

Foster innovation and value recognition of life-course immunisation in Europe to protect people against evolving health challenges. 99

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# INTRODUCTION

In 2024, Vaccines Europe continued its efforts to unlock the full potential of immunisation. This year marked a pivotal moment with the EU elections, ushering in a new Parliament and Commission, setting the tone for the next five years. The **mission letter** to Commissioner for Health and Animal Welfare Olivér Várhelyi reinforced the need to prioritise prevention, preparedness, and health resilience. Our new strategy for 2024-2026 builds on this momentum, ensuring that immunisation remains at the core of Europe's health and economic agenda.

The economic value of immunisation has been further highlighted, with the report by The European House – Ambrosetti making a strong investment case for vaccines. As we navigate a complex health landscape, ensuring a resilient vaccine supply chain is essential, and our latest paper outlines key actions to safeguard supply chain resilience.

We have also continued to advance innovation, with an updated **pipeline review** showcasing the next generation of vaccines and their potential impact on public health. Europe needs to be ready to evaluate these new innovative vaccines to ensure access for the population.

We have put forward three **quiding principles** for evaluating vaccines in the context of the EU HTA Regulation.

This year also saw the 5<sup>th</sup> annual EU Flu Day, where a patient story took centre stage, reinforcing the realworld benefits of vaccination against respiratory infections such as flu, RSV, and COVID-19. Immunisation's role in broader health priorities has been recognised, notably in the Council's conclusions on cardiovascular disease (CVD), which underline the advantages of flu vaccination for people with CVD, as well as in the Council's recommendations on vaccine-preventable cancers.

While significant progress has been made, challenges remain in data collection, digitalisation, vaccine access, and addressing vaccine hesitancy. To build resilient immunisation systems, Europe must foster an environment supporting vaccine innovation and uptake. As we embark on this new political cycle, we look forward to working with all stakeholders to drive progress and ensure that prevention remains a cornerstone of European health security.

**Executive Director Vaccines Europe** 

Sibilia Quilici

# **FOREWORD**

Innovation remains the driving force behind progress in healthcare, ensuring we stay ahead of evolving health threats. Yet, while immunisation has long been one of the most effective public health interventions, Europe's ability to lead in immunisation innovation is at risk. The latest EFPIA-Vaccines Europe Clinical trials report highlighted a concerning trend: the EU's share of global immunisation clinical trials has halved from 17% in 2018 to just 8% in 2023.

Where vaccine research, development and manufacturing happens matters.

By fostering a more innovationfriendly environment, the EU can regain its position as a global leader in immunisation, reinforcing its competitiveness and securing long-term public health and economic benefits. A robust, forward-looking approach to immunisation innovation is not just a necessity, it is a strategic imperative for Europe's future.









# **ABOUT VACCINES EUROPE**

#### Who we are

Vaccines Europe is a specialised vaccines group within the **European Federation** of Pharmaceutical Industries and Associations (EFPIA), the association representing the biopharmaceutical industry operating in Europe.

Created in 1991 to provide a voice for the vaccine industry in Europe, Vaccines Europe represents vaccine companies of all sizes operating in the continent. It currently includes all the major global innovative and research-based vaccine companies, including small and mediumsized enterprises.

The Vaccines Europe team has continued to grow, and in 2024 we welcomed two new team members, strengthening our work in the area of electronic patient information, and enhancing administrative support to the team.

### Mission & strategic priorities

By fostering innovation and enhancing the recognition of the value of lifecourse immunisation in Europe, our mission is to protect individuals against evolving health challenges.

# WE HAVE 4 STRATEGIC PRIORITIES:









# **Attractiveness**

Create attractive conditions and incentives for investment in R&D and manufacturing

# Regulatory

Contribute to streamlining & harmonisation of the regulatory framework

#### Value

Promote value recognition and timely immunisation systems population access to immunisations

Drive resilient and uptake



#### **Enablers**

Across these priorities, we advocate for the full value of immunisation and funding to address current and future challenges.

VACCINES EUROPE - ANNUAL REPORT 2024

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### Member companies in 2024

In 2024, there were three changes to our membership. IDT Biologika left and HIPRA joined Vaccines Europe. In July 2024, VBI Vaccines initiated restructuring proceedings and ceased being a member of Vaccines Europe.































# **National Vaccine Industry Groups network**

We strongly collaborate with National Vaccine Industry Groups (NVIGs), bringing together vaccine manufacturers at national level, to ensure collaboration and alignment across the industry on key vaccine policy initiatives, both at EU level and nationally.



Our NVIGs network includes 26 associations in 25 countries: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, The Netherlands (2 associations), United Kingdom

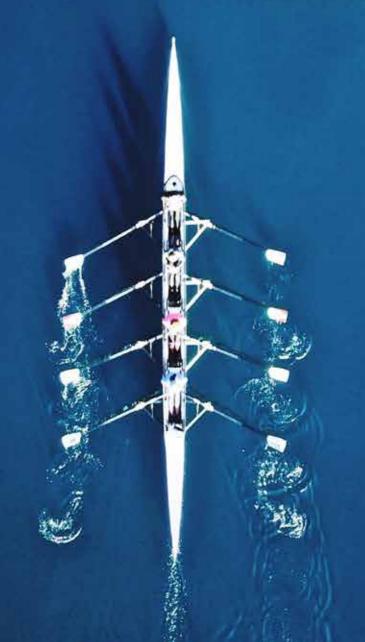




#### How we work

Vaccines Europe's activities include working on every part of the vaccine **ecosystem:** Research & innovation, regulatory affairs, manufacturing & supply, market access & public policy, immunisation financing and vaccine acceptance.





# **W**accinesToday

We recognised early the need for an independent and reliable source of **information** about vaccination for the general public. For this reason, since 2011, following the H1N1 pandemic, we have sponsored Vaccines Today, an online platform for discussing vaccines and vaccination.

Vaccines Today is **run by an editor, in** consultation with an independent **Editorial Board** composed of experts in the field of vaccination, including external medical doctors, patient and civil society representatives, and representatives from Vaccines Europe member companies. Vaccines Today is certified by the World Health Organization's Vaccine Safety Net.

Vaccines Today has over

- 20,000 followers on X,
- 3,700 followers on LinkedIn and
- 9,000 followers on Facebook.







innovative vaccines in development

VACCINES EUROPE PUBLIC POLICY PRIORITIES **VACCINES EUROPE PIPELINE REVIEW 2024** 

> To support informed decisionmaking, it is increasingly important for regulators and policymakers to have a clear understanding of the vaccines currently in development. In response to this, we have published the third edition of our annual pipeline review, offering an updated overview of the R&D activities of Vaccines Europe member companies. This year's report identifies 98 vaccine candidates across 12 technology platforms, with 42% targeting diseases for which no authorised vaccine currently exists.

The review highlights the expanding role of vaccines, and monoclonal antibodies, in addressing complex global health priorities, including antimicrobial resistance (AMR), climate-related health risks, and the consequences of an ageing population. With more than 80% of the vaccine pipeline focused on adult use, the findings reaffirm the importance of life-course immunisation strategies. These approaches not only strengthen public health systems but also offer significant economic value.



With the rapid evolution of the policy environment within the EU and beyond, it is more important than ever to demonstrate the value of the pharmaceutical sector for Europe's health, economy and resilience. EFPIA and Vaccines Europe published 3 reports showcasing innovative treatments and vaccines in development, the economic footprint of the industry and the clinical trial ecosystem in Europe.



#### The **EFPIA 2024 Pipeline Review**

explores vaccine innovation in the context of public health challenges across Europe and globally. As healthcare systems face mounting pressure from ageing populations, climate change, and the spread of antimicrobial resistance (AMR), the role of immunisation is paramount for long-term health system sustainability and preparedness. In a quickly evolving landscape, the report underscores the importance of investment in vaccine development to address emerging

and persistent threats. Immunisation can help combat AMR through novel vaccines, which could reduce the need for antibiotics and slow resistance. It also highlights promising work on vaccines for chronic viral infections associated with non-communicable diseases (NCDs), such as certain cancers. These examples reflect a broader trend: the integration of vaccination into strategies for preventing complex, multi-factorial diseases, and strengthening public health resilience.







Vaccines represent a vital and growing segment of the pharmaceutical industry, contributing not only to public health but also to Europe's economic resilience and technological leadership. As part of the wider life sciences sector, vaccine development and manufacturing are key drivers of innovation, investment, and high-skilled employment. New research highlighted the pharmaceutical industry's strong economic impact, contributing €311 billion to the EU economy in 2022 and supporting 2.3 million jobs. The report indicates a steady decline in Europe's share of global R&D investment. Despite remaining three times more productive than the EU economy overall, the sector faces a competitiveness gap, with productivity per worker still well below the US, where gross value added per hour is twice as high. Urgent policy action is needed to boost European competitiveness and future-proof innovation.





# **ASSESSING THE CLINICAL** TRIAL ECOSYSTEM **IN EUROPE**

Vaccines are an essential pillar of the pharmaceutical industry and a strategic asset for Europe's public health and innovation ecosystem. Yet, despite their importance, new data show that the clinical research environment for vaccines in Europe is under growing pressure. The EFPIA-Vaccines Europe report, "Assessing the Clinical Trial Ecosystem in Europe", reveals a significant decline in the EU/EEA's share of global clinical trials, from 22% in 2013 to just 12% in **2023**, despite a 38% increase in trials worldwide. This decline has resulted in 60,000 fewer European patients accessing innovative treatments.

Vaccines are among the areas most affected. The EU/EEA share of global immunisation clinical trials has dropped from 17% in 2018 to just 8% in 2023, and Phase 3 immunisation trials conducted in the EU during the same period have fallen by 50%. This signals serious risks for Europe's role in future vaccine development. EFPIA and Vaccines Europe call for urgent and coordinated policy action to modernise Europe's clinical trial landscape. Simplifying procedures, reducing delays, and enabling greater harmonisation are essential steps to revitalise Europe's competitiveness and secure its capacity to lead in vaccine innovation.





# THE VALUE OF PREVENTION **FOR ECONOMIC GROWTH** AND THE SUSTAINABILITY OF HEALTHCARE, SOCIAL CARE, **AND WELFARE SYSTEMS**

The value of prevention for economic growth and the sustainability of healthcare, social care, and welfare systems report by The European House -Ambrosetti, supported by IFPMA and Vaccines Europe, underscored the urgent need to shift from a reactive to a proactive healthcare model. With slow economic growth and increasing pressure on public finances, investing in preventive healthcare, especially immunisation, can generate significant economic returns, reducing longterm healthcare costs and increasing productivity. Adult immunisation returns up to 19 times its initial investment, rising to 33 times for pneumococcal vaccines. However, prevention remains underfunded, with just 0.5% of healthcare budgets allocated to immunisation. The report calls for urgent policy reforms to recognise prevention as a strategic investment, ensuring long-term economic resilience and sustainability.



# VACCINES EUROPE REFLECTIONS ON ENHANCING SUPPLY CHAIN RESILIENCE

Ensuring a resilient and sustainable vaccine supply chain is essential to prevent shortages and strengthen Europe's manufacturing footprint.

The Vaccines Europe reflections on enhancing supply chain resilience paper identified key vulnerabilities, including complex production processes, packaging restrictions, supplier limitations, and unpredictable demand forecasting.

Manufacturers are tackling these challenges by diversifying suppliers, implementing shortage prevention plans, and securing multiple raw material sources. However, policy action is needed to enhance resilience, including improving demand transparency, standardising EU packaging, fostering collaboration, and investing in a skilled workforce. Strengthening supply chains will be key to ensuring reliable vaccine access across EU Member States.



# PREPARING FOR THE EUROPEAN UNION'S REGULATION ON HEALTH TECHNOLOGY ASSESSMENT FOR VACCINES:

GUIDING PRINCIPLES FOR EVALUATING VACCINES IN JOINT HEALTH TECHNOLOGY ASSESSMENT IN THE EUROPEAN UNION

Within the EU HTA Regulation, vaccines can be subject to joint scientific consultations as of January 2025, and subject to joint clinical assessments as of 2030. It is crucial that vaccines are appropriately evaluated within this framework. Unlike therapeutic medicines, vaccines require specific assessment methodologies that account for their preventive nature, long-term societal benefits, and public health impact. However, current HTA processes lack vaccine-specific criteria, creating inconsistencies across EU Member States. This article, published in the peer-reviewed journal *Value in Health*, outlines three guiding principles with 13 recommendations to standardise vaccine evaluation, improve evidence generation, and ensure timely access to new vaccines. Integrating National Immunisation Technical Advisory Groups (NITAGs) into the EU HTA framework is a key step to align national and EU-level processes, reduce duplication, and accelerate vaccine access.







# COLLABORATIONS

**CONTRIBUTIONS TO THE WORK OF STAKEHOLDERS** 

A total of 20 consultation and survey **submissions** in response to consultations from the European Medicines Agency (EMA), the European Commission (EC) and others.



A total of 68 meetings with stakeholders such as the European Medicines Agency (EMA), the European Commission (EC), Health Emergency Preparedness and Response Authority (HERA) and the European Directorate for the Quality of Medicines & HealthCare (EDQM).

**INTERACTIONS WITH POLICYMAKERS** 

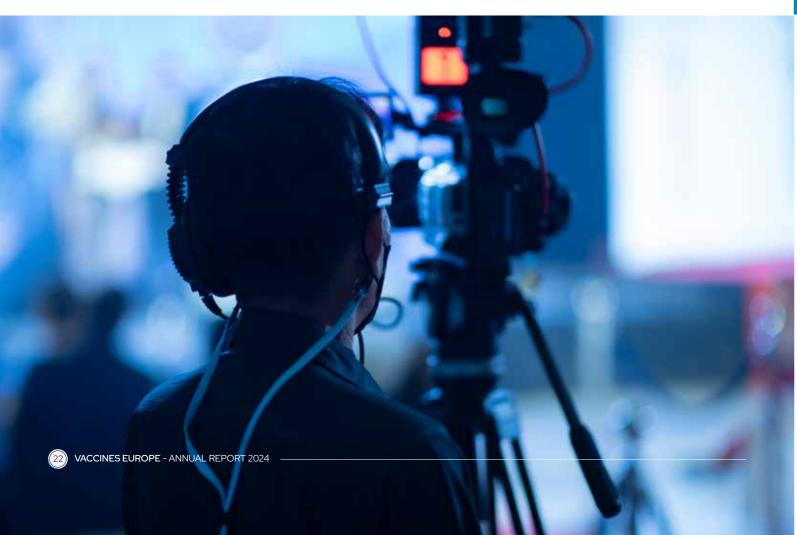
interactions with Members of the European Parliament and Permanent Representatives of Member States.



# **VACCINES EUROPE EVENTS**

# **EVENTS**

- On 23<sup>rd</sup> April, during European Immunisation Week, Vaccines Europe and pharma.be co-organised the hybrid event "Data driven life course immunisation: What are we waiting for?"
- On 15<sup>th</sup> October, Vaccines Europe and the **Association for Innovative Pharmaceutical Manufacturers** (AIPM) co-organised the "Immunisation for Life" conference in Budapest, Hungary.
- The fifth annual EU Flu Day, organised by the Steering Group on Influenza Vaccination, of which Vaccines Europe is a member, took place on 16th October titled "15 years on: Updating the EU's 75% uptake target to manage the triple threat of Flu, COVID-19, and RSV".
- On 13<sup>th</sup> November, Vaccines Europe organised a Policy Debate and Networking Reception at the European Parliament.





# **GRANTS**

Civil Society Organisations and Associations representing healthcare professionals play an important role in raising awareness on the importance of immunisation to their networks.

In line with our ambition to gather the broadest array of stakeholders to develop common efforts towards holistic immunisation policies, in 2024, Vaccines Europe supported the Coalition for Life-Course Immunisation (CLCI) and the European Specialist Nurses Organisation (ESNO) with unrestricted grants, as well as the Sapienza University of Rome.









### **Adult Immunization Board**

The Adult Immunization Board (AIB) is an advisory board established with the aim of contributing to the reduction of the impact of vaccinepreventable infections and diseases in European adults. Their primary goal is to provide evidence-based guidance on fundamental technical and strategic issues, while monitoring the progress of adult immunisation programmes at European and (sub)national levels.

The AIB is supported for its activities and meetings by an unrestricted grant from Vaccines Europe.

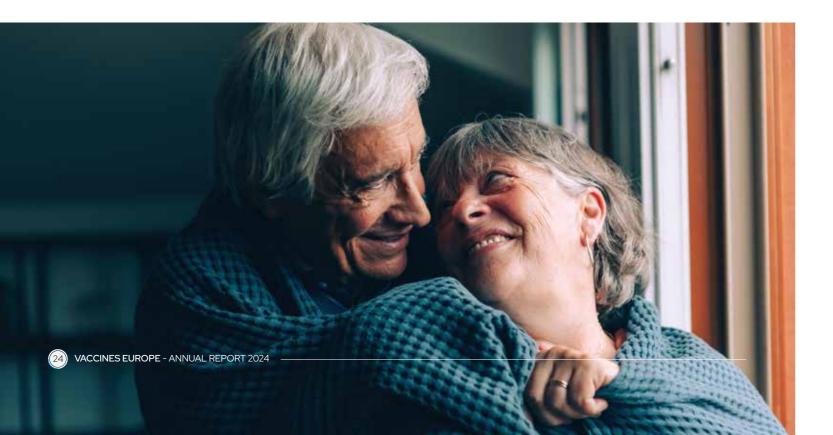
### **Mission Board on Vaccination in Europe**

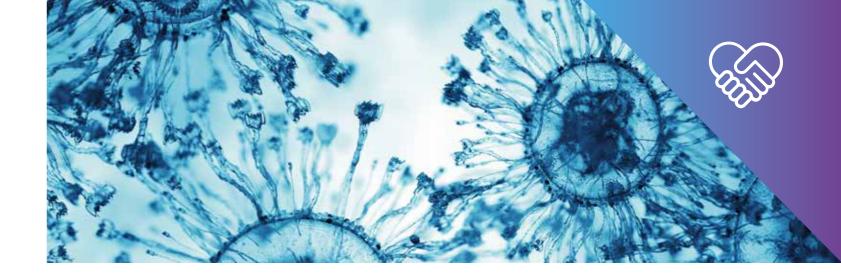
The Mission Board on Vaccination in Europe is a new multi-disciplinary, multi-stakeholder initiative that aims to provide thought-leadership on, and recommendations to strengthen immunisation systems in Europe, with a specific focus on decision-making related to vaccination policies and programmes.

The work of the Mission Board on Vaccination in Europe Secretariat is enabled by funding from Vaccines Europe.









# **PARTNERSHIPS**

Vaccines Europe collaborated with a number of initiatives, organisations and institutions in 2024, including the Innovative Health Initiative, the EU Health Coalition, the Federation of European Academies of Medicine (FEAM), the Health Emergency Preparedness and Response Authority (DG HERA), the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the European Medicines Agency (EMA).

#### **EUVABECO**



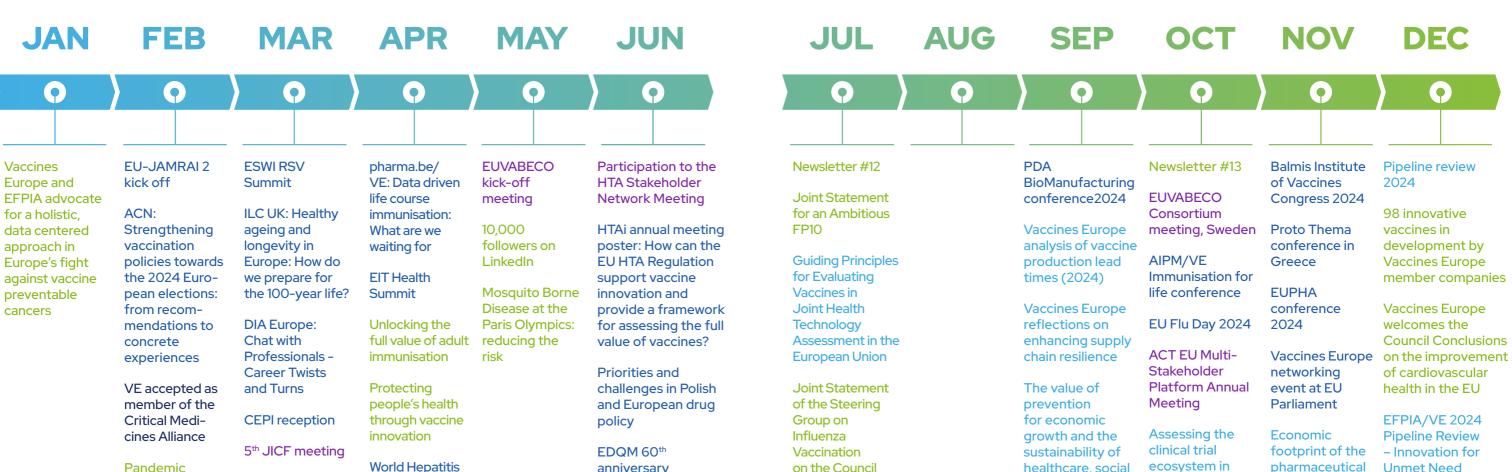
In 2024, Vaccines Europe contributed actively as a consortium member of **EUVABECO** (European Vaccination Beyond COVID-19), a European Commission-funded project designed to provide EU Member States with enhanced ways to deploy tools for better vaccination practices, addressing both routine immunisations and outbreak responses. Accommodating diverse contexts to enable cross-border deployment, the project brings together a consortium of 14 partners and will run from January 2024 until mid-2026.

As part of this effort, Vaccines Europe led the development of the Draft Implementation Plan for the Electronic Patient Information Leaflet (ePIL), drawing on the expertise of our member companies.

This key deliverable outlines practical steps to transition from paper-based to digital patient information formats, ensuring greater accessibility and clarity for citizens across Europe.

In 2024, the EUVABECO project also launched its pilot phase, testing draft implementation plans for five innovative vaccination tools, including the ePIL. As part of our contribution to broader stakeholder engagement and public awareness, Vaccines Europe published an article on the role of ePILs in streamlining vaccine distribution across Europe and shared a video message during the European Public Health Association (EUPHA) Conference in Lisbon, reinforcing our commitment to digital health innovation and vaccine transparency.

# **TIMELINE 2024**



Conclusions on

the Future of the

European Health

Roundtable by

The European

"The value of

for economic

growth and the

sustainability of

healthcare, social

care and welfare

systems"

Ambrosetti

prevention

Union

House -

Partnerships in Protection

Events

(+) Others

Paper/report

**Communications** 

Meeting/workshop

Public/professional consultation

Preparedness:

Long COVID: Understanding and combatting an increasing burden

**#VaccineVoices:** Prof. Pierre Van Damme interview

Launch of the MBVE Consensus Report in the European **Parliament** 

Newsletter #11

Vaccines Europe response to JCA implementing act public consultation

**EU** Immunisation Strategy: From Progress to Excellence

**World Hepatitis** Summit 2024 poster

Life science industry concerns over the workability of **EU HTA** 

AIB technical meeting

European **Immunisation** Week campaign

anniversary conference

Is the EU HTA Regulation ready for vaccine innovation and fill-in the promise of improved availability?

5<sup>th</sup> vaccine expert meeting of the Mediterranean regions of Spain

**EMA** Communication **Perception Survey** 2024

Vaccines Europe welcomes the Council Recommendations on vaccinepreventable cancers

6<sup>th</sup>JICF meeting

**ESNO Congress** 2024

healthcare, social care and welfare systems

Only an urgent shift towards prevention-based Europeans, healthcare can secure economic stability for EU health systems

EFPIA. Vaccines Europe and its members respond to the announcement of the College of Commissioners and publication of their mission letters

Refreshed Vaccines Europe website

Annual report 2023

ecosystem in Europe

60,000 fewer clinical trial places for despite global surge in research projects

**World Vaccines** Congress Europe 2024

Vaccines Europe response to draft implementing act for EU HTA Joint Scientific Consultations Medicinal **Products** 

> **CEE Policy** Summit

industry report

R&D spending

Despite a

decade of

in Europe

outpaced by

the US - with

competition

**NOVA Center** 

vaccination as

a key priority

for health and

economic

wellbeing

increasing

from China

for Global

Health:

7<sup>th</sup> JICF meeting

**EMA-VE** annual meeting

member companies

**Council Conclusions** 

**Unmet Need** 

Patients and society set to benefit from innovation which gradual growth, could "alleviate significant global disease burden

Joint Statement of the Steering Group on Influenza Vaccination on the **Council Conclusions** on the improvement of cardiovascular health in the Longevity: Adult European Union

> The Strategic Research and **Innovation Agenda** of the European partnership on Pandemic Preparedness (BE **READY NOW)**

Newsletter #14

AIB country meeting





# OUR EXTERNAL ENGAGEMENT ACROSS EUROPE IN 2024

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In 2024, we participated in events in 11 European countries in-person or virtually:

Sweden

Hungary

Croatia

Portugal

Spain Greece

France

Belgium

The Netherlands

Poland

Italy

# CONCLUSION

As Europe confronts a landscape marked by evolving public health threats and increasing geopolitical instability, the imperative to protect public health and harness the full value of immunisation has never been clearer. Immunisation is not only a cornerstone of individual well-being but also a strategic asset for economic resilience, competitiveness, and the broader health security of the EU. Building resilient healthcare systems capable of withstanding future shocks requires sustained investment and collaboration. By working together across sectors and borders, we can move decisively toward a shared vision of healthier populations, stronger economies, and a more secure Europe.

# ABOUT THE VACCINES EUROPE TEAM

At Vaccines Europe, our work covers the issues and complexity of the vaccine ecosystem from end-to-end with dedicated experts and working groups in Research & Innovation, Regulatory Affairs, Manufacturing and Supply, Market Access, Public Affairs and Communication.

We are dedicated to preventing the preventable, ensuring health for all and that no one is left behind when it comes to vaccine-preventable diseases.

In 2024, we welcomed Ingrid Weindorfer and Eva Antunano to our team.



Sibilia Quilici Executive Director



Laurent Louette
Director, Public Affairs
& Country Liaison



Anna Czwarno Director, Regulatory, Manufacturing & Supply



Charlotte Vernhes Director, Scientific & Medical Affairs



Anna Vicere Associate Director, Public Affairs & Access Policy



Andreea Iordache Manager, Science & Regulatory Affairs



Polina Zoteva Communications Lead



Anne Meynaerts Administrative Assistant



**Ingrid Weindorfer** Project Manager



**Eva Antunano** Assistant Manager





Vaccines Europe, is a specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), the professional association of the innovative pharmaceutical industry in Europe.

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