



EVM¹, the voice of the vaccine industry in Europe - EVM Policy Priorities in the EU 2009/2010 -

EVM members are committed to working in partnership with EU institutions to support policies to prevent diseases and improve public health and increase the competitiveness of industry in Europe. To support achievement of these broad objectives, EVM looks forward to working with you on the following issues:

1. Increase awareness on the value of vaccines, vaccination and their contribution to European health and welfare by supporting:

⇒ A Council Recommendation on childhood immunisation

Communicable diseases do not stop at the border, therefore coordination and action at EU level is necessary to increase and/or maintain high childhood vaccination coverage rates, as set out by the Commission 'Europe for Patients' initiative². The need for coordinated EU action is reinforced by the increasing migration of families between Member States, and the re-appearance of certain diseases, e.g., measles, due in most cases to decreases in vaccination coverage.

⇒ Activities around the European Immunisation Week – EIW-

The successful scale up of immunization controls in Europe against most infectious diseases over the years has meant that nowadays, many parents and health professionals no longer fear these diseases. Awareness on the value of vaccination is waning, but is critical to ensure appropriate immunisation levels amongst of the EU population to prevent resurgence of vaccine preventable diseases. The EIW provides an opportunity for the EU and national Governments to advocate the proper implementation of immunisation programmes. <http://www.euro.who.int/eiw>

⇒ Ongoing policy debate on EU workforce for health (Green Paper)³

All doctors, nurses and other health professional staff are responsible for the diagnosis and care of patients with infectious diseases. EU and national policies should therefore concur to provide up-to-date, high-quality training on existing and new vaccines. Additionally, vaccination of healthcare workers is a key element for the promotion of patient safety and the prevention and control of nosocomial infections.

2. Protect EU populations against existing and emerging health threats by advocating for:

⇒ The approval of the Council Recommendation on seasonal influenza vaccination

On 8 July 2009, the Commission adopted a proposal for a Council recommendation on seasonal influenza vaccination to increase seasonal influenza vaccination of the elderly and of those at risk, is essential to both protect European citizens' health and to strengthen pandemic preparedness in Europe⁴. Effective prevention against seasonal influenza in each Member State demands prevention in the EU as a whole.

¹ EVM (European Vaccine Manufacturers) member companies are major suppliers of vaccines worldwide, producing the majority of vaccine doses in Europe. EVM members are: Baxter, Crucell, GlaxoSmithKline Biologicals, MedImmune, Novartis Vaccines, sanofi pasteur, sanofi pasteur MSD, Solvay Biologicals, and Wyeth Vaccines. For more information about EVM, please visit the EVM website <http://www.evm-vaccines.org/>

² http://ec.europa.eu/health-eu/europe_for_patients/policies_actions/index_en.htm

³ EVM reply to the public consultation on the green paper on the EU Workforce for Health available at: <http://www.evm-vaccines.org/pdfs/EVM%20Reply%20to%20the%20consultation%20on%20the%20GREEN%20PAPER.pdf>

⁴ The Commission proposal is available at: http://ec.europa.eu/health/ph_threats/com/Influenza/influenza_en.htm



⇒ **Coordinated response for pandemic influenza**

WHO has declared that the Novel AH1N1 Influenza virus constitutes a global health threat. The EU has an important role to play facilitating the sharing of best practise in the implementation of pandemic plans. The Commission has been coordinating Member States response to H1N1 since April 2009 and adopted in September 2009 a Communication on H1N1 preparedness and response as well as Staff Working Papers⁵. Enhanced collaboration and regular communications between all EU stakeholders are essential to provide strong co-ordination in the fight against pandemic influenza.

⇒ **The recognition of the role of vaccination in reducing antimicrobial resistance⁶**

The preventive use of antibacterial vaccines protects individuals and communities against the infectious diseases. Moreover, it reduces the chance of being infected by bacteria, reduces the need for antibiotic treatment and thus the likelihood of acquiring antibiotic-resistance. A programme to combat antibiotic resistance will need to combine a variety of approaches including the rational use of existing antibiotics, preventing underlying infections through vaccination and discovering new antibiotics.

3. Foster the competitiveness of the vaccine industry in Europe by supporting:

⇒ **A favourable policy and regulatory environment to support and sustain innovation, economic growth and employment**

EVM Members have 60% of their R&D projects and 90% of their production located in Europe, and are major contributor to Europe's knowledge based economy and skilled labour force⁷. A favourable regulatory environment based on sound and reasonable risk-benefit balance and to reward value of innovation, is critical to the development of future breakthrough vaccines.

⇒ **Balanced legislation on the protection of animals used for scientific purposes⁸**

Animal studies are critical part of the development and manufacture of vaccines. Ongoing discussions on the legislation on the protection of animals used for scientific purposes should strike the right balance between high animal welfare standards and the need for research and public health priorities.

⇒ **Best practices sharing at EU and national level to ensure EU citizen's timely access to new and innovative vaccines**

Following marketing authorisation approval, some national systems could allow better and faster introduction of new vaccines. Delays in the recommendation, pricing and reimbursement process create inequalities in access to vaccination across Europe and in the absence of vaccination, translate into non-avoided burden of diseases.

⇒ **Transparent health technology assessment (HTA) cooperation in the framework of the Cross-border healthcare directive**

Good governance principles, including stakeholders' participation and transparency, should be ensured in the proposed HTA network. The fundamental differences between vaccines and prescription drugs should be taken into account in the work of the network.

⁵ The Commission Communication and Staff Working Papers are available at: http://ec.europa.eu/health/ph_threats/com/Influenza/novelflu_en.htm. For more information on H1N1 influenza pandemic, please go to <http://www.evm-vaccines.org/spip.php?article93>

⁶ See EVM proposal to the Commission on vaccination and antimicrobial resistance http://www.evm-vaccines.org/pdfs/proposal3_collectdata_antimicrobial_resistance_and_vaccination.pdf

⁷ Source EVM Survey 2008

⁸ EVM position available at: http://www.evm-vaccines.org/pdfs/vaccines_and_animal_welfare_fin.pdf