



# VACCINES EUROPE CALL FOR ACTION

**PREVENTION FIRST: VACCINATION  
AT THE HEART OF PUBLIC HEALTH**

Vaccines Europe calls for **EU leadership** to develop a **comprehensive EU vaccination strategy** aimed to support Member States in implementing effective national immunisation programmes

CALL FOR ACTION



## PREVENTION FIRST: VACCINATION AT THE HEART OF PUBLIC HEALTH

Vaccines Europe calls for EU leadership to develop a comprehensive EU Vaccination Strategy aimed to support Member States in implementing effective National Immunisation Programmes by:

### 1 • IMPLEMENTING A HOLISTIC EU APPROACH TO PREVENTION

Strengthen the role of prevention on the EU Health Agenda, and integrate life-course immunisation as part of EU disease prevention programmes

### 2 • ACCELERATING CITIZEN ACCESS TO INNOVATIVE VACCINES

Promote innovative public private partnership approaches and foster a thriving ecosystem encouraging investment in innovation

### 3 • ENHANCING EU CITIZENS' PROTECTION AGAINST PREVENTABLE DISEASES

Prevent costly outbreaks of preventable diseases putting unnecessary strains on health, healthcare systems, and the economy by implementing effective national immunisation programmes

### 4 • SUPPORTING A STRONGER EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

Empower the centre with a leadership role in facilitating the assessment of the medical value of vaccines

### 5 • BUILDING EFFECTIVE COMMUNICATIONS STRATEGIES AND STAKEHOLDER ENGAGEMENT

Understand, identify and address issues of acceptance of vaccination in the interest of public health



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An industry for healthy lives

# IMPLEMENT A HOLISTIC EU APPROACH TO PREVENTION

## VACCINES EUROPE CALLS ON EU POLICY-MAKERS TO

## KEY FACTS



### ENSURE

that EU health policies adopt a holistic approach to prevention, integrating life-course immunisation as part of **disease prevention** programmes. In particular, the EU should reconcile action to prevent and tackle chronic conditions with effective immunisation programmes aimed to address the **burden of infectious diseases**



### PROMOTE

and improve equitable and timely access to vaccination across **all age groups** by promoting and supporting programmes to reach underserved and vulnerable populations as part of EU action to **reduce health inequalities**



### ACKNOWLEDGE

and include immunisation in the **EU Semester** process as vaccination constitutes a smart and cost-effective way of **investing in health** contributing to both health and economic growth that needs to be protected from budget cuts



### IMPROVE

the measurement and assessment of government spending on prevention, including vaccination, as data is currently scant, fragmented and difficult to collate. This would significantly improve ability to identify gaps and inform more **effective resource allocation** strategies<sup>6</sup>

The European Union has the responsibility of ensuring a **high level of human protection encouraging cooperation between Member States** and lending support to their action (Art. 168 TFEU).

Vaccines do not only save lives<sup>1</sup>, but also improve quality of life. Nevertheless coverage levels are falling alarmingly across the EU with the **re-emergence of preventable diseases** which are **costly on health, healthcare systems & the economy**.

**More elderly people** will be burdened by several **chronic conditions** at one time, running the risk of complications brought on by infections<sup>2</sup>.

**Europe must work together** to ensure that **target groups of all ages** are not deprived of the benefits vaccination brings to health and wealth today and in the future.

**Vaccination of adults & seniors** is as important to the 21<sup>st</sup> century's public health as child vaccination.

**Primary prevention** currently represents **only 2.7%<sup>3</sup> of overall Member States health spending on average**. This is not sustainable or efficient and more investment is necessary to keep people healthier for longer<sup>4</sup>.

Healthcare systems are facing major structural and delivery changes. Opportunities **for investing in programmes to prevent<sup>5</sup>** rather than treat disease must be maximised.



- 1 UK NHS (2013)**  
"How vaccination saves lives"  
• [www.nhs.uk/Conditions/vaccinations/Pages/vaccination-saves-lives.aspx](http://www.nhs.uk/Conditions/vaccinations/Pages/vaccination-saves-lives.aspx)
- 2 Council Conclusions (2010)**  
"Innovative approaches for chronic diseases in public health and healthcare systems"  
• [www.consilium.europa.eu/uedocs/cms\\_Data/docs/pressdata/en](http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/cms_Data/docs/pressdata/en)
- 3 OECD (2013) Health Data**  
• [www.oecd.org/els/health-systems/health-spending-continues-to-stagnate-says-oecd.htm](http://www.oecd.org/els/health-systems/health-spending-continues-to-stagnate-says-oecd.htm)
- 4 Council Conclusions (2013)**  
"Reflection process on modern, responsive and sustainable health systems"  
• [www.consilium.europa.eu/uedocs/cms\\_Data/docs/pressdata/en/lsa/118282.pdf](http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/118282.pdf)
- 5 European Commission (2013)**  
SWD Investing in Health  
• [http://ec.europa.eu/health/strategy/docs/swd\\_investing\\_in\\_health.pdf](http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf)
- 6 European Commission (2012)**  
Annual Growth Survey for 2013  
• [http://ec.europa.eu/europe2020/pdf/ags2013\\_en.pdf](http://ec.europa.eu/europe2020/pdf/ags2013_en.pdf)



# ACCELERATE CITIZEN ACCESS TO INNOVATIVE VACCINES

## VACCINES EUROPE CALLS ON EU POLICY-MAKERS TO



### FOSTER

early stage dialogue between public health, regulatory, payer, and industry bodies on priorities and gaps to address unmet medical needs and facilitate **earlier assessment of innovative vaccines**



### DEVELOP

appropriate guidance for Member States for a correct **implementation of the timelines pursuant to the Transparency Directive<sup>2</sup>** with regards to the vaccines' recommendation phase for inclusion in national immunisation programmes



### PROMOTE

cooperation on vaccine-specific **Health Technology Assessment (HTA)** as vaccines have specific characteristics that differentiate them from curative pharmaceutical treatments; HTA organisations should strengthen coordination to identify good practice in evaluating preventive interventions



### SUPPORT SMEs

The Commission should continue to **foster the growth of early-stage businesses** and develop **sound policies** to spur innovation and support competitiveness of the vaccine sector



### ESTABLISH

EMA regulatory pathway to support the development of **therapeutic vaccines**

## KEY FACTS

**8 to 18.5<sup>1</sup>**

The standard R&D model for vaccines development and market access is costly, **overlapping and lengthy** (from 8 to 18.5 years) with **uncertainties on market demand.**

This model is no longer viable and there is a need for a more comprehensive approach to R&D that streamlines pre-clinical, clinical and health-economics approaches. This would **encourage innovation for unmet medical needs.**

**6.4 years time lag before citizen access<sup>3</sup>**

The time it takes for populations to access new vaccines in the EU is very lengthy, with **6.4 years as the estimated time lag between marketing authorisation and effective population access to new vaccines.**

The reason behind almost **90%<sup>3</sup>** of these delays is the time to issue a recommendation from National Immunisation Technical Advisory Groups concerning the introduction of the vaccine in national immunisation programmes.

Along with established players in the vaccine sector, which have a track record of innovation, **smaller companies are an important source of fresh ideas, new jobs and economic growth in Europe<sup>4</sup>.**

**Therapeutic vaccine developers need a clearer regulatory environment** in order to better design clinical trials, facilitate or accelerate market access and reduce clinical development costs.



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**1 IFPMA (2013)**

Vaccine Research & Development  
• <http://farm9.staticflickr.com>.

**2 Council Directive 89/105/EEC**

of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

**3 PR Blank et al. (2013)**

Population access to new vaccines in European countries.  
*Vaccine*; 31(27):2862-7

**4 European Commission (2013)**

A Recovery on the Horizon?  
*Annual Report on European SMEs 2012/2013*.

# ENHANCE EU CITIZENS' PROTECTION AGAINST PREVENTABLE DISEASES

## VACCINES EUROPE CALLS ON EU POLICY-MAKERS TO

## KEY FACTS

**STRENGTHEN**  
and encourage political commitment to improve the implementation of the **2009 Council Recommendation<sup>1</sup>** on seasonal influenza vaccination by undertaking appropriate EU level action to address the **worrying decline and poor monitoring of vaccine coverage rates for the elderly and other priority target groups**. There is also a need to address other policy gaps identified in the Commission interim report<sup>2</sup>

**IMPROVE**  
capacity and preparedness for influenza pandemics in the EU through better implementation of **seasonal influenza immunisation programmes** (as capacity for seasonal and pandemic vaccine production is strictly interlinked) and support for pandemic R&D<sup>5</sup>

**HIGHLIGHT**  
the role played by available vaccines<sup>7</sup> in promoting a more rational use of antimicrobial agents in EU action plans addressing antimicrobial resistance; furthermore EU R&D for health programmes should **secure funding for research to develop next generation vaccines**

**PREVENT**  
the **re-emergence** of avoidable and costly outbreaks of vaccine-preventable diseases<sup>9</sup> through effective implementation of current immunisation programmes

**38,500 deaths / season** on average due to influenza viruses<sup>3</sup>.

The Commission reports **a worrying decline in uptake and support for influenza vaccination**, even among **healthcare professionals<sup>2</sup>** — This reiterates the need to develop **appropriate targeted communications** and training programmes.

In the EU, patients across all age groups with **underlying chronic conditions constitute about 50% of the influenza vaccination gap<sup>4</sup>**, and are one of the most vulnerable yet challenging target group to reach.

**Only two EU Member States meet the 75% vaccination target** against seasonal influenza for the elderly established in the Council Recommendation. The average elderly vaccination rate for other Member States where coverage is reported ranges **between 40 to 60%<sup>6</sup>**, well below pre-set targets.

The vaccine industry is a strategic sector not **only to protect citizens' health** and for the European economy, but also **to react effectively** to emerging health threats.

The ongoing measles, rubella, and whooping cough outbreaks in EU and other regions of the world are putting **unnecessary and preventable strains on healthcare systems**.

**Antimicrobial resistance and healthcare associated infections** are on the rise across all EU countries and constitute **one of the most serious threats to health**. The death toll attributed to healthcare associated infections is **comparable to that of road accidents<sup>8</sup>**.

For example, in 2002-2003 the direct **costs of measles** incurred by the national health service of Italy were **€17.6-22 million**. This would have paid for vaccinating up to 1.9 million children, which would also have prevented many cases of mumps and rubella. The 5 154 hospitalisations during this period cost about **€8.8 million<sup>10</sup>**.



**1 Council Recommendation 2009/1019/ EU on Seasonal Influenza Vaccination**

- <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>

**2 European Commission (2014)**

- SWD State of play on implementation of the Council Recommendation of 22 December 2009 on seasonal influenza vaccination (2009/1019/EU)
- [http://ec.europa.eu/health/vaccination/docs/seasonflu\\_staffwd2014\\_en.pdf](http://ec.europa.eu/health/vaccination/docs/seasonflu_staffwd2014_en.pdf)

**3 ECDC, Basic facts on influenza for healthcare professionals**

- [www.ecdc.europa.eu/en/healthtopics/seasonal\\_influenza/basic\\_facts/pages/factsheet\\_professionals\\_seasonal\\_influenza.aspx](http://www.ecdc.europa.eu/en/healthtopics/seasonal_influenza/basic_facts/pages/factsheet_professionals_seasonal_influenza.aspx)

**4 Pr caud et al. (2014)**

- Annual public health and economic benefits of seasonal influenza vaccination in the EU27, BMC Public Health, Submitted.

**5 WHO (2013)**

- Priority Medicines for Europe and the World
- [www.who.int/medicines/areas/priority\\_medicines/MasterDocJune28\\_FINAL\\_Web.pdf?ua=1](http://www.who.int/medicines/areas/priority_medicines/MasterDocJune28_FINAL_Web.pdf?ua=1)

**6 ECDC (2014)**

- Technical Report - Implementation of the Council Recommendation on Seasonal Influenza Vaccination 2009/1019/EU
- <http://ecdc.europa.eu/en/publications/Publications/Implementation-seasonal-influenza-vaccination-Council-Recommendation-Jan-2014.pdf>

**7 Vaccines Europe (2013)**

- Role of Vaccination in reducing Antimicrobial Resistance
- [www.vaccineseurope.eu/wp-content/uploads/2013/09/AMR-and-Vaccines-June-2013.pdf](http://www.vaccineseurope.eu/wp-content/uploads/2013/09/AMR-and-Vaccines-June-2013.pdf)

**8 ECDC (2010)**

- Strategies for Disease Specific Programmes 2010-13
- [www.ecdc.europa.eu/en/publications/publications/100714\\_cor\\_strategies\\_for\\_disease-specific\\_programmes\\_2010-2013.pdf](http://www.ecdc.europa.eu/en/publications/publications/100714_cor_strategies_for_disease-specific_programmes_2010-2013.pdf)

**9 WHO Europe (2013)**

- Seven Key Reasons Why Immunisation must remain a priority in the WHO European Region
- [www.euro.who.int/\\_\\_data/assets/pdf\\_file/0017/84302/Seven\\_Key\\_Reasons.pdf](http://www.euro.who.int/__data/assets/pdf_file/0017/84302/Seven_Key_Reasons.pdf)

**10 Filia A et al. (2011)**

- Measles in Italy, July 2009 to September 2010. Eurosurveillance, 16(29)



# STRONGER EUROPEAN CENTRE FOR DISEASE PREVENTION & CONTROL (ECDC)

PREVENTION FIRST

## VACCINES EUROPE CALLS ON EU POLICY-MAKERS TO

## KEY FACTS



### STEP UP

the European Centre for Disease Prevention and Control's (ECDC) **leadership role** in providing Member States with guidance and facilitating **assessment of the medical value of vaccines**. This would support more effective and comprehensive implementation of **national immunisation programmes**



### ENABLE

the ECDC to collect post-marketing authorisation data to support the **evaluation of vaccine safety and effectiveness** throughout the lifecycle of the vaccine



### SUPPORT

improved capability and approaches to **effectively monitor vaccination coverage rates** across all key target groups and vaccine-preventable diseases in all EU Member States by encouraging the implementation of appropriate and innovative reporting and tracking systems at national, regional, and local healthcare and vaccination delivery level



### ESTABLISH

an EU mechanism or structure to **advise on innovative vaccines** needed to address unmet medical needs for EU populations

Demographic pressure and increasing burden of chronic diseases require a **shift towards a life-course approach to vaccination**<sup>1</sup>.

The ageing demographic requires the **facilitation of a life-long vaccination calendar** in EU countries by providing **evidence for national decision-making**<sup>2</sup>.

More safety and effectiveness data are being **required by regulators** and **only a few EU countries are able to provide this data**.

Vaccination policies for adults are not consistent across Europe, including the meaning of "recommended vaccine" which is not comparable among countries. **Coverage data for adults should be collected routinely like for children vaccination**<sup>4</sup>.

For key risk groups, there is **limited data available and insufficient monitoring** which makes the assessment of current and future trends on vaccine coverage difficult<sup>3</sup>.

The development of innovative vaccines requires **constant investment in breakthrough technology** and is a **costly & lengthy** process that can take more than 20 years from R&D through to availability on the market.

Solid data should be available to **assess unmet medical needs and prioritise new vaccine development**.



- 1 SAATI (2013)**  
Adult Vaccination - A Key Component of Healthy Ageing  
• [www.ilcuk.org.uk/index.php/publications/publication\\_details/adult\\_vaccination\\_a\\_key\\_component\\_of\\_healthy\\_ageing](http://www.ilcuk.org.uk/index.php/publications/publication_details/adult_vaccination_a_key_component_of_healthy_ageing)
- 2 ECDC (2014)**  
ECDC Strategic Multi-Annual Programme 2014-20 - Working Together to Reduce the Burden,  
• [www.ecdc.europa.eu/en/aboutus/Key%20Documents/Strategic-multiannual-programme-2014-2020.pdf](http://www.ecdc.europa.eu/en/aboutus/Key%20Documents/Strategic-multiannual-programme-2014-2020.pdf)
- 3 European Commission (2014)**  
SWD State of play on implementation of the Council Recommendation of 22 December 2009 on seasonal influenza vaccination (2009/1019/EU)  
• [http://ec.europa.eu/health/vaccination/docs/seasonflu\\_staffwd2014\\_en.pdf](http://ec.europa.eu/health/vaccination/docs/seasonflu_staffwd2014_en.pdf)
- 4 Kanitz et al (2012)**  
Variation in adult vaccination policies across Europe: an overview from VENICE network on vaccine recommendations, funding and coverage.  
*Vaccine*. 2012 Jul 27;30(35):5222-8

# BUILD EFFECTIVE COMMUNICATIONS STRATEGIES AND STAKEHOLDER ENGAGEMENT

## VACCINES EUROPE CALLS ON EU POLICY-MAKERS TO

## KEY FACTS



### PROVIDE

EU leadership for more effective, consistent and streamlined health communication on the prevention of communicable diseases by assisting countries to develop their own strategies. The ECDC could establish a **network of sentinels to monitor attitudes towards vaccines and vaccination** across EU countries to inform evidence-based **communications programmes**



### DESIGN

**tailored programmes** to improve **healthcare workers' vaccination rates** and bolster their expertise in communicating effectively about **vaccines and vaccination needs to their patients**



### FACILITATE

EU-level coordination to develop **harmonised curricula for training** in vaccines and vaccinology across **Member States**



## KEY FACTS

Europe is experiencing significant falls in coverage for preventable diseases along with **eroded confidence and trust in the value of vaccines and vaccination**.

The EU has a collective responsibility to reverse this worrying trend & develop **targeted and effective communication** on the value of vaccination.

ECDC and the WHO have a critical role to play in supporting **the future development of health communication** in the field of communicable disease prevention and control<sup>1</sup>. Embracing **new communications and online media tools** and promoting stakeholder dialogue is crucial.

**Healthcare workers are at increased risk of contracting infections and further transmitting them to patients**. Immunisation against vaccine-preventable diseases would protect them and act as barrier against the spread of infections, but **uptake rates for healthcare professionals have often been low**<sup>2</sup>.

About **37%** of medical students and **38%** of nursing students do **not feel confident enough to communicate about vaccine benefits and safety**, and more than **85%** expressed the need for more training on immunisation<sup>3</sup>.

**Education in vaccinology** should be based on a network of European centres of excellence in vaccinology and **combine different teaching approaches** such as e-learning, practical training, and residential courses<sup>4</sup>.

Education and training focused on health communication in the prevention and control of communicable diseases is currently **underdeveloped across Member States** given the complexities and the multidisciplinary nature of health communication involving a vast range of skills drawing from a number of disciplines including health, **education, public health, health promotion, social marketing and information technology**<sup>1</sup>.



**1 ECDC (2014)**

Technical Report - Health Communication and its role in the Prevention and Control of Communicable Diseases in Europe,  
• [www.ecdc.europa.eu/en/publications/Publications/health-communication-communicable-disease-europe.pdf](http://www.ecdc.europa.eu/en/publications/Publications/health-communication-communicable-disease-europe.pdf)

**2 Galanakis et al. (2013)**

Ethics of mandatory vaccination for healthcare workers. Euro Surveill. 2013;18(45);pii=20627.  
• [www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20627](http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20627)

**3 European Vaccine Initiative (2011)**

Report TRANSVAC Stakeholder Workshop, 07 October 2011, p.16  
• [www.transvac.org/sites/default/files/uploads/TRANSVAC/Roadmap\\_Stakeholder/TRANSVAC\\_WorkshopReport\\_111007\\_final.pdf](http://www.transvac.org/sites/default/files/uploads/TRANSVAC/Roadmap_Stakeholder/TRANSVAC_WorkshopReport_111007_final.pdf)

**4 European Vaccine Initiative (2011)**

Report TRANSVAC Stakeholder Workshop, 07 October 2011, p.17  
• [www.transvac.org/sites/default/files/uploads/TRANSVAC/Roadmap\\_Stakeholder/TRANSVAC\\_WorkshopReport\\_111007\\_final.pdf](http://www.transvac.org/sites/default/files/uploads/TRANSVAC/Roadmap_Stakeholder/TRANSVAC_WorkshopReport_111007_final.pdf)





Vaccines Europe is the specialised vaccine industry group operating within the European Federation of Pharmaceutical Industries and Associations (EFPIA). It represents innovative research-based global vaccine companies as well as small and medium-sized enterprises operating in Europe.

For more information visit, [www.vaccineseurope.eu](http://www.vaccineseurope.eu)