

Danish Organisation Strategy 2023-2026 for Gavi, the Vaccine Alliance (GAVI)

Introduction:

GAVI's key results:

1. Introduce and scale-up coverage of high-impact vaccines for disease prevention
2. Strengthen health systems to increase equity in immunisation
3. Improve sustainability of immunisation programmes
4. Ensure healthy markets for vaccines and related products

Justification for support:

Gavi's mandate and work is highly relevant for key Danish priorities and interests on global health – sustainable development through immunization and promotion of healthy populations and communities. By improving health thorough immunization Gavi's work supports the Danish goals on stronger pandemic prevention and response through stronger health systems.

- Gavi meets the requirements of an effective multilateral organisation and is considered fit for purpose. The organisation works together with national governments, private sector and civil society to leverage each stakeholder's comparative advantage to fund immunisation and to shape the vaccine market.
- Gavi demonstrates transparency and accountability in its operations, and its compliance with fiduciary and social requirements and safeguards is strong.

From 2000 to 2021, Gavi's programmes helped vaccinate more than 1 million children. Gavi currently operates in 57 countries, covering approximately 50 percent of the global birth cohort. 19 countries have transitioned out of Gavi-support.

How we will ensure results and monitor progress:

- Monitoring of progress within prioritised areas will be done through annual reports, participation in Gavi briefings and meetings.
- Denmark will seek to influence Gavi through participation in the Nordic+ Constituency.

Risk and challenges:

- Competing priorities and lack of capacity and capability among partner countries.
- Insufficient demand and vaccine hesitancy
- Investments in health system strengthening does not materially improve programmatic outcomes
- Global supply shortage of vaccines
- Insufficient donor support
- Misuse of funds and fraud

File No.	2023-28069				
Responsible Unit	MNS				
<i>Mill. DKK</i>	2023	2024	2025	2026	total
Commitment	25	25	25	25	100
Projected Disb.	25	25	25	25	100
Duration of strategy	2023-2026				
Finance Act code.	§ 06.36.03.17				
Desk officer	Marie My Warborg Larsen				
Financial officer	Antonio Ugaz-Simonsen				

SDGs relevant for Programme

 No Poverty	 No Hunger	 Good Health, Wellbeing	 Quality Education	 Gender Equality	 Clean Water, Sanitation
 Affordable Clean Energy	 Decent Jobs, Econ. Growth	 Industry, Innovation, Infrastructure	 Reduced Inequalities	 Sustainable Cities, Communities	 Responsible Consumption & Production
 Climate Action	 Life below Water	 Life on Land	 Peace & Justice, strong Inst.	 Partnerships for Goals	

Budget

Annual budget 2022 from Gavi's externally audited consolidated financial statements:

Total: 2,054 mio. USD

Danish involvement in governance structure

1. Denmark vil become member of the Nordic+ Constituency

Strat. objectives

To save lives and protect people's health by increasing equitable and sustainable use of vaccines

Priority results

1. Health security, pandemic preparedness and health system strengthening
2. Addressing the effects of climate change on health
3. Equity, access and gender equality

Core information

Established: 2000

Headquarters: Geneva

Board member: Eighteen members are representative board members and nine members are unaffiliated/independent board members

Reach: Gavi currently operates in 57 countries



MINISTRY OF FOREIGN AFFAIRS
OF DENMARK

Organisation Strategy

Gavi | 2023-2026

DRAFT August 2023

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1. Objective

This organisation strategy for the cooperation between Denmark and Gavi, the Vaccine Alliance (Gavi) forms the basis for the Danish support to Gavi and is the foundation for Denmark's partnership and dialogue with Gavi. It sets out Danish priorities for Gavi's performance within the overall framework established by Gavi's own strategy 2020-2025 (cf. annex 1). This strategy covers the period 2023-2026. In 2023, Gavi has conducted a Midterm Review as a basis for discussions on the development of the next strategic framework 2025-2029.

Evidence shows that immunisation programmes are one of the most successful and cost-effective public health interventions. Immunised communities are healthier and better educated, their household economics are bolstered, and the next generation will grow up and be more productive members of societies (refer to section 3.2). Gavi's partnership model and strategic priorities to strengthen health systems and ensure healthy markets for vaccines and related products are aligned with Denmark's partnership approach, which brings together government, private partners, and civil society organisations as well as innovative instruments to make development assistance more sustainable and effective.

The overall objective of Denmark's engagement with Gavi is – in line with Denmark's strategy for development cooperation – to contribute to the achievement of the United Nation's Sustainable Development Goals (SDGs). There is a particular focus on SDGs prioritised by Denmark in countries and areas that are hit the hardest by poverty, conflict, and climate change, namely 1 (no poverty), 3 (good health and well-being), 5 (gender equality), 6 (clean water and sanitation), 13 (climate action), and 17 (partnerships in a changing world). The Danish development cooperation is rooted in a human rights-based approach and the principles of 'leave no one behind', non-discrimination, participation, transparency, and accountability across the development cycle.

This strategy builds on 'the organisation strategy for Denmark's Support to Gavi 2018-2022' and identifies key strategic priorities for the partnership and dialogue between the Danish Ministry of Foreign Affairs (MFA) and Gavi. It outlines specific goals and results that Denmark will pursue in cooperation with Gavi and like-minded partners.

2. The organisations

Background: Gavi is an international alliance established in 2000 to improve access to and affordability of new and underused vaccines for children living in the poorest countries in the world. The backdrop of establishing Gavi was a stalling in the progress in international immunisation in the late 1990s. The Gavi partnership model is designed to leverage financial resources and technical expertise to shape a healthy market mechanism and make vaccines more affordable, available and the supply more reliable. By increasing equitable uptake and coverage of vaccines in lower-income countries, the partnership delivers on the mission to save children's lives and protect people's health.

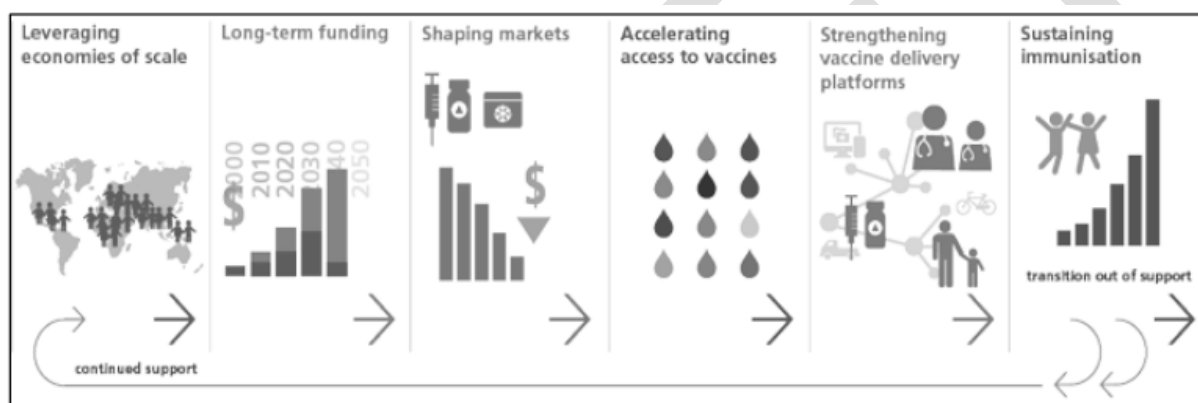
Denmark is one of the six original donors in the alliance. Other partners include civil society organisations, developing country governments, developing country pharmaceutical industry, industrialised country pharmaceutical industry, and research and technical institutes.

Vision and mission: In June 2019, the Gavi Board approved a new five-year strategy with the vision of ‘Leaving no one behind with immunisation’ and a mission to save lives and protect people’s health by increasing equitable and sustainable use of vaccines.

From 2000 to 2021, Gavi’s programmes helped vaccinate more than 1 million children. Gavi currently operates in 57 countries, covering approximately 50 percent of the global birth cohort. 19 countries have transitioned out of Gavi-support.

Fundamental for the Gavi business model is that support includes an exit strategy for implementing countries to take over their national immunisation programmes. Countries receiving support have to co-finance programmes and work towards sustainable national budget allocation for national immunisation programmes. The business model and the theory of change is illustrated below in figure 2.1

FIGURE 1: THE GAVI BUSINESS MODEL AND THEORY OF CHANGE



Gavi strategy 2020-2025

Gavi’s current strategy Phase V is supported by four goals:

Goal 1 – the vaccine goal, to be achieved through three strategic objectives: (1) strengthening countries’ prioritisation of vaccines; (2) support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases; and (3) enhance outbreak response through availability and strategic allocation of vaccine stockpiles.

Goal 2 – the equity goal, to be achieved by: (1) helping countries extend immunisation services to zero-dose children, defined as children who failed to receive any routine vaccination, and under-immunised by building stronger primary health care platforms; (2) supporting countries to ensure that immunisation services harness innovation and are well-managed and sustainable; and (3) work with countries and communities to build resilient demand and to address gender-related barriers to immunisation.

Goal 3 – the sustainability goal, to be achieved by: (1) strengthening political and social commitment to immunisation; (2) promoting domestic public resources for immunisation and primary health care to improve allocative efficiency; and (3) preparing and engaging self-financing countries to maintain/increase performance.

Goal 4 – the health markets goal, to be achieved by: (1) ensuring sustainable, healthy market dynamics for vaccines and immunisation-related products at affordable prices; (2) incentivising innovation for the development of suitable vaccines, and (3) scaling up innovation in immunisation-related products.

In the light of the impact of the COVID-19-pandemic on global health in general and the set-back in routine-vaccination in particular, the Gavi strategy 2021-2025 was updated with the Board's adoption of the Gavi 5.1 strategy. Gavi 5.1 builds on the lessons of the pandemic and acknowledge new challenges in global health security posed by the increasing number of outbreaks and their profound societal, economic, and technological impact of the environment in which Gavi operates. The 5.1 strategy will serve as a bridge to Gavi 6.0 (for the period 2026-2030) by reflecting the changing context of recent years.

2.1 Management

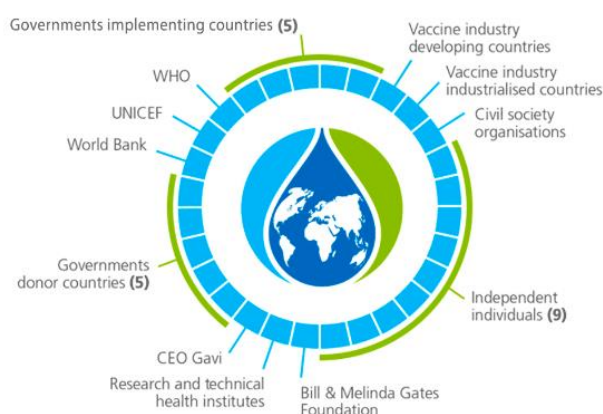
Gavi is a Swiss foundation with international institution status in Switzerland. The Gavi secretariat is based in Gavi's headquarters in Geneva, with support from an office in Washington DC. The secretariat is led by the chief executive officer.

The Gavi secretariat is responsible and accountable for the day-to-day operations of the Gavi alliance as they are set forth in the operations procedures determined by the Board. Main responsibilities include mobilisation of resources to fund programmes; coordination of programme approvals and disbursements; policy development and strategic initiative implementation; monitoring and evaluation; legal and financial management; and administration for the Gavi Board.

2.2 Governance and accountability

Gavi is governed by a Board, which is the highest decision-making body of the alliance. The Board is comprised of 18 "representative seats", 9 seats for independent or "unaffiliated" individuals and one seat for the Gavi Chief executive officer. Donor countries have five seats, shared in constituencies. Denmark is currently not member of a constituency, but in dialogue with the Nordic+ Constituency about joining. The Nordic+ currently comprises of Norway, Sweden, Finland and Switzerland with Norway representing the constituency on the Board until the end of 2023. The Nordic+ Constituency is consensus driven and positions are developed in collaboration prior to the two annual board meetings. The Danish priorities are in line with the priorities of the Nordic+ Constituency.

FIGURE 2: GAVI BOARD COMPOSITION



The Gavi Board is responsible for strategic direction and policy-making. Key tasks of the board include; adopting strategies and procedures necessary for the administration and management of Gavi, overseeing the operation of the vaccine alliance; and monitoring programme implementation.

An independent internal audit function (named “Audit and Investigations”) was established in 2009 to evaluate and strengthen risk management, internal control, and governance. The work of Audit and Investigations extends not only to the secretariat, but also programmes and activities of Gavi’s in-country programmes, including grant recipients. The accountability framework of Gavi comprises of the following:

1. *Internal audit*, responsible for evaluating and improving the effectiveness of the organisation’s risk management, control, and governance processes.
2. *Programme audit*, evaluating programmes in-country to assess whether Gavi support, including cash, vaccines and related supplies, has been used as intended. Audits take into account both financial and programmatic aspects.
3. *Investigations and counter-fraud*, responsible for making evidence-based investigations of possible misuse or other misconduct with Gavi and Gavi-supported programmes in-country.
4. *Whistleblower (confidential) reporting*, receiving reports from internal and external sources on potential misuse or misconduct of Gavi resources.

2.3 Financial resources

Denmark has since 2000 contributed a total of DKK 310 million in core contributions to Gavi, which include an extraordinary contribution of DKK 10 million to support preparation for the launch of the human papilloma virus (HPV) vaccine. In addition to the core contribution to Gavi, Denmark contributed an extraordinary DKK 190 million in 2021-2022 to the Gavi COVAX Advance Market Commitment (COVAX AMC), a financial mechanism within COVAX that supports low- and middle-income countries to COVID-19-vaccines through procurement, and support to delivery and logistics related to COVID-19 vaccines.

TABLE 1: DENMARK’S PLANNED CONTRIBUTION TO SUPPORT TO GAVI 2023-2026 IN MILLION DK*

2023	2024	2025	2026
25	25	25	25

*Subject to annual parliamentary approval of the Danish Finance Act

At the last replenishment conference in 2020, hosted by UK in London, world leaders pledged USD 8.8 billion for Gavi's 5.0 strategy, 2021-2025. Gavi's total annual income in 2022 was DKK 13,984 million (USD 2,055 million). Table 2 present a breakdown of the revenue by source during the current strategy period¹. This only includes core Gavi programmes and not COVAX.

TABLE 2: GAVI INCOME BY SOURCE, IN MILLIONS USD

Year	2021	2022
Governments and private donors	1,080	1,474
Investments and other income	125	(54) ²
Other revenue	434	634
Total	1,639	2,054

Major donors include United States, United Kingdom, Norway, Germany, Canada, Sweden and the Netherlands. In total, government contributions constitute approximately three quarters of the total funding to Gavi. The rest consists of private contributions from foundations (e.g. the Bill & Melinda Gates Foundation) and others.

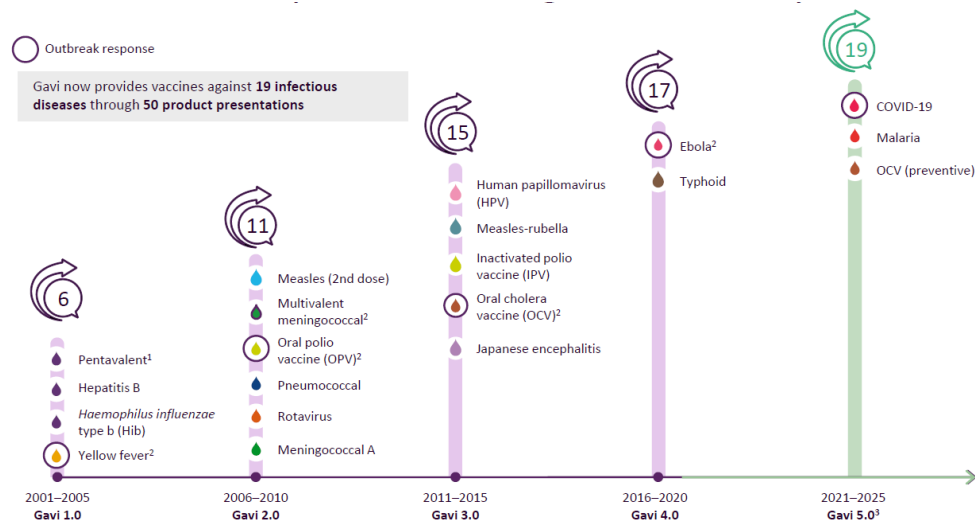
3. Lessons learnt, key strategic challenges and opportunities

Since its inception in 2000, Gavi has contributed to the immunisation of 1 billion children and supported countries in averting more than 16-17 million deaths. From 2000-2017 vaccination programmes has contributed to a 70 percent reduction in vaccine-preventable child deaths and a 50 percent reduction in under-5 mortality rate in the countries where Gavi operates. When the alliance was founded, it supported vaccines against three diseases. Today, Gavi supports vaccines against 19 diseases, cf. figure 3 below on the expansion of the Gavi vaccine portfolio from 2000 till today.

FIGURE 3: THE EXPANSION OF GAVI'S VACCINE PORTFOLIO FROM 2000-2023

¹ The figures in table 2 are from Gavi's externally audited consolidated financial statements, which are prepared in conformity with accounting principles generally accepted in the United States. Governments' and private donors contributions are reported as revenues in the year in which payments are received or unconditional promises are made. So depending on when a grant agreement is signed, the level of contributions in the grant agreement and/ or when payment is received – this affects the timing in which the amount can be recognised as revenue.

² Negative interest on money in the bank, placements of IFFIm contributions.



In the current strategy period 130 million children have been immunised, which indicates that Gavi is on track to deliver the 2025 target of immunising an additional 300 million children, preventing 7-8 million deaths.

3.1 Present and new challenges

Despite significant progress overall and in the Gavi 2020-2025 strategic period, challenges and risks remain in terms of meeting the strategic goals. The pandemic magnified global inequalities in access to vaccines and other countermeasures and took a disproportionate toll on the most vulnerable countries and communities.

Coming out of the pandemic, the world is facing multiple crises. Increasing debts and rising inflation has left countries with fiscal constraints. The impact of climate change, rising levels of conflict and insecurity, including food insecurity, and health systems that are strained after the pandemic all amount to a challenging environment for the Alliance, partners, and not least implementing countries and communities.

The COVID-19 pandemic demonstrated that countries with strong health systems - including strong immunisation programmes - and swift access to countermeasures and vaccines were best placed to respond to the pandemic. Moving forward there is a need to learn from the pandemic and integrate experiences and lessons-learned in a stronger and more robust global health security infrastructure. There is a need to define Gavi's role in the global architecture for pandemic preparedness, prevention and response. Furthermore, Gavi's country-programmes has an important role to play in building stronger health system capacity to prepare, prevent and respond to disease outbreaks with pandemic potential.

Climate change causes vector-borne diseases carried by mosquitos, such as malaria, yellow fever, and dengue to spread to new areas and regions. At the same time, extreme weather caused by climate change damages local health infrastructure and disrupts health delivery services. Increasing climate change in connection with urbanisation also increases the risk of the emergence of new diseases capable of spreading from wild animals to humans.

The World Health Organisation (WHO) has estimated that the number of un- or under-vaccinated children grew from 17 million in 2019 to 25 million in 2021. At the same time, outbreaks of vaccine-preventable diseases have increased. In 2022, Gavi supported 40 campaigns in response to outbreaks - a 75 percent increase compared to 2021. This upwards trend is continuing in 2023. In terms of extending the power of increased immunisation there is a need to resume the targeted focus on reaching zero-dose children to prevent further backsliding of immunisation and recover from set-backs during the pandemic. Delays to key vaccine rollouts, e.g. HPV vaccine, as countries have been forced to prioritise during the pandemic, also needs attention.

The Gavi business model is based on partner countries taking increased ownership of their immunisation programmes by contributing more domestic resources over time. Six countries are expected to transition out of Gavi support from 2020-2025, falling short of the goal of 10 countries. Also, countries are expected to fall USD 200 million short of the USD 3.6 billion target for self-financing and co-financing by 2025. At the same time, newer vaccines with increased prices and higher than expected prices for existing programmes are challenging the sustainability of Gavi's co-financing model. Recognising these issues, the Gavi Board has updated the transition policy. As an alliance, Gavi will work closely with transitioning countries to establish the strong political commitment necessary to lay the foundation for sustainable national immunisation programmes.

Inequalities in immunisation programmes persist and United Nations Gender Development Index shows that immunisation coverage is better in more equal countries. Structural barriers, in particular gender, can also prevent children from being immunised. While there is no significant difference in immunisation coverage rates for girls and boys, the status of women in a society impacts her ability to access health services and therefore also her children's likelihood of being immunised regardless of their sex. The challenges are numerous: women's lack of household financial resources to pay for indirect cost, limited education and health literacy, as well as security and mobility issues. For all children to have access to vaccines, gender barriers need to be addressed. Women and girls' lack of access to health services is also a challenge in relation to cervical cancer. Every year 266,000 women die from cervical cancer, 80% of the cases are in developing countries. If the current trend continues, cervical cancer deaths can outpace maternal mortality. It is estimated that HPV-vaccines can prevent up to 90% of all cervical cancer cases, which means that today, women die from cervical cancer that is preventable.

To address the gender barriers, Gavi has an extensive gender policy in place. With the gender policy Gavi has committed to increasing immunisation coverage by supporting countries to overcome gender-related barriers to accessing immunisation services and promoting equity of access for all genders to immunisation and related health services that respond to their different needs.

3.2 The relevance and effectiveness of Gavi in relation to the international development and humanitarian agenda

Immunisation is a global public good and remains one of the most effective ways to save lives. Our response to the COVID-19 pandemic demonstrated the power of vaccinations, but it also served as a reminder that no one is safe until everyone is safe. The Gavi mandate to save lives and protect against

future disease outbreaks, epidemics, and pandemics remains important to secure progress on achieving the sustainable development goals, in particular poverty reduction (SDG 1), good and health and well-being (SDG 3), equality in education (SDG 4), decent work and economic growth (SDG 8), peace and strong institutions (SDG 16), and partnerships for goals (SDG 17).

Strong health systems and better public health support long-term stability and create jobs and contribute to reduced inequality. Gavi's public-private partnership model drives progress in immunisation by supporting healthy markets, reducing prices, promoting innovation and sustaining supply and demand.

Vaccinations build resilience to mitigate disaster in humanitarian settings, whether from conflict, instability, climate change, or natural disasters, and have a positive impact on the health and well-being of communities. Gavi adopted a Fragility, Emergency and Refugees Policy (FER policy) in 2017 with the aim of: 1) articulating criteria for identifying a subset of Gavi countries that are affected by fragility, as per international standards; 2) providing guidance on adapting certain Gavi policies to tailor them to the local context; and 3) detailing flexibilities that can be extended in the case of an emergency and for Gavi countries hosting refugees. An evaluation of the FER policy in 2021 concluded that the FER policy is robust enough to allow flexibility in Gavi policies and operations in countries facing fragility, emergencies, or refugee situations. The policy would benefit from a revised application mechanism enabling prompt decision-making where immediate action is required.

4. Justification for support and priority areas

The overall mission of Gavi to promote sustainable development through immunisation and promotion of healthy populations and communities are in line with the Danish priorities for global health. Denmark's priorities in global health are defined in the Danish development strategy "The World We Share" and in the How-to note for Social sectors and social Safety nets. The objectives in "The World We Share" is to contribute to the fulfilment of the UN Sustainable Development Goals (SDGs). The main goal on health in "The World We Share" is supporting access to healthcare services in fragile countries and regions, with particular focus on marginalised groups, women, children and young people. Based mainly on SDG 3 Denmark's priorities in global health include strengthening local, regional and global health and health security, including pandemic prevention, preparedness and response, stronger health systems, and access to primary care. Denmark's priorities in global health also recognise the effect of climate change. Pressure on nature and population growth has a negative effect on public health. Therefore, the integration of climate mitigation and adaptation in global health initiatives is crucial. Gavi's focus on gender equality and empowerment of women is in line with the Danish priority for gender equality as a crosscutting issue in Danish development cooperation.

The priority areas and results to be achieved are based on the link between Denmark's strategic priorities for sustainable global development, Gavi's strategic priorities and the challenge and opportunities described in section 3.1 above.

Health security, pandemic preparedness and health system strengthening

Strong institutions, robust health systems and resilient supply chains are critical for health globally, regionally and locally and for countries to be able to develop and maintain immunisation programmes. This includes technical capacity to administer and deliver vaccines, operational capacity to plan and execute programmes and an open dialogue on priorities and needs to designing and operating well-

functioning health systems. Denmark is committed to take part in efforts to strengthen health security and pandemic preparedness at the local, national and global level alongside likeminded and multilateral partners. Likewise, Gavi's goal is to explore new ways to partner with others to build resilience at country level and contribute to the overall global pandemic prevention. This includes addressing the inadequate manufacturing capacity and lack of diversification of supply chains.

Denmark will continue to support Gavi's promotion of health system strengthening and the integration of lessons learned from the pandemic to build stronger and more robust country capacity to address disease outbreaks and prevent pandemics. Denmark will also support Gavi's work on contributing to a higher level of global health security by building stronger production capacity and more resilient supply chains to ensure equal and timely access to vaccines and other countermeasures.

Addressing the effects of climate change on health

Climate change is creating conditions for preventable diseases to spread, and climate emergencies damage local infrastructure and disrupt essential health services. Furthermore, climate change exacerbates the risk of antimicrobial-resistant bacteria (AMR) by spreading resistant bacteria to new areas and creating conditions for development of new resistant bacteria and fungi. Six of Gavi's vaccines protect against AMR diseases by reducing transmission of sensitive and resistant strains and preventing people from catching hard-to-treat infections. Vaccines also contribute to the battle against AMR by reducing the unnecessary antibiotic use.

Globally, the health sector is responsible for around 5 percent of the total greenhouse gas emissions. Gavi – together with partners, including UNICEF, is focused on mitigating emissions related to immunisation programmes. This is for example done by introducing sustainable energy solutions in the cold chain or leveraging new and more energy-efficient technology in delivering vaccines, e.g. the use of drones to reach remote areas instead of using trucks and vans.

Denmark will support Gavi initiatives to address the effects of climate change and climate emergencies on health and health systems in its mission. Denmark will work to ensure that the updated Gavi strategy for 2026-2030 includes ambitious goals on addressing climate change and its effects on Gavi's core mission and programme. This includes goals on how to further mitigate emissions related to immunisation programmes, including e.g. more sustainable waste management.

Equity, Access and Gender Equality

Equity, equal access to health services, and gender equality are values underpinning the Danish development strategy on global health. The Danish approach emphasises a human rights based approach to development as the basis for the development of sustainable and equal societies. Denmark places strong emphasis on gender equality and the rights of women and girls, including sexual and reproductive health and rights. This includes access to vaccines such as HPV. The revitalisation of the HPV vaccination programme is based on a tailored approach for reaching women and young girls. In June 2020, a revised gender policy was approved by the Gavi Board, which includes initiatives to encourage and advocate for

women's and girls' full and equal participation in decision-making related to health programmes and wellbeing. Furthermore, Gavi has established a new gender-responsive funding system as part of the overall gender policy.

Denmark will closely follow Gavi's work with development and strengthening of the gender policy and the ability to identify and address actual gender barriers for accessing immunisation. Denmark will furthermore work to ensure that the newly established gender-responsive funding system is implemented and evaluated to ensure the overall effectiveness of the programme.

5. Monitoring and reporting

Gavi is an international alliance between multiple private partners (including the funding partners; WHO, World Bank, Unicef and Bill & Melinda Gates Foundation), donor governments, partner countries, and civil society organisations. Denmark's ability to influence the strategy and operating model of Gavi is through its participation in the Nordic+ Constituency. Each constituency has a seat at the Board..

MFA will seek to influence the development of the Gavi strategy 6.0 for the period 2025-2030 by emphasising the priority areas in collaboration with the Nordic+ Constituency. The influence of the constituency is relatively high as it is a homogeneous group that is able to leverage each other strengths to influence the overall strategic direction and decision making.

To monitor performance and progress of Gavi strategy 2020-2025 there is specific goals and objectives for each strategic goal. The results are based on Gavi's results framework and progress monitoring systems. Overall, the Gavi goals and indicators contribute to the achievement of the SDGs and the Danish priorities. The secretariat monitors progress based on Gavi's indicators, and reports to the Board on the progress.

6. Risk and assumptions

The Gavi Alliance recognises that risks must be taken into consideration and managed carefully. To manage risks, the Gavi Board has adopted a risk policy in 2014. A yearly report provides an update on risk management across the alliance, including an analysis of trends affecting Gavi's risk profile and changes in top risks compared to previous years.

While not an immediate health emergency, the COVID-19 pandemic continuously influences the environment in which Gavi operates with a significant impact on the risks facing the Alliance.

Competing priorities and lack of capacity and capability. The Alliance is based on collaboration and involvement of partner countries. However, many partner countries continue to have insufficient capacity and capabilities to develop, maintain, restore, and strengthen immunisation programmes. For countries that have transitioned out of Gavi-supported programmes there is a risk that they fail to sustain progress. Of the 19 countries that have transitioned out of Gavi support as of 2022, 13 have not yet introduced at least one of pneumococcal conjugate vaccine (PCV), rotavirus vaccine, or HPV vaccine. Competing

priorities in a time of multiple crisis is the reality for Governments in implementing countries around the world. This makes continued commitment and capacity to collaboration an area of attention.

Insufficient demand and vaccine hesitancy. High levels of demand are critical to reach every child and every community and to achieve high levels of vaccine uptake. Demand can be affected by vaccine hesitancy, due to immunisation not being actively prioritised by parents and caretakers, and by lack of data on zero-dose/under-immunised children. Vaccine confidence depends on trust on the safety and efficiency of vaccines and the systems and health workers delivering them. The experience of roll-out of covid-19 vaccines have in some countries and communities led to increased vaccine hesitancy, which needs to be actively addressed as a drop in demand for vaccines would negatively affect Gavi's ability to achieve its overall mission.

Health systems strengthening. During the current Gavi strategy 2020-2025, Gavi is expected to invest approximately 2 billion USD in the strengthening health systems in partner countries to reach zero-dose children, improve cold-chain equipment, and other optimisation platforms, including digital platforms. There is a risk that the investments in health system strengthening does not materially improve programmatic outcomes due to systematic and programmatic bottlenecks, such as gaps in workforce, design of the overall health system, grants and programmes duplicate other programmes, or if grants are not big enough to have a significant impact.

Global supply of vaccines. Gavi tries to mitigate supply shortages by its market-shaping strategy to help build and support a healthy global vaccine market. The strategy enables manufacturers to produce vaccines in quantities, and at prices, that are sustainable for lower-income countries. However, some markets continue to be of low health, due to lack of supplier diversity as well as limited capacity for manufacturing expansion. Sustained supply security continues to be dependent on factors and assumptions outside the scope and influence of Gavi, such as global production capacity, (lack) of supplier diversity, and lack of introduction of new technologies, that may influence manufacturers capacity. A stronger global diversification of supply chains and vaccine manufacturer will help secure global supplies.

Continued donor support. The continued support from donors is crucial to sustain Gavi's programmes and keep up with a growing birth-cohort. Global economic setbacks and uncertainty, a changing geopolitical environment, and competing priorities in development (such as climate change, migration, security, education) as well as a general domestic strain on resources in most countries, poses a risk to continued donor support. Reduced donor support and access to financing, will undermine achievements and risk further backsliding leading to increased risk of a re-emergence of covid-19 as well as the risk of new pandemics caused by vaccine-preventable diseases.

Misuse of funds and fraud. The risk of deliberate misuse of Gavi support and Gavi funds remains high in time of economic uncertainty, low morale after years struggling with the pandemic, and financial pressure. At the same time, countries and implementing partners were under pressure to spend faster to deliver progress during the immediate health emergency setting aside some of the usual processes for procurement, oversight and assurance. Gavi acknowledges that during the duration of a health

emergency, risks may increasingly materialise despite efforts to mitigate them. In case of actual misuse, however, Gavi will always require reimbursement as a condition for continued support. It is the responsibility of the internal auditor, under the supervision of the Board, to conduct investigations and counter-fraud, which conducts an evidence-based examination of possible misuse and other misconduct within Gavi, in Gavi-supported programmes in countries, or which otherwise impact upon the organisation.

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7. Annex

2.4 Annex 1

GAVI, THE VACCILANCE ALLIANCE STRATEGY 2020-2025

[Phase 5 \(2021–2025\) \(gavi.org\)](https://www.gavi.org/phase5)

2.5 Annex 2

GAVI RISK POLICY (2014)

[Travel and Non-travel Business Related Expense Policy and Reference Manual \(gavi.org\)](https://www.gavi.org/travel-and-non-travel-business-related-expense-policy-and-reference-manual)

2.6 Annex 3

GAVI RISK APPETITE STATEMENT VERSION 3.0

[Board Document Template \(gavi.org\)](https://www.gavi.org/board-document-template)

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