term commitment to support a sustainable African vaccine manufacturing base, and to improving African pandemic and outbreak vaccine supply resilience.

World leaders, health groups and pharmaceutical firms announced US\$1.2 billion in funding at a summit in Paris to produce vaccines in Africa, which is facing numerous health crises.

The AVMA "will be an essential step towards a genuine African vaccine market," French President Emmanuel Macron said at the opening of the Paris Summit.

Three quarters of this funding will come from Europe. Germany will contribute US\$318 million, France put in US\$100 million and the UK US\$60 million. Other donors include the United States, Canada, Norway, Japan and the Gates Foundation.

The Covid-19 pandemic demonstrated the unequal global distribution of vaccines, as wealthy countries home to big pharma firms snapped up most doses, leaving Africa far behind.

The new strategy aims to move vaccine production to Africa to give the continent more sovereignty—and avoid history repeating itself.

Another mechanism discussed was the *Day Zero Financing Facility* for *Pandemics*, a suite of instruments that will seek to make financing accessible in the first 100 days of a major public health emergency. The Board approved the parameters for the DZF's new *First Response Fund*, which sets aside US\$500 million for rapid response to emergencies. Following the Board's decision, the scope of the First Response Fund was confirmed as core Gavi-eligible countries, with potential for exceptions if needed, and targeted mainly to *WHO Public Health Emergencies of International Concern* without existing vaccine programs. The Board also agreed that the funds could be used to procure, alongside vaccines, syringes and ancillaries, personal protective equipment, cold chain, surge capacity, health system and community preparedness and response activities.

## AMR Looms Large (cont.)...

Biopharmaceutical Accelerator – is a recent innovation in the industry's AMR equation. Created in 2016, CARB-X provides funding to companies working on AMR-related diagnostics, therapeutics and vaccines. Its pipeline, focused on the "greatest bacterial threats to humans" includes work with GSK and other philanthropic organizations. With financial backing from numerous organizations and government sources, including the Biomedical Advanced Research and Development Authority (BARDA), CARB-X recently announced its 2024 funding round to fill R&D gaps, asking for applicants focused on where AMR burden is the highest.

But because bacteria can become resistant to antibiotics and they need to be used sparingly, it remains a tough sell for pharma.

"We need these antibiotics on the shelf, but we need to be very

careful about when they're used," said Emily Wheeler, director of infectious disease policy a Biotechnology Innovation Organization. "That's a good thing for public health, but it makes a really challenging business model in a traditional market dynamic that is based in the drug space on volume of use."

Some new antimicrobial products are making their way through pharma's pipeline. Earlier this year GSK announced positive results from a phase 3 trial testing a new antibiotic to treat gonorrhea which has become one of the most common superbugs. The drug could be on the market by 2025. GSK was also granted fast track designation by the FDA for its experimental gonorrhea vaccine candidate NgG in 2023.

CARB-X has partnered with GSK on a few of its antimicrobial candidates and providing funding for a phase 1 small molecule drug aimed at preventing urinary tract infections plus vaccine candidates for streptococcus and Salmonella enterica.

The need for more collaboration between the pharma industry and outside funding sources comes as recent studies on the impact of AMR reveal the problem is much bigger than once thought. According to the World Health Organization, an estimated 1.27 million deaths occur globally in 2019 as a direct result of bacterial AMR. Another recent study published in *The Lancet* found there were an estimated 250,000 deaths in Africa directly attributed to AMR and another 1.05 million deaths associated with AMR in 2019. In fact, AMR killed more people in Africa in 2022 than either HIV or malaria.

Along with incentives supporting AMR R&D such as CARB-X, the PASTEUR Act has been introduced in Congress multiple times and would include US\$6 billion in funding for AMR drugs. More than 250 organizations support the bill. Thus far, the bill has been tied up in committee and has yet to pass. For pharma, collaboration will be key to solving the AMR threat.

## Around the Globe (cont.)...

- A global alert about fake versions of *Ozempic* which has become popular as a way of losing weight has been issued by the **World Health Organization (WHO)**. The drug is sometimes known as a "skinny jab" despite its main purpose being a treatment for type 2 diabetes. The WHO said the fake medicines could pose a danger to health. The organization advised people to source the drug only through reputable sources, such as a doctor, rather than obscure sites online or through social media. Fake batches have been seized by the authorities in the UK. US and Brazil.
- An alarming spike in the number of cholera cases has been reported, according to the World Health Organization (WHO). Cases have been reported across countries in Africa, East Asia, America, Europe and the Eastern Mediterranean region. The Eastern Mediterranean region reported the highest number of cases, followed by the African region, the Americas, the Southeast Asia, and the European region. Africa has the second-highest cases, with 92,789 cases from 14 countries. Immediate action is needed to stem a spike in cholera cases amid worldwide shortages of vaccines, the said on Wednesday. Millions of people are at risk of cholera as the vaccine's only producer, South Korean EuBiologics, is unable to keep up with demand, the WHO's International Coordinating Group on Vaccine Provision (ICG) said.

(Sources: Associated Press, Press Releases, and Scrip Citeline)