

Vaccination and EU policies: How to strengthen cooperation at EU level?

Vaccines Europe perspective

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Vaccines Europe represents



12 research-based companies, including SMEs



operating in Europe

80% of Vaccines Europe members' production is in Europe



Worldwide Suppliers



86% is exported outside Europe with 50% of exports going to humanitarian groups (UNICEF, PAHO, GAVI)

Source: *The EU Vaccine Industry in Figures*, Vaccines Europe
<http://www.vaccineseurope.eu/about-vaccines/vaccines-europe-in-figures/>










Vaccines Europe and the EU initiatives

Common Goals for EU Citizen and Public Health

Vaccines industry has a **long-standing expertise and experience in the vaccines development and manufacturing** with the objective of providing to population **safe, effective and innovative vaccines of the highest quality.**

THE VALUE OF VACCINES

 26	VACCINES PROTECTING AGAINST 26 VACCINE PREVENTABLE DISEASES
 5	VACCINATION PREVENTS FIVE PREMATURE DEATHS EVERY MINUTE
 -49%	BETWEEN 1990 AND 2013 DECREASED MORTALITY IN CHILDREN BELOW 5 BY 49%
2-3 	VACCINES SAVE BETWEEN 2 TO 3 MILLION LIVES EVERY YEAR FROM DIPHTHERIA, TETANUS, PERTUSSIS (WHOOPING COUGH), AND MEASLES
	VACCINES CONTRIBUTE TO THE FIGHT AGAINST ANTIMICROBIAL RESISTANCE
	VACCINES SAVE AND IMPROVE LIVES ACROSS THE ENTIRE LIFE COURSE (NEW BORN, CHILDREN, ADOLESCENTS, PREGNANT WOMEN, ADULTS, OLDER AGE GROUPS)
25 	IN THE COMING DECADE, VACCINES ARE PROJECTED TO SAVE 25 MILLION MORE PEOPLE

Vaccine Research and Development



- Vaccines Europe supports the Commission's intention to **increase the effectiveness** and efficiency of EU and national vaccine research and development
- Vaccines Europe conducted a prioritization exercise and selected **7 research areas** of the first-ever strategic European roadmap outlining the science and technology investments required for vaccines innovation:



- ✓ Explore emergent in-vitro bioassay technologies and improve in-vitro assay for antibody functional screening
- ✓ Research for selection and analysis of epitopes
- ✓ Support research on structural vaccinology
- ✓ Create a toolbox of adjuvants with well-defined profile to shape the immune response
- ✓ Better approach to a combined use of vectors, adjuvants, routes of immunisation
- ✓ Identify innovative design of clinical trials and methodologies to profile volunteers earlier in this trials at an earlier stage
- ✓ Develop expertise and support infrastructures to perform controlled challenges in humans.

Vaccines Europe agrees on launching a **multi-stakeholder reflection** beyond fundamental research to explore how **to overcome barriers** to the development of the next generation of vaccines capable of addressing **unmet medical needs**, including antimicrobial resistance and healthy ageing.

Vaccine Supply and Preparedness



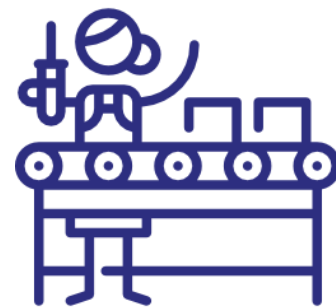
Vaccines are highly technical biological products with complex and lengthy manufacturing, control and release processes.



between 5 and 10 years

are needed to build and license a new facility

Costs up to 600 M for building single manufacturing unit



Up to more than
24 months to produce

Up to 600 manufacturing steps

Up to 680 quality tests (quality control represents 70% of time)

Before the vaccine reaches clinics, doctors and patients



Thousands of
Employees involved

Vaccine Supply and Preparedness

Industry Proposals*

- **Implementing a mechanism to allow dialogue** between industry and national competent health authorities for vaccination programme implementation would enable industry to anticipate and **plan manufacturing accordingly**
- **Reducing the number of specific national/regional packaging and labelling requirements** to facilitate transfer of vaccines
- **Streamlining regulatory requirements in Europe and worldwide** will improve the sustainability of vaccine supply

Vaccines Europe Members are committed to working with stakeholders to ensure a reliable supply of safe, effective and innovative vaccines.

*Vaccines Europe Priorities for Vaccination Policies in Europe, May 2017

Industry position on the different initiatives

Immunisation Information Systems - “IIS”

- Immunisation Information Systems are the **cornerstone of improved vaccination policies in a digital Europe**
- IIS could help close the gaps in immunisation coverage at all ages in life, by facilitating:

Clinical decision support

Patient engagement & citizen empowerment

Vaccination coverage assessment

Outbreak control & emergency preparedness

Vaccine safety and effectiveness assessment

Tracking of the real-life impact of vaccination on disease burdens and flag trends in VPD evolution

Vaccines Europe members could **actively contribute** to information technology and data management, knowledge and expertise

Industry position on the different initiatives

Vaccine hesitancy and uptake

- Vaccines Europe sees the actions proposed by the Commission to address the vaccine hesitancy determinants of confidence, complacency and convenience, including **stronger engagement of physicians, nurses and pharmacists**, as crucial in view of **improving the uptake** of effective vaccines and **avoid outbreaks** of Vaccine Preventable Diseases
- Vaccine Europe considers that member states are in the lead to address these important issues and should indicate if and how they want industry support.

- **Engage EU and national HCP organisations to increase HCP awareness and education on benefits of vaccination**
- **Organize pan EU-vaccination campaigns**
- **Facilitate patient access to vaccination by considering other channels such as pharmacies, etc.**

- **Vaccines Europe supports an online platform www.VaccinesToday.eu**

More info on the Vaccines Europe position can be found at <https://www.vaccineseurope.eu/eu-initiatives-on-vaccination/>

Thank you for your attention!



Website: www.vaccineseurope.eu

Twitter: <https://twitter.com/VaccinesEurope>

