#### **Generation Gavi:**

Partnering to protect health through life-saving vaccines







#### Contents

| Introduction: A partnership defined by impact  Advancing 20 years of progress |  |
|---|--|
|   |  |
| В   | Strengthening health systems through immunization programs |
| c   | Sustaining immunization                                    |
| D   | Achieving a healthy vaccine ecosystem                      |

#### Seth Berkley

Chief Executive Officer
Gavi, the Vaccine Alliance

Gavi, the Vaccine Alliance, helps protect nearly half the world's children against deadly and debilitating infectious diseases. Since Gavi was formed in 2000, its mission to save lives, reduce poverty and protect the world against the threat of epidemics, like COVID-19, has helped vaccinate more than 760 million children in the world's poorest countries. This has not only helped save more than 13 million lives in the long term, but has also generated more than USD\$ 150 billion in economic benefits in Gavisupported countries. None of this would have been possible without the partnership of the members of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

Through Gavi's public-private partnership business model, it has fostered a unique collaboration between industry and global health that has played a critical role in its success. Relentless vaccine innovation has enabled disease elimination, protection and prevention - and contributed towards Sustainable Development Goals on health, climate action, gender equality, poverty and more. Over the past 20 years, IFPMA and its members have nurtured Gavi's potential into something that has changed the future for hundreds of millions of people. From the very first Gavi-funded doses of hepatitis B vaccine, which were administered in Mozambique in 2001, and the approval of the Ebola vaccine in 2019, to the delivery of vaccines to remote communities by autonomous drones in Rwanda and Ghana, IFPMA is helping Gavi to succeed and innovate. And by supporting the work of governments and civil society, pharmaceutical manufacturers are helping protect the most valuable resource on earth: its children.

Today, Gavi supports vaccines against 17 infectious diseases, with more already in the pipeline. Now it's time for Gavi's champions, investors, partners and supporters to carry the alliance through its next five-year strategic period, from 2021 to 2025. Together, we've already vaccinated an entire generation of children - "Generation Gavi" - while IFPMA and its members are working every day to encourage the discovery of and access to new life-saving vaccines. Building on the strength of this relationship, we can deliver on our plans to protect the next generation. It's an investment we can't afford



## Thomas Cueni

Director General

International Federation of Pharmaceutical Manufacturers & Associations

As the world faces its first global pandemic in living memory, affecting hundreds of millions of people around the world, it is not surprising that global attention has fixed on the search for a vaccine, which could help to control the spread of the novel coronavirus, COVID-19, and the need to ensure equitable access to new vaccines once these have been developed.

In a matter of months, the pharmaceutical industry has been galvanized in an unprecedented manner to quickly find innovative solutions to contain and end COVID-19, on the one hand, and by doing so in a way that is socially responsible on the other hand.

Using the latest technologies and leveraging deep and collaborative networks across public and private sectors; laboratories, researchers and scientists around the world have mobilized to discover vaccine candidates and put them into clinical trial. The pace and progress of this work has surprised many commentators and the watching world.

However, as Director General of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), I see firsthand the impressive capabilities available today to research, develop, manufacture and distribute safe, high-quality and effective vaccines.

and determination that has helped transform the health of the world's children, led to the rapid development of a licensed vaccine and a further seven vaccine candidates for Ebola, and that is behind a promising vaccine pipeline, which includes research in malaria, tuberculosis, multivalent meningitis and respiratory syncytial virus (RSV).

It is the same expertise

Such sustained vaccine innovation lies at the heart of our partnership with Gavi, the Vaccine Alliance. As a unique collaboration, the alliance has been at the forefront of combining vaccine innovation with sustained immunization programming. It is a partnership that has solidarity at its heart.

From the near eradication of polio, to the mass distribution of the pentavalent vaccine, which offers protection to children from five major infectious diseases, the partnership has extended the benefits of immunization to some of the poorest countries in the world and created a generation of children who are more likely to survive and thrive than ever before.

As we commence a new chapter in the story of vaccine innovation, IFPMA, its affiliates and its members reaffirm their commitment to supporting Gavi's mission to protect future generations from disease. As we share with you in the following pages, much has been achieved, but as we aim for securing the health and wellbeing of all, there is more that can be done to bring lifesaving vaccines to those who need them the most, while also ensuring we protect the gains of the past. Let science and collaboration continue to prevail.

We congratulate Gavi on its twentieth anniversary and look forward to deepening our collaboration during the 2021 to 2025 strategic period.



#### Richard Torbett

**Chief Executive** 

The Association of the British Pharmaceutical Industry

Much has changed in the world since Gavi held its last replenishment conference in 2015, not least the COVID-19 global pandemic.

Against this unprecedented backdrop, the UK will shortly convene Gavi's donors and partners to address the support and collaboration the alliance needs to achieve its goals over the next five years.

The UK is one of the six original donors to Gavi and continues to be a major supporter, having committed GBP £1.44 billion – or almost a quarter of their total funds – over the past five years.

In its lifetime, Gavi has protected a generation of children; 760 million of whom are more likely to survive and thrive into adulthood.

With a world leading pharmaceutical industry, and a longstanding commitment to Gavi, the UK is well placed to support the international cooperation needed to protect the world from infectious diseases.

As Chief Executive of the Association of the British Pharmaceutical Industry, it is a privilege to showcase in these pages the commitment and contribution of our members: companies at the cutting-edge of science, whose mission it is to tackle the world's healthcare challenges.

The passion and commitment of our members here in the UK and around the world mean we are in a unique position to support Gavi on the two most pressing fronts we face: helping reach a further 300 million children in the next five years with lifesaving vaccines and, together with the wider life sciences community, playing our role in the response to COVID-19 by developing vaccines, diagnostics and treatments.

In the months ahead, the shared ambition and expert collaboration that has come to define Gavi will be needed more than ever, as we work together to protect and advance the remarkable progress that has been achieved, and fight an urgent global health emergency.

This new reality demands a renewed commitment to working in partnership. Our success in the years ahead, as in the past, will depend on the strength of this collaboration.

There is no better time than now to agree on how to protect future generations from infectious disease.





Gavi/2013/Manpreet Romana

# "More children have been immunized with a wider range of vaccines than at any time in history"

**The Investment Opportunity 20**21-2025, Gavi

Partnering to protect health through life-saving vaccines



Gavi/2011/Christine McNab

## A Partnership Defined By Impact

#### Since its inception, Gavi has come to protect a generation of children; **760 million**

### of them who are more likely to survive and thrive into adulthood.

New vaccines are helping control the spread of the deadly Ebola virus

HPV vaccines are protecting a generation from HPV-related diseases, including cervical cancer

New malaria vaccines are averting millions of deaths every year

The Advance Market Commitment has accelerated uptake of new innovative vaccines, protecting millions of children against pneumococcal disease

The upcoming wP-IPV hexavalent combination vaccine will support the achievement of the polio endgame

Established in 2000 to provide children everywhere with protection from infectious diseases, Gavi, the Vaccine Alliance has grown to become a powerful partnership between public and private organizations. Through a unique operating model, the alliance has harnessed the expertise of a wide range of organizations, including vaccine manufacturers, research institutes, civil society groups and public health authorities. The combined strength and collaboration of alliance members has increased the uptake of life-saving vaccines, enabling the benefits of immunization to be extended to some of the poorest around the world.2

As Gavi marks its twentieth anniversary, one remarkable achievement stands out among many, that more children have been immunized with a wider range of vaccines than at any time in history.<sup>3</sup>

As founding partners, International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) member companies have made the significant long-term investments needed to both manufacture a reliable supply of existing vaccines and to develop a robust pipeline of innovative new vaccines. Today, IFPMA members provide 13 vaccine formulations and presentations to Gavi countries for use in routine immunization, preventative campaigns and emergency stockpiles.<sup>4</sup>

Research-based vaccine companies have a long track record of research and development for diseases disproportionately affecting the poorest countries. Members are contributing to the on-going goal of polio eradication, the control of malaria and diarrheal diseases, and more recently the rapid response to the Ebola outbreak, with the first vaccine being pregualified by the World Health Organization (WHO) in November 2019, and the ongoing race to develop a vaccine against COVID-19. The benefits of the partnership to scaling vaccine innovation is clear: Gavi provides aggregated demand and secured financing for the purchase of vaccines, which enables IFPMA's innovative biopharmaceutical members to scale-up vaccine manufacturing capacity to supply the volumes required.

Gavi/2013/Bart Ver Weji



Today, IFPMA members' engagement with Gavi extends beyond vaccine manufacture and supply; it ranges from vaccine development, testing, production, storage, and distribution, to supporting national procurement, ensuring health systems have the capacity to deliver and administer vaccines, training for healthcare workers and immunization managers, and building the capacity of vaccine manufacturers in the global south. This work has not only produced life-saving vaccines, it has helped to increase access to them through the development and introduction of stateof-the-art vaccine packaging, storage and distribution solutions. These innovations have led to reductions in the number of vaccines that need to be refrigerated, improved effectiveness, and reduced the number of required shots through combination vaccines.

However, there are growing challenges that threaten to undermine this hard-won progress. From a rise in outbreaks of vaccine-preventable diseases, such as measles and yellow fever, to the growing consequences of climate change, pollution, migration and humanitarian crises, the mission of Gavi is as relevant today as it was in 2000 when the alliance was launched.

As the partnership enters its next strategic period (2021-2025), IFPMA and its members will stand with Gavi in support of our collective ambition to roll out the most comprehensive package of protection to date to the world's poorest countries and vaccinate the remaining 20% of children around the world without access to new vaccines.<sup>6</sup>

As we live through the current and unprecedented COVID-19 global health emergency, we are reminded daily of the importance of partnership and collaboration between the public and private sectors to achieve global health security and improved health outcomes for individuals and families. It also underscores the important work Gavi has done to build stronger and more resilient healthcare systems.

As one of Gavi's longest standing partners, IFPMA members will continue their support to bring long-term vaccine sustainability to the world and expand the availability of vaccines to fight the 18 diseases targeted by Gavi in the next period, compared with just 6 in 2000.

Building on this shared impact, IFPMA members are in a unique position to support Gavi's key goals during the 2021-2025 strategic period. In the following pages, we look at some of the achievements that position IFPMA members to support Gavi to scale vaccine innovation, strengthen health systems, sustain immunization and achieve a healthy vaccine ecosystem.



Gavi/2019/Tony Noel

Taking into account healthcare costs, lost wages and productivity due to illness, as well as the broader benefits of people living longer, healthier lives, there is US\$ 54 returned on every US\$ 1 invested in immunization in Gavi-supported countries.8

# Vaccines remain one of the most cost-effective ways to save lives and promote good health and well-being.

By preventing illness, death and long-term disability, Gavi-supported vaccines have helped generate more than US\$ 150 billion in economic benefits between 2000 and 2017.9

## Scaling Vaccine Innovation

During the last 20 years of Gavi, IFPMA members have invested in a sustained program of vaccine innovation that has helped transform the health of the world's children. Today, vaccines exist that prevent and control a wide range of infectious diseases that have historically been the leading cause of childhood mortality, including polio, measles, malaria, rotavirus and pneumonia. 10

Building on this important success. over the last decade or so, several new vaccines have been introduced with the help of Gavi and IFPMA members. This new generation of vaccines are targeting specific diseases such as meningitis, neglected infectious diseases like Ebola, non-communicable diseases such as the human papillomavirus (HPV), and a new malaria vaccine, RTS,S. On the horizon are vaccines for new targets such as the respiratory syncytial virus (RSV).

And innovation hasn't stopped there, as IFPMA members have developed and scaled new combination, liquid and heat stable vaccines and transformed the supply chain over the last 20 years. This innovation has improved coverage, equity and extended the benefits of immunization to those who need it most.

One of the greatest achievements of our time is the development of multiple polio vaccines delivered through sustained immunization campaigns. Before the availability of vaccines, polio was the leading cause of permanent disability in children. With effective vaccines developed and accessible, health policymakers began to work towards polio eradication. The number of wild poliovirus cases has fallen by over 99% since 1988, taking polio to the brink of eradication. It is a powerful example of how vaccine innovation and partnership can come together to help eliminate a disease across the world.11

Since 1988, IFPMA members have been a key partner in the Global Polio Eradication Initiative (GPEI), which now works closely with Gavi to strengthen routine immunization systems. Through significant research breakthroughs, IFPMA members have developed inactivated polio vaccines (IPV) to supplement and eventually replace live oral polio vaccines (OPV) - this is in line with the GPEI driven transition to remove wild polio virus from communities.12 Different presentations of these vaccines have increased ease of storage, administration, and manufacturing according to the program's needs.



Gavi/2018/Duncan Graham-Rowe

Working with UNICEF and Gavi, IFPMA members Sanofi Pasteur and GSK have provided billions of doses of polio vaccines and have supported the rollout to children around the world through an unprecedented worldwide registration program. Sanofi Pasteur is the largest IPV manufacturer, supplying 80% of the IPV doses delivered to UNICEF.13 More recently, to achieve and sustain a polio-free world, Sanofi Pasteur has been working on the development of an IPV and whole cell pertussis containing hexavalent vaccine, specifically designed for Gavi countries14 and lower-and middle-income countries (LMICs). This more advanced combination vaccine will help LMICs to strengthen their pediatric immunization programs and maintain the high IPV coverage across the pediatric population (along with higher DTP3 coverage). This combined vaccine will also contribute towards maintaining a polio-free world.

Thanks to the pneumococcal Advance Market Commitment (AMC), an innovative funding mechanism and donor commitments have enabled Gavi, GSK & Pfizer to support the scale-up of manufacturing to ensure the introduction of the pneumonia vaccine for children in the world's poorest countries. 15 This innovative partnership has prevented the deaths of over half a million children in developing countries over the past decade. Since 2007, with the support of Gavi, 183 million children have received the pneumococcal conjugate vaccine (PCV), which protects against the leading cause of pneumonia. This program has prevented more than 1.5 million childhood deaths. Vaccination coverage in Gavi-supported countries has now reached 41%, up from 35% in 2015 and almost equals the global average of 42%.16

Polio cases have fallen by over

> Rotavirus vaccines, which protect against the deadliest form of diarrhea in young children, have protected more than 100 million children with the help of Gavi and its partners. There are now 45 Gavi-supported countries using cost-effective rotavirus vaccines to safeguard children.<sup>17</sup> Using rotavirus vaccines in Gavi-supported countries could prevent 180,000 deaths and save USD\$ 68 million in treatment costs every year.18

> As a long-standing partner in the fight for the prevention and epidemic control of meningitis, IFPMA members are supporting the implementation of the "Defeating Meningitis 2030 Roadmap" through the development, manufacture and supply of innovative conjugated and multivalent vaccines.19

Malaria is among the world's most serious global health challenges, causing hundreds of millions of deaths each year, mostly among young children in Sub-Saharan Africa.<sup>20</sup> Following decades of research and development, IFPMA member GSK, in partnership with PATH, a global health organization, developed a vaccine that is now part of routine immunization programs. Research continues, with GSK committing more than USD\$ 300 million for the total remaining development and manufacturing costs, and phase IV studies that will continue to assess the safety, effectiveness and impact of the vaccine.21

Gavi/2009/Olivier Asselin



But innovation has not only been limited to the development of vaccines for individual infectious diseases. To overcome the low uptake in low-income countries of separate vaccines against diphtheria, tetanus, whooping cough, hepatitis B and Haemophilus influenzae type b, IFPMA members, including GSK, Sanofi Pasteur and Johnson & Johnson, have developed an all-in-one vaccine that protects against all five of these major diseases. These innovative combination vaccines - some of them not requiring reconstitution - reduced cold chain storage requirements and were easier to administer than the earlier reconstituted combinations. In 2001, Gavi began making the liquid pentavalent vaccine part of routine immunization programs; by 2018, more than 467 million children had been immunized.<sup>22</sup>

Neglected infectious diseases, such as Ebola, that occur in developing countries can hinder the advancement of the world to better health. The drive to develop a vaccine for the Ebola virus shows what health authorities, the pharmaceutical industry and alliances like Gavi can do when faced with a public health crisis.

## "There is now one licensed Ebola vaccine and seven candidate Ebola vaccines at different phases of development"

When a large and complex outbreak of Ebola occurred in West Africa in 2014 - resulting in 11,300 deaths in the region - WHO declared Ebola an international public health emergency. WHO developed a plan to fight the disease, including fast-tracking access to experimental treatments and vaccines.23 To address the crisis in West Africa, IFPMA members such as GSK, MSD and Johnson & Johnson undertook efforts to accelerate the development of Ebola vaccines in collaboration with other stakeholders including with WHO, the Innovative Medicine Initiative, U.S. National Institute of Allergy and Infectious Disease (NIAID), BARDA and others.24 Highlighting the effective policy tools available to Gavi, the alliance offered a new Advance Purchase Commitment to all manufacturers working on candidate vaccines in Phase I+.25

Gavi/2015/Phil Moore



Resulting from this period of rapid innovation and collaboration, there is now one licensed Ebola vaccine and seven candidate Ebola vaccines at different phases of development. Together, with an approved vaccine, these coordinated efforts will help control the Ebola outbreak in West Africa. <sup>26</sup>

Alongside their commitment to communicable diseases, scientists have been exploring new approaches to vaccines for non-communicable diseases such as cancer, particularly following the breakthrough discovery that cervical cancer can be caused by the human papillomavirus (HPV).

Since that important discovery, IFPMA members, MSD and GSK, have gone on to develop vaccines that protect against 70%-90% of cervical cancer cases. Besides the HPV vaccine, which prevents not only cervical cancer, but also vaginal, vulvar and anal cancer, there is one other globally approved cancer prevention vaccine – the hepatitis B vaccine that helps prevent liver cancer.<sup>27</sup>

antibodies and pandemic influenza preparedness, including an assessment of potential vaccine supply and demand interventions.

But innovation isn't limited to the research and development of vaccines. IFPMA members are using their expertise and innovation to constantly improve the logistical challenges of storing and transporting vaccines. This 'cold-chain' system is critical to moving vaccines at the correct temperatures from the point of manufacture to the

The success of vaccines in preventing

disease means that the demand for

high. One disease area that remains

deaths each year, mostly among young

new innovative vaccines remains

a target for vaccine innovation is

malaria, which causes 435,000

children in Africa.28 To see if RTS,S,

a vaccine that has shown in clinical

trials to significantly reduce malaria in

children, is effective under real world

conditions, it was introduced in 2019

in Ghana, Kenya and Malawi through

a WHO-coordinated pilot program.

The program is supported by Gavi

and manufacturer, who is donating

10 million vaccine doses.<sup>29</sup> There is

also progress on a new vaccine for

typhoid, developed by GSK Vaccines

Institute for Global Health (GVGH) and

transferred in 2013 under a licensing

agreement to Biological ELtd, an Indian

biotechnology company. 30 If approved

for prequalification by WHO, the vaccine

will be eligible for use in endemic regions

under the Gavi umbrella

including GSK, the vaccine's developer

and several other organizations,

reaching the remotest parts of the world.

For example, IFPMA members
Pfizer and GSK have helped address
cold-chain challenges through
innovative work in packaging. While
Pfizer has developed a multi-dose vial
(MDV) for its pneumococcal vaccine
that significantly reduces storage
requirements and shipping costs, 31
GSK has developed a new four-dose
vial presentation of its pneumococcal
vaccine to help address cold-chain
challenges, and a new blow-fill-seal
technology to deliver compact, singledose rotavirus vaccines. 32

point of use. Vaccines often have specific

these can be especially hard to sustain in

storage requirements for maintaining

vaccine potency, and the logistics of

Other vaccine innovations in progress

include: multivalent conjugated

meningitis vaccines, respiratory

syncytial virus (RSV) monoclonal

Nine Gavi countries are now using the new four-dose vial pneumococcal vaccine. The blow-fill-seal tube innovation has reduced the amount of space required by 30 percent, as compared with the previous presentation. These innovations leave more cold chain space available for transporting and storing more vaccines - ultimately protecting more children from rotavirus and other vaccine-preventable diseases.

In a key breakthrough, Sanofi Pasteur has developed a controlled temperature chain (CTC) for the cholera vaccine that allows it to reach the last mile. Using an innovative approach, vaccines can be kept at temperatures outside of the traditional cold chain of +2°C to +8°C for a limited period under monitored and controlled conditions. In addition, Sanofi Healthcare India Private Ltd has received WHO approval for use at temperatures as high as 40°C for up to 14 days; this development is a real game-changer in vaccines management.<sup>34</sup>

Introducing and scaling-up vaccines requires sustained and continued investment, something that Gavi is committed to achieving. And, while an incredibly important part of the story, innovation in vaccines needs to work in tandem with the strengthening of health and immunization services, something we look at in the following pages.



avi/2009/Oliver Asselir

#### Strengthening Health Systems

To expand and deliver access to lifesaving vaccines, particularly to those communities underserved and under immunized, IFPMA members assist Gavi-supported countries to develop sustainable vaccination programs that harness partnerships and innovation.

Consider efforts to eliminate cervical cancer caused by the human papillomavirus (HPV). The majority of HPV cases and deaths from cervical cancer occur in low-income countries. especially in Africa. Without better cervical cancer prevention and control, deaths were expected to rise to 416.000 by 2035, IFPMA members. MSD and GSK, having developed vaccines that protect against 70%-90% of cervical cancer cases, then supported national vaccination programs in the low-income countries that needed the vaccine the most.

MSD established a grant program to help communities in low-income countries design, implement, and evaluate HPV vaccination programs with the goal of developing a successful adolescent immunization model. The program included the aid of leading experts to navigate barriers, while MSD donated over 1.3 million free doses to 25 institutions in 21 countries. Using its experience from the program, MSD also established HPV immunization programs in other areas, such as Bhutan and Rwanda. With support from MSD, each country successfully completed a national roll-out of schoolbased vaccination programs, with each achieving greater than 90% vaccine coverage in their first year.35

Likewise, GSK, working with Gavi, has distributed 1.9 million doses of its HPV vaccine, dramatically reducing the risk of cervical cancer for some 855,000 girls in Cambodia, São Tomé and Zimbabwe by preventing HPV infection. Zimbabwe, which suffers the fifth highest rate of cervical cancer in the world, introduced HPV vaccines into the country's routine immunization program in 2018, and, with a supply of the necessary doses, is closer to its goal of immunizing more than 800,000 girls across the country. 36

Other partnerships and innovations have also ensured that life-saving vaccines are accessible to everyone who needs them, no matter where they live. In a partnership with the International Rescue Committee (IRC) and Google, the Pfizer Foundation has run the mReach program, a technology-enabled platform that enables healthcare workers to identify children who require followup regarding immunizations. During the two-year project implementation period in Uganda, a total of 12,949 (74%) out of 17,454 children under the age of one were immunized as a result of project activities.37 Pfizer has also teamed up with Zipline, Gavi, the Bill and Melinda Gates Foundation and the UPS Foundation to support the Government of Ghana in establishing a medical drone delivery system to ensure access to routine vaccines and essential medicines in some of the country's most hard-to-reach areas.38



Gavi/2014/Duncan Graham Rowe

"Pfizer has also teamed up with Zipline, Gavi, the Bill and Melinda Gates Foundation and the UPS Foundation to support the Government of Ghana in establishing a medical drone delivery system"

In addition to innovative programs that have enabled vaccines to reach excluded and remote communities, IFPMA members have supported Gavi's efforts to strengthen health systems through stronger, more sustainable national immunization programs, GSK has, for example, contributed GBP£1.2 million to the STEP program,39 which builds skills among local immunization supply chain managers in Gavi countries, and has, since 2019, committed GBP £1.5 million over three years to a GSK-Save the Children partnership focused on strengthening immunization programs in the Somali region of Ethiopia. 40 Johnson & Johnson has also supported the STEP program by enabling supply chain experts from the company to train local supply chain managers in several Gavi countries.

Further, IFPMA members now also transfer vaccine innovation technology to those institutions able to support its successful rollout across the countries and communities where they are needed most.

For example, GSK's candidate vaccine against tuberculosis is the first in more than a century to demonstrate substantial protection against the disease and is now licensed to the Bill & Melinda Gates Medical Research Institute (MRI) for further development. If successful, this vaccine could help save millions of lives globally.41 Similarly, in 2013, GSK transferred a new typhoid vaccine to Biological E Ltd. Having already received market authorization from the Indian Health Regulatory Agency, if approved by WHO, the vaccine will be eligible for use in endemic regions under the Gavi umbrella.42

Thanks to public-private partnerships, IFPMA member Sanofi Pasteur has also performed several industrial technology transfers to vaccine manufacturers in middle-income countries (MICs). These transfers help build local capacities and respond to domestic vaccine needs such as ex IPV Biopharma and the hexavalent vaccine in South Africa.43



Gavi/2016/Kate Holt

## Gavi-supported stockpiles have helped immunize more than

# 90 million people

Gavi/2013/Adrian Brooks





avi/2016/Kate Holt



The remaining critical component to strengthening health systems and immunization programs, is preparing to deal with epidemics or even new pandemic threats, such as the one the world is now experiencing with the far-reaching spread of the novel coronavirus, COVID-19. In addition to the efforts to discover an effective vaccine to protect against COVID-19, IFPMA members are already contributing to proposals and discussions around the feasibility and potential for launching new vaccine delivery innovations that would enable the provision of vaccines safely and effectively at scale.44

To prepare health systems and the global community to act swiftly and effectively to epidemic threats, Gavi, IFPMA members and other global health stakeholders have already made significant investments and devoted considerable resources to multiyear immunization projects involving manufacturing, stockpiling, and system preparedness. Stockpiling vaccines makes it possible to quickly respond to outbreaks of infectious diseases; that's why IFPMA members, mainly led by Sanofi Pasteur, contribute to the global vaccine stockpiles that mitigate the risk posed by infectious, epidemic diseases, including yellow fever, cholera, meningitis and other diseases.

Through stockpiling, IFPMA members nanufacture, reserve and make available vaccine doses in case of outbreaks. Between 2006 and 2019. Gavi-supported stockpiles have helped immunize more than 90 million people.45 For example, due to the recent outbreak of the Ebola virus in the Democratic Republic of the Congo, Gavi increased the global emergency stockpile of Ebola vaccines to 500,000 doses, up from 300,000 doses, 46 In addition. IFPMA members have been long-standing partners for epidemic preparedness, contributing to WHO's stockpile of meningococcal disease, yellow fever and cholera vaccines since 2004.

With additional investment and a brandnew facility, Sanofi Pasteur has doubled its capacity to respond to public health emergencies. This investment allowed a supply of four million doses of yellow fever in a record time to Angola during a previous outbreak. 47 Since 2017, greater global collaboration has led to the creation of the Coalition for Epidemic Preparedness and Innovations (CEPI). This new publicprivate collaboration aims to better coordinate the development of future vaccines against targeted epidemic pathogens identified by WHO. As a partner since CEPI's launch at Davos in 2017. IFPMA members have shared vaccine research and development experience and expertise, and committed to CEPI through its Scientific Advisory Committee to continue sharing scientific knowledge and collaborate towards the development of vaccines for unmet needs.

Building on this work and to support Gavi's strategic goals over the period 2021-2025, IFPMA members plan to be a significant collaborator not only by sustaining vaccine innovation and developing and supplying vaccines, but through further supply chain innovation, technology enabled immunization programming and pandemic preparedness.

Gavi/2012/Olivier Asselin



## Sustaining Immunization **Programs**

Gavi/2013/Jiro Ose



To meaningfully and sustainably extend the benefits of immunization to those most in need, programs should be built upon the unique needs of the country -including its immunization system maturity, economic situation, political will and ability to measure the burden of disease and impact of vaccine introduction. The goal of sustainable vaccination should be a progressive transition from Gavi support towards fully self-sufficient, country-adapted and evidence-based immunization programs for countries' populations. Gavi's rising support for industry's expanding portfolio of vaccines has enabled countries to build the capacity needed to conduct over 400 vaccine introductions and campaigns, and contain numerous disease outbreaks.48

Gavi/2014/Duncan Graham Rowe

Key areas for continued collaboration to improve the sustainability of immunization programs include improving procurement capacity, demand predictability and volume commitments. That's why JFPMA and its members engage in multipartner platforms to provide technical assistance and build capacity around the manufacturing and forecasting processes needed to supply vaccines in the right amounts at the right time. Consistent and accurate visibility into long-term demand forecasting

is key to supply security. Developing

future solutions will require a better

In addition, IFPMA and its members,

working alongside other key global

health partners, will continue to act

as advocates in driving political will

and advancing the health of people

strengthening national commitments

to immunization is critical to protecting

around the world, particularly for those

Gavi's mission, but also the goals of the

new Immunization Agenda 2030 and

communities currently underserved.

Sustained, resilient immunization

programs are central to achieving

the Sustainable Development

Goals (SDGs). 49

for vaccination. Maintaining and

understanding of each country's

vaccine procurement practices.



Over the period 2021-2025, there is an opportunity to support Gavi countries in ensuring sustained national immunization programs can serve as a foundation for delivering and expanding essential primary healthcare services, while also tackling other key health threats, such as antimicrobial resistance. We recognize, however, that countries will be challenged in the months, and potentially years, ahead as the COVID-19 pandemic spreads and disrupts the provision of routine immunization. We therefore welcome the quick leadership of WHO in providing guidance on managing and protecting immunization services during national responses to the SARS-CoV-2 virus.50 IFPMA and its members, working with Gavi and other partners, will use our collective medical expertise to support global healthcare systems to manage the unprecedented increase in pressure they are currently experiencing.

## Achieving **A Healthy** Vaccine Ecosystem



Gavi/2013/Adrian Brooks



A healthy ecosystem for vaccines is crucial to support sustainable innovation, demand and supply. As part of a healthy vaccine ecosystem, IFPMA members, through their significant long-term investments in a robust pipeline of innovation, health partnerships and supply capacity, are supporting countries to meet demand, achieve their specific vaccine preferences and build supply security. Gavi's role is crucial in this, sharing insights on vaccine demand, helping to secure financing, enabling the purchasing of vaccines and preparing IFPMA members for the scale-up of manufacturing capacity when it is needed.

Policymakers can support a wellbalanced vaccine ecosystem through continuing to work together to secure the key components of a strong manufacturing supply chain, including: ensuring a fair return through tiered pricing, more longterm accurate demand forecasts, flexible procurement practices, and convergence of regulatory, packaging and labelling requirements.

Sustained collaboration across these underlying regulatory, infrastructure, financing and supply issues will be crucial if we are to strengthen healthcare systems, identify sustainable financing mechanisms, and reduce the add-on costs of health products and services along the supply chain.

Ensuring a healthy vaccine ecosystem is also critical for the future introduction of new vaccines. In the near future. vaccine development will benefit as we better understand pathogens and immune responses, while research will also benefit from smarter platform technologies and the increased use of advanced data analytics. For example, vaccines that use messenger RNA (mRNA) can guide cells to prevent disease, as well as offer flexible design, cost-effective production and safer administration

There are also projects underway to deploy vaccine adjuvants that improve vaccine efficacy and reduce the amount of vaccine antigen required per dose, allowing more vaccine doses to be produced and therefore contributing to the protection of more people. Progress is also being made in the manufacturing processes for developing and manufacturing vaccines. For example, IFPMA member Sanofi Pasteur is developing a new generation of yellow fever cell culture technology that has been shown to speed up, improve robustness, and simplify the manufacturing process. This, in turn, will enable us to better control the disease and rapidly respond to outbreaks and epidemics.

IFPMA members are at the forefront of such developments and will continue applying their expertise to develop effective, safe and high-quality vaccines. In partnership with Gavi, the principles of a healthy ecosystem can ensure the continued success of scaling vaccine innovation to save lives, protect health and prevent the spread of disease.

#### "In the final decade of the SDGs, Gavi can provide prevention, protection and prosperity to hundreds of millions more communities and families...

Partnering to protect health through life-saving vaccines

...With the political will and investment of countries and the ingenuity of Gavi and its partners, including its donors, we can achieve a world where vaccines work for all."

The Investment Opportunity 2021-2025, Gavi

# Protecting The Next Generation: Our Commitments

Gavi/2019/Qiwok

The mission of Gavi, the Vaccine Alliance continues to inspire and motivate IFPMA members, including the world's leading research-based vaccine manufacturers.

By uniting partners around a bold and ambitious agenda, Gavi has supported nearly half the world's children to be protected against deadly and debilitating infectious diseases.

To grow our collective impact over the next five years, IFPMA members commit to innovate new vaccine solutions, reach the most in need and underserved, support the strengthening of immunization services, prepare for public health emergencies, and partner to maximize impact.

Working together, we can scale vaccine innovation through sustained immunization, to ensure no one is left behind.

Partnering to protect health through life-saving vaccines

IFPMA and its members make five major commitments to support Gavi's mission to reach 300 million more children with the full protection of the broadest vaccine portfolio in history:

Bring to life new vaccine solutions that save lives, protect health and prevent the spread of disease

Reach the most in need and underserved by innovating throughout the supply chain and ensuring the availability of high-quality vaccines to meet existing and growing demand

Support the strengthening, sustainability and resilience of national immunization services

Prepare for public health emergencies to ensure the rapid sharing of information, the deployment of scientific expertise and the delivery of vaccines for use in outbreak responses

Partner to share capabilities, expertise and maximize the impact of life-saving vaccines

"We pledge to play our part in protecting the health of the next generation"









Partnering to protect health through life-saving vaccines







- Gavi, the Vaccine Alliance, 'Prevent, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- Gavi, the Vaccine Alliance, 'Gavi@20 The story of an Alliance that today protects half the world's children', accessed April 2020 https://www.gavi.org/sites/ default/files/publications/Gavi\_at\_20\_years.pdf
- Gavi, the Vaccine Alliance, 'Prevent, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/ files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- UNICEF, 'Pricing Data', accessed May 2020 https:// www.unicef.org/supply/pricing-data
- World Health Organization, 'Ten threats to global health in 2019', accessed April 2020 https://www.who. int/news-room/feature-stories/ten-threats-to-globalhealth-in-2019
- Gavi, the Vaccine Alliance, 'Preven, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/ files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- Gavi, the Vaccine Alliance, 'Prevent, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/ files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- 8. Gavi, the Vaccine Alliance, 'Fact & Figures', accessed May 2020 https://www.gavi.org/programmesimpact/our-impact/facts-and-figures
- Gavi, the Vaccine Alliance, 'Fact & Figures', accessed May 2020 https://www.gavi.org/programmesimpact/our-impact/facts-and-figures
- World Health Organization, 'Children: Reducing Mortality', accessed May 2020 https://www.who.int/ news-room/fact-sheets/detail/children-reducingmortality
- World Health Organization, '10 Facts on Polio Eradication', accessed April 2020 https://www.who. int/features/factfiles/polio/en/
- World Health Organization, 'Immunization, Vaccines and Biologicals: IPV Introduction, OPV Withdrawal and Routine Immunization Strengthening, accessed April 2020 https://www.who.int/immunization/diseases/ poliomvelitis/endgame\_objective2/en/
- Sanofi Pasteur, 'Access to Vaccines', accessed May 2020 https://www.sanofi.com/-/media/project/ one-sanofi-web/websites/global/sanofi-com/ home/common/docs/download-center/access\_to\_ vaccines\_2018.pdf/
- 14. Gavi, the Vaccine Alliance, 'Gavi Board starts framing Alliance's approach to 2021-2025 period', accessed May 2020 https://www.gavi.org/gavi-board-startsframing-alliance-s-approach-to-2021-2025-period
- 15. Gavi, the Vaccine Alliance, 'World's poorest children among first to receive new life-saving pneumococcal vaccines', accessed April 2020 https://www.gavi.org/news/media-room/worlds-poorest-children-among-first-receive-new-life-saving-pneumococcal-vaccines.
- 16. Gavi, the Vaccine Alliance, 'Fact & Figures', accessed May 2020 https://www.gavi.org/programmesimpact/our-impact/facts-and-figures
- Gavi, the Vaccine Alliance, 'Rotavirus Vaccine Support', accessed April 2020, https://www.gavi.org/ types-support/vaccine-support/rotavirus
- Atherly DE, Lewis KDC, Tate J, Parashar UD, Rheingans, RD. Projected health and economic impact of rotavirus vaccination in GAVI-eligible countries: 2011-2030. Vaccine. 2012;30(Suppl 1):A7-A14)

- World Health Organization, 'Defeating meningitis by 2030: Development of the Roadmap', accessed April 2020 https://www.who.int/emergencies/diseases/ meningitis/en/
- 20. World Health Organization, 'Malaria: Key Facts', accessed April 2020 https://www.who.int/en/news-room/fact-sheets/detail/malaria
- Kaslow et al. 'Vaccine candidates for poor countries are going to waste', Nature. 2018. Vol. 564 (337). Page 339, accessed May 2020 https://media.nature.com/ original/magazine-assets/d41586-018-07758-3/ d41586-018-07758-3.pdf
- 22. Gavi, the Vaccine Alliance, 'Pentavalent Vaccine Support', accessed May 2020, https://www.gavi.org/ types-support/vaccine-support/pentavalent
- 23. World Health Organization, 'Modernizing the arsenal of control tools: Ebola vaccines', accessed April 2020 https://www.who.int/csr/disease/ebola/one-yearreport/vaccines/en/
- 24. The International Federation of Pharmaceutical Manufacturers & Associations, 'Ebola', accessed May 2020 https://www.ifpma.org/subtopics/ebola/
- 25. Gavi, the Vaccine Alliance, 'Ebola vaccine purchasing commitment from Gavi to prepare for future outbreaks', accessed May 2020 https://www.gavi. org/news/media-room/ebola-vaccine-purchasingcommitment-qavi-prepare-future-outbreaks
- 26. World Health Organization, 'Major milestone for WHO-supported Ebola vaccine', accessed April 2020 https://www.who.int/news-room/detail/18-10-2019major-milestone-for-who-supported-ebola-vaccine
- 27. World Health Organization, 'Human Papillomavirus (HPV) and Cervical Cancer', accessed April 2020 https://www.who.int/news-room/fact-sheets/detail/ human-papillomavirus-(hpv)-and-cervical-cancer
- World Health Organization, 'Malaria: Key Facts', accessed April 2020 https://www.who.int/en/newsroom/fact-sheets/detail/malaria
- World Health Organization, 'Malaria vaccine pilot launched in Malawi', accessed March 2020 https:// www.who.int/news-room/detail/23-04-2019malaria-vaccine-pilot-launched-in-malawi
- 30.GKS, 'Inside the Vaccines Institute for Global Health', accessed May 2020 https://www.gsk.com/en-gb/ responsibility/inside-the-gvgh/
- 31. Pfizer, 'Pfizer Receives World Health Organization Prequalification for Multi-Dose Vial Presentation of Prevenar 13®, accessed May 2020 https://www.pfizer.com/news/press-release/press-release detail/pfizer\_receives\_world\_health\_organization\_prequalification\_for\_multi\_dose\_vial\_presentation\_of\_prevenar\_1
- 32. GSK, 'GSK receives World Health Organization Prequalification for Synflorix pneumococcal vaccine four-dose vial', accessed May 2020 https://www.gsk. com/en-gb/media/press-releases/gsk-receivesworld-health-organization-prequalification-forsynflorix-pneumococcal-vaccine-four-dose-vial/
- 33. Gavi, the Vaccine Alliance, 'Product information for vaccines and cold chain equipment: Detailed product profiles slide kit', accessed May 2020 https://www. gavi.org/our-alliance/market-shaping/productinformation-vaccines-cold-chain-equipment
- 34. World Health Organization, 'WHO Prequalified Vaccines: Cholera: Inactivated Oral', accessed April 2020 https://extranet.who.int/gavi/PQ\_Web/ PreviewVaccine.aspx?nav=0&ID=249
- 35. The International Federation of Pharmaceutical Manufacturers & Associations, 'Innovation for a Healthier World: Hallting Cervical Cancer', accessed April 2020 https://www.ifpma.org/wp-content/uploads/2016/02/IFPMA\_Vaccine\_Healthier\_World\_verF.pdf
- 36. The International Federation of Pharmaceutical Manufacturers & Associations, 'Global Health Progress: Gavi, the Vaccine Alliance: GSK', accessed April 2020 https://globalhealthprogress.org/collaboration/qavi-the-vaccine-alliance/

- 37. The International Federation of Pharmaceutical Manufacturers & Associations, 'Increasing Access to Vaccines in Rural and Urban Settings with mTech', accessed April 2020, https://www.ifpma.org/global-health-matters/increasing-access-to-vaccines-inrural-and-urban-settings-with-mtech/
- 38. Gavi, the Vaccine Alliance, 'Ghana launches the world's largest vaccine drone delivery network', accessed May 2020 https://www.gavi.org/news/media-room/ ghana-launches-worlds-largest-vaccine-dronedelivery-network
- 39. The International Federation of Pharmaceutical Manufacturers & Associations, 'Global Health Progress: Strategic Training for Executives Programme (STEP), accessed April 2020 https://globalhealthprogress.org/collaboration/strategic-training-for-executives-programme-step/
- 40.GSK, 'Save the Children Partnership', accessed May 2020 https://www.gsk.com/en-gb/about-us/savethe-children-partnership/
- 41. GSK, 'GSK licenses tuberculosis vaccine candidate to the Bill & Melinda Gates Medical Research Institute for continued development', accessed May 2020 https://www.gsk.com/en-gb/media/press-releases/ gsk-licenses-tuberculosis-vaccine-candidate-to-thebill-melinda-gates-medical-research-institute-forcentificated development/
- 42. Biological E Limited, 'K T Rama Rao Inaugurates BE's Plant at Genome Valley & Unveils Typhoid Conjugate Vaccine, accessed May 2020 http://www.biologicale. com/news.html
- 43. Biovac, 'Biovac tech transfer with Sanofi Pasteur', accessed May 2020 http://www.biovac.co.za/biovactech-transfer-with-sanofi-pasteur/
- 44. The International Federation of Pharmaceutical Manufacturers & Associations, 'COVID-19: The biopharmaceutical industry is leading the way in developing vaccines, treatments & diagnostics' accessed April 2020 https://www.ifpma.org/covid19/
- 45. Gavi, the Vaccine Alliance, 'Prevent, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/ files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- 46. Gavi, the Vaccine Alliance, 'Gavi Board Approves New Ebola Vaccine Programme' accessed April 2020 https://www.gavi.org/news/media-room/gavi-boardapproves-new-ebola-vaccine-programme
- 47. World Health O rganization, 'Yellow fever global vaccine stockpile in emergencies', accessed May 2020 https://www.who.int/news-room/featurestories/detail/yellow-fever-global-vaccine-stockpilein-emergencies
- 48. Gavi, the Vaccine Alliance, 'Prevent, Protect, Prosper: 2021-2025 Investment Opportunity', accessed April 2020 https://www.gavi.org/sites/default/ files/publications/2021-2025-Gavi-Investment-Opportunity.pdf
- 49. World Health Organization, 'Immunisation Agenda 2030: A Global Strategy To Leave No One Behind' accessed April 2020 https://www.who.int/ immunization/immunization\_agenda\_2030/en/
- 50. World Health Organization, 'Protecting lifesaving immunization services during COVID-19: New guidance from WHO' accessed May 2020 https://www.who.int/immunization/news\_guidance\_immunization\_services\_during\_COVID-19/en/

#### **About IFPMA**

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) represents research-based pharmaceutical companies and associations across the globe. Research-based pharmaceutical companies make a unique contribution to global health as innovators of lifesaving and life-changing medicines and vaccines, which improved millions of lives around the world. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

#### **Global Health Progress**

IFPMA hosts Global Health Progress, an interactive knowledge hub highlighting over 250 collaborations between the innovative biopharmaceutical industry and more than 1200 partners to support the Sustainable Development Goals (SDGs). Users can explore collaborations by SDG target, disease area, program strategy, and more. Our cross-sector partnerships are continually learning from each other, and through our deep and trusted collaborations we share insights and best practices from our experiences. Check out Global Health Progress www.globalhealthprogress.org.

@IFPMA ifpma.org @GlobalHealth IFPMA

#### **About ABPI**

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

abpi.org.uk @ABPI UK ABPI