

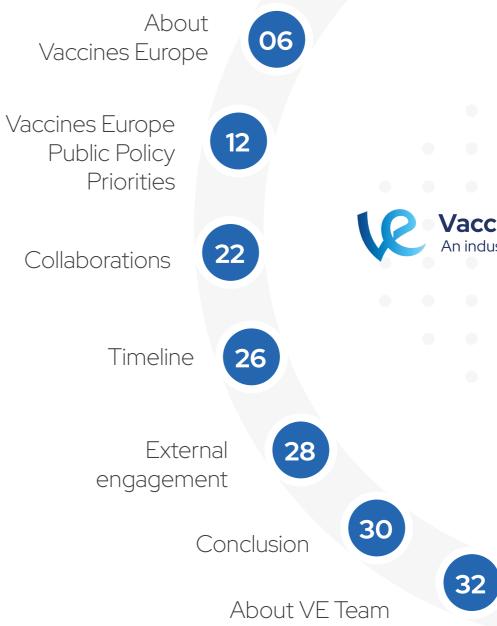
ANNUAL REPORT

A YEAR IN REVIEW





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INTRODUCTION

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We have seen that collaboration works: most recently it enabled us to develop, manufacture and deliver safe and effective COVID-19 vaccines in record time, helping to contain the pandemic.

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We are facing a number of challenges, such as Europe's ageing population and climate change, which could impact people's lives. Vaccination is one prevention tool we have available, that can already be used to safeguard people's health and build resilient healthcare systems and societies.

The challenges of today and tomorrow are complex and addressing them requires all stakeholders to join forces. We have seen that collaboration works: most recently it enabled us to develop, manufacture and deliver safe and effective COVID-19 vaccines in record time, helping to contain the pandemic. This first Vaccines Europe Annual Report aims to provide our stakeholders with an overview of who we are, what we do and with whom we collaborate to secure a sustainable and resilient vaccines environment in Europe. From encouraging vaccine innovation, to ensuring people at every stage of life are protected against vaccine-preventable diseases, we need to work together across the vaccine ecosystem, for a healthier future.

> Sibilia Quilici, Executive Director Vaccines Europe



FOREWORD

The value of vaccination – for public health, for our societies as well as for the economy – is well established and recognised. We're witnessing a shift towards life-long immunisation – immunisation at every stage of life – children, adolescents, adults, older adults, pregnant women and vulnerable people. We need urgent action to bring adult immunisation programmes to the same level as children's programmes. This would require prioritising sustainable immunisation financing, as a form of smart spending associated with significant socioeconomic, clinical and environmental gains.

Protecting people from vaccine-preventable diseases also means providing the right environment to develop vaccines and immunisation solutions to tackle the health challenges of today and tomorrow. By ensuring Europe is

Protecting people from vaccine-preventable diseases also means providing the right environment to develop vaccines and immunisation solutions to tackle the health challenges of today and tomorrow.

an attractive place for research, development (R&D) and manufacturing, vaccine innovation can thrive. However, innovation on its own is not enough. There are huge disparities in vaccine access across Europe today, which need to be urgently addressed.

As Vaccines Europe member companies, we are committed to continue our work within these areas, together with all stakeholders of the EU vaccine ecosystem. An ambitious EU Immunisation Strategy would bring Europe back in the game to place public health at the heart of European policies.

Florence Baron-Papillon, President of Vaccines Europe







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 researchbased vaccine companies, including small and medium sized enterprises.

The Vaccines Europe team has grown over the last 2 years with the addition of experts in their field. In 2022, we have welcomed new team members who have allowed us to reinforce our Public Affairs and Country Engagement activities, our contribution in European regulatory, scientific and pandemic preparedness affairs, as well as our collaboration with key EU stakeholders, including the European Medicines Agency (EMA), the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the new Health Emergency Response Authority (HERA). We have also strengthened our Market Access expertise.



Mission & strategic priorities

By strengthening our expertise, we aim to drive a sustainable and resilient vaccines environment in Europe, protecting people against infectious diseases at all stages of life.

ABOUT VACCINES EUROPE WE HAVE 3 STRATEGIC PRIORITIES:





Innovation

Achieve supportive, competitive and sustainable policy and regulatory environments for vaccines research and innovation, development, manufacturing and supply

vaccination

Across these priorities, Vaccines Europe focuses on:

Adult immunisation - Childhood vaccination schedules are well established across the European Union (EU) but that's not the case for adult immunisation. Vaccines Europe calls for prioritising adult immunisation policies in Europe.

EU's attractiveness for the vaccine industry - There is a worrying trend of pharmaceutical investment in R&D leaving Europe. Vaccines Europe is focusing on improving the EU's attractiveness of the vaccine industry in the EU.



Access

Ensure greater recognition of the value of vaccination, including vaccine innovation, translated into **timely and** broader market access to

Value

Build resilient immunisation systems as part of the transformation of health systems across Europe, thereby driving increased vaccine coverage rates at all stages of life

VACCINES EUROPE - ANNUAL REPORT 2022 (7

Member companies in 2022



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.



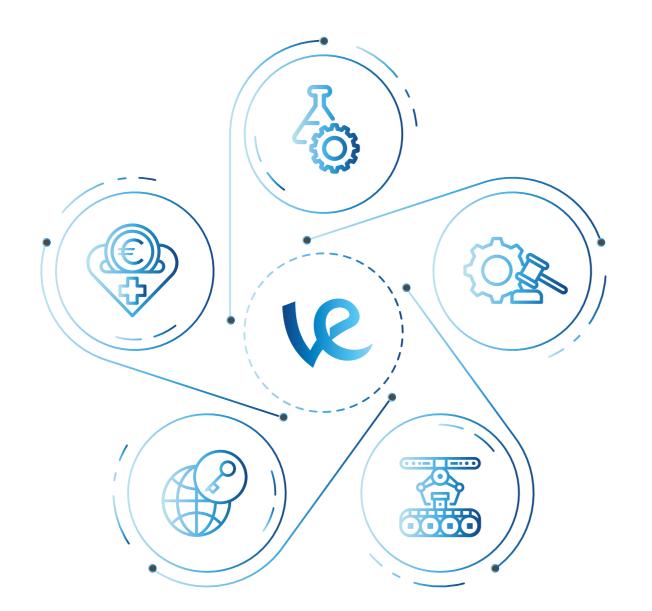
Our NVIGs network includes 24 countries: Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Italy, Latvia, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the Netherlands & the United Kingdom.



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.



Vaccines Today

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 (WHO)'s Vaccine Safety Net.

In 2022, Vaccines Today launched its LinkedIn page, which gained over 600 subscribers in its first few months. Vaccines Today 's LinkedIn page now has more than 1,300 followers, the Facebook page has 9,000 followers, and the Twitter account has more than 20,000 followers.





VACCINES EUROPE PUBLIC POLICY PRIORITIES

VACCINES EUROPE PUBLIC POLICY PRIORITIES VACCINES EUROPE REVEALS THE FIRST EVER PIPELINE REVIEW OF ITS MEMBERS

The COVID-19 pandemic is undoubtedly the biggest healthcare challenge we have faced to date. However, today, there are a number of other health threats that we must prepare for, such as the rise of acute respiratory infections, climate change and antimicrobial resistance (AMR). Vaccination is one of the most successful prevention tools and is instrumental in addressing the burden of infectious diseases and preparing for upcoming challenges. It is essential that regulators and policy makers are aware of the innovative vaccines currently under development, so they can plan the necessary resources accordingly. This year, we published the first ever Vaccines Europe pipeline review 2022, featuring 100 vaccine candidates from Vaccines Europe member companies.

Innovation



VACCINES EUROPE PUBLIC POLICY PRIORITIES

VACCINES MARKET ACCESS PATHWAYS ACROSS EUROPE NEED TO BE ENHANCED

VACCINES EUROPE PUBLIC POLICY PRIORITIES



Vaccines are very specific products, andwhere we proposed enhancing vaccine marketthe way the population accesses themaccess pathways and decision-making throughdiffers hugely from the system for accessingfour principles. Embracing these principles canmedicines. There is a huge disparity acrosshelp reduce time to access, fight inequalitiesEurope not only in the time to populationin access, support the shift towards life-courseaccess, but also in how market accessimmunisation, improve vaccine confidence andpathways work. We published a policy papersupport resilient healthcare systems.

Innovation / Access



JOINT CLINICAL ASSESSMENT FOR VACCINES SHOULD TAKE INTO ACCOUNT VACCINE SPECIFICITIES

Health Technology Assessments (HTA) aim to assess the value of new products, such as a medicine or a vaccine, for the population. The EU HTA Regulation is therefore an opportunity to address inequalities in the time to access new vaccines. However, there is currently limited experience in applying HTA methodologies to vaccines, in particular to clinical assessments. It is essential to ensure vaccine-unique features are accounted for in the future European-wide clinical HTA methodology and processes, and we have previously put forward **our proposals**. In November 2022, we participated in the workshop "The need to account for vaccine specificities in the implementation of the EU Regulation on Health Technology Assessment" organised by the European Public Health Association as part of their European Public Health Conference in Berlin. At the event, we presented our ongoing project on developing guiding principles for joint clinical assessments for vaccines, which will be published in 2023.

VACCINES EUROPE PUBLIC POLICY PRIORITIES JOINT PROCUREMENT OF VACCINES IN EUROPE

The vaccine ecosystem is highly complex, and the way vaccines are procured, either in times of pandemics or in normal times, plays a significant role in its sustainability. Joint procurement of medical countermeasures including vaccines - is an important mechanism for Europe to secure more equitable access and an improved security of supply of those countermeasures to address outbreaks of serious cross border threats. However, due to its complexity, this mechanism should only be used where it can improve access to vaccines and should be limited to situations where purchase and supply of products cannot be ensured by other means.



Between June and September 2021, EFPIA and Vaccines Europe conducted interviews across eight companies who signed a contract with the European Commission on COVID-19 vaccines and therapeutics. There was a consensus amongst manufacturers that joint purchasing agreements outside of pandemics would not work in the current context. Based on these interviews, we provided recommendations for the EU to increase the speed and effectiveness of negotiations with manufacturers in the context of joint advance purchase agreements for cross border health emergencies. These recommendations include taking a more holistic approach to negotiations, developing a framework or standard operating procedure, and strengthening the overall legal framework.

Innovation / Access

VACCINES EUROPE PUBLIC POLICY PRIORITIES **THE COMPLEXITIES OF VACCINE SUPPLY CHAINS**

The vaccine supply chain is hugely complex. In January 2022, Vaccines Europe published a paper in the journal Health

Policy, identifying the six root causes of vaccine shortages in Europe. One of the key challenges that adds to the inefficiency of the supply chain is the requirement for countryspecific packs. The packaging and labelling of vaccines, including the printed Patient Information Leaflet, must be translated into the 24 official EU languages. This enormous diversity creates inefficiencies in the supply chain and limits our ability to respond to a crisis, as described in this **infographic**. To tackle this challenge, we recommend adopting common EU packaging in Europe and replacing the printed Patient Information Leaflet with an electronic leaflet that's up-to-date and immediately available in all EU languages.

EUROPE

Value

VACCINES EUROPE PUBLIC POLICY PRIORITIES **ADULT IMMUNISATION POLICIES SHOULD BE PRIORITISED ACROSS**

Immunisation schedules for children are well established across the EU but this isn't the case for adults. COVID-19 vaccination campaigns, which targeted adults, demonstrated the complexity of implementing such vaccination campaigns in an efficient manner. The risk of infections is trending towards higher burden in the adult population. The 2022/2023 winter season demonstrated this with a 'tripledemic' of flu, COVID-19 and RSV.

Vaccines are crucial not only for children's health but also for the health of adults, thereby supporting healthcare system resilience. However, the low uptake of existing vaccinations for adults demonstrates the lack of country readiness, and the need for a change in mindset and in health infrastructure in EU Member States. In our Policy paper on Adult Immunisation, we call for four actions to protect adults against vaccine-preventable diseases.

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Steering Group on Influenza Vaccination

MAKING INFLUENZA VACCINATION A PRIORITY ACROSS EUROPE Flu causes up to 70,000 deaths every year in

VACCINES EUROPE PUBLIC POLICY PRIORITIES

Europe alone. Yet, flu vaccination coverage rates are generally low. The average coverage rate across Europe was 44% in 2017, far below the 75% target set by the WHO. To support awareness of influenza, Vaccines Europe initiated the Steering Group on Influenza Vaccination three years ago. The Steering Group currently has 11 members, including Vaccines Europe.

In 2022, for the third annual EU Flu Day, the Steering Group on Influenza Vaccination organised the webinar *Making influenza* vaccination a priority across Europe, hosted by MEP Dolors Montserrat. The webinar brought together key stakeholders from across Europe to shine a light on the challenges and opportunities of influenza vaccination. The event was attended by 75 people in total and was supported by a social media campaign.

Value

Innovation Innovation / Access

Value



PANDEMIC

In May 2022, Vaccines Europe, jointly with EFPIA, published a report on the "Lessons learned from COVID-19 pandemic" leveraging what would need to be prioritized in the short, medium and long term for Europe to be better prepared for future pandemics.

COVID-19 has shown that coordinated action at EU level is necessary to effectively prepare and respond to health emergencies. The creation of the Health Emergency and Response Authority (DG HERA) is a first step towards putting Europe on the front foot in addressing global health threats.

countermeasures.



VACCINES EUROPE PUBLIC POLICY PRIORITIES PREPAREDNESS

In 2022, Vaccines Europe was selected to be part of the Joint Industry Cooperation Forum (JICF) created by DG HERA, as a platform of interaction between Agency and industry representatives on different topics. The JICF aims to support Europe in becoming better prepared for upcoming crossborder health threats. Our representatives participated in two JICF meetings, actively providing input into different key areas from HERA's Work Plan, including, but not limited to, lessons learned from COVID-19, R&D funding gaps, EU capacity and scale-up capabilities, procurement and stockpiling of medical

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VACCINES EUROPE PUBLIC POLICY PRIORITIES

A CALL FOR ACTION ON VACCINE-PREVENTABLE CANCERS ACROSS EUROPE



Approximately 13% of cancers diagnosed globally in 2018 were attributed to carcinogenic infections, such as viruses and bacteria. Among the most important infections associated with cancers are Human Papillomaviruses (HPV) and Hepatitis B viruses (HBV) for which vaccines are available. In 2021, Vaccines Europe welcomed the ambition of Europe's Beating Cancer Plan. It sets clear targets for HPV vaccination as a central element of efforts to eliminate HPV-related cancers, as well as improving access to and uptake of vaccines against Hepatitis B in order to reduce liver cancer. To raise awareness of these targets, Vaccines Europe organised a hybrid event in October 2022 at the European Parliament called "Beating Cancer through prevention: A call for action on vaccine-preventable cancers across Europe" hosted by MEP Nicolás González Casares. A total of 52 people participated in the event online and in person.

Value



Vaccine hesitancy is one of the biggest health threats of our time, as identified by the WHO in 2019. Recent research by the Vaccine Confidence Project suggests that COVID-19 boosted vaccine confidence, but this has now returned to 2018 levels. This needs to be urgently addressed.

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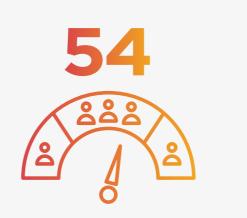
de Martel C, Georges D, Bray F, Ferlay J, Clifford GM. Global burden of cancer attributable to infections in 2018: a worldwide incidence analysis. Lancet Glob Health. 2020;8(2):e180-e190.

As part of our ongoing work on building vaccine confidence, in 2022 we adopted the Vaccines for Life campaign, developed by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Throughout the year, we shared the stories of colleagues from the industry working in the vaccines field, and emphasised the value of the life-course approach to vaccination.



COLLABORATIONS

COLLABORATIONS **CONTRIBUTIONS TO THE WORK OF STAKEHOLDERS**



COLLABORATIONS **INTERACTIONS WITH POLICYMAKERS**

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

A total of **54 consultation** submissions, survey completions and meetings with stakeholders such as the European Commission,

European Medicines Agency, Heads of Medicines Agencies and EUnetHTA21.



COLLABORATIONS

VACCINES EUROPE EVENTS

3 events:

- In 2022, Vaccines Europe organised a hybrid event in the European Parliament on vaccinepreventable cancers called "Beating Cancer through prevention: A call to action on vaccine-preventable cancers across Europe".
- Together with the Steering Group on Influenza Vaccination, we co-organised the webinar "#EUFluDay 2022: Making flu vaccination a priority across Europe".
- We organised a lunch symposium during the European Public Health Conference 2022 in Berlin called "Enhancing pathways for vaccine assessments and national decision-making a driver of resilient health systems".

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COLLABORATIONS

Civil society organisations and associations representing healthcare professionals play an important role in raising awareness of the importance of immunisation within their networks.

In line with our ambition to gather the broadest array of stakeholders to develop common efforts towards holistic immunisation policies, in 2022, Vaccines Europe supported the two following organisations with unrestricted grants: the **European Specialist Nurses Organisation**. (ESNO) and the **Coalition for Life-Course Immunisation** (CLCI).

COLLABORATIONS INNOVATIVE HEALTH INITIATIVE



The Innovative Health Initiative (IHI) is a publicprivate partnership between the EU and Europe's life science industries that was launched in January 2022, with an overall budget of €2.4 billion. Half of this budget comes from in-kind contributions of industry participants. Vaccines Europe is one of the five industry associations that came together for this partnership, alongside EFPIA, COCIR, EuropaBio and MedTech Europe.

Adult Immunisation Board

The Adult Immunization Board (AIB) is a new advisory board established with the aim of contributing to the reduction of the impact of vaccine-preventable infections and diseases in European adults. Its 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.







TIMELINE 2022



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Vaccine CEO

Public Hearing

Parliament #2

at the European

EU Flu Day 2022

Beating Cancer

A call for action

through

prevention:

on vaccine-

preventable

Europe – VE

► VACCINE

Event

cancers across

Forum (Poland)

Enhancing Pathways for Vaccine Assessments and National Decision-Making

Lunch symposium on 'Enhancing pathways for vaccine assessments and national decisionmaking – a driver of resilient health systems' at the European Public Health Conference

Workshop on 'The need to account for vaccine specificities in the implementation of the EU Regulation on Health Technology Assessment' at the European Public Health Conference

Expert Conference on Vaccination by the Czech Presidency of the Council of the European Union

Pro-vaccinationForum (Romania)

 Alliance in Healthcare (Czech Republic)

European Cancer Summit

D Euractiv Public health and disease prevention – What benefits for an adult immunisation policy in Europe? (Belgium)

Vaccination and Public Health Conference (Greece)

Second HERA JICF

VE Members Pipeline Review 2022

DEC

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Prioritising Adult Immunisation Policy in Europe

European Vaccines Initiative documentary

VE Newsletter #6





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In 2022, we participated in events in 7 European countries: Poland, Romania, Bulgaria, Germany, Czech Republic, Belgium, Greece

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OUR EXTERNAL ENGAGEMENT ACROSS EUROPE IN 2022





CONCLUSION

Our work in 2022 spanned across the vaccine ecosystem, from innovation in research and development, to equitable access, to recognising the value of vaccination. In 2023, we will continue building on this work, with strong emphasis on the importance of adult immunisation, what would make Europe attractive to the vaccine industry and the importance of keeping vaccination high on the European political agenda.

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ABOUT 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.

Our Team



Sibilia Quilici Executive Director



Laurent Louette Director, Public Affairs & Country Liaison



Anna Czwarno Director, Regulatory & Science



Anna Vicere Senior Manager, Access Policy & Public Affairs



Andreea lordache Junior Manager Science & Regulatory Affairs





Anne Meynaerts Administrative Assistant

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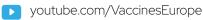


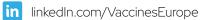




Vaccines Europe, is a specialised vaccines group within the European Federation of Pharmaceutical Industries and Associations (EFPIA), the professional association of the innovative pharmaceutical industry in Europe.







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