



Message from the EVM President



Didier Hoch, the new EVM President, has expressed his willingness to cooperate with the EU and public health officials on a range of issues, including public health threats.

“Vaccines play a vital role in the prevention of infectious diseases, a role that now extends to meeting new challenges such as biological threats, SARS or an influenza pandemic.” Vaccine R&D will also continue to be an EVM priority. To that end, EVM will continue its efforts in stimulating a supportive environment in Europe for enhanced vaccine protection and coverage, while promoting Europe’s attractiveness as a site for vaccine research and innovation.

Do you know what vaccines are doing for your health?

Vaccination has safely and effectively prevented more death and disease due to infectious agents than any other public health intervention, with the exception of improved sanitation and safe drinking water. The tremendous impact of vaccines on public health is evident when one looks at the achievements in eradicating smallpox, eliminating polio from many continents, controlling measles in the Americas and parts of Europe, reducing the incidence of liver cancers caused by the hepatitis B virus, and dramatically reducing the incidence of other diseases such as tetanus, diphtheria, rubella, and bacterial meningitis, among others.

Vaccination is a preventive health measure that is highly cost-effective, which contributes to both social and economic development by reducing hospitalisations, permanent disabilities, costly treatments and loss of productivity in the workplace.

Did you know that the European vaccine industry

- is the largest supplier of vaccines in the world, producing approximately 80% of vaccines used worldwide
- is the largest supplier to UNICEF of vital paediatric vaccines, including polio vaccines
- has developed vaccines specifically designed for the needs of developing countries (e.g., combined paediatric vaccines against diphtheria, tetanus, pertussis, hepatitis B, and invasive Hib disease)
- is working in collaboration with the public sector in joint R&D activities and in clinical trials partnerships to develop vaccines against diseases that particularly burden developing countries (e.g., dengue fever, leishmaniasis, rotavirus, HIV, malaria and tuberculosis, among others)
- contributes significantly to Research & Development with over half of all global vaccine R&D being carried out in Europe by EVM member companies
- has production facilities not only in Europe but across the globe through international collaboration and joint ventures
- submits its novel products to a centralised procedure to obtain EU licensing (e.g., all hepatitis B vaccines, hepatitis B-containing combination vaccines, as well as the pneumococcal conjugate vaccines, among others).

The vaccine industry – its beginnings

The vaccine industry is, in some respects, a unique sector. Its origins can be traced back to national public institutes or to small, often state-owned companies that were set up by national governments to ensure that communities would have access to basic health needs, particularly vaccines for the prevention of diphtheria, tetanus, pertussis and poliomyelitis. With their close historical ties to national public health organisations vaccines were, from the very beginning, out of the mainstream of the broader pharmaceutical market. The private sector was mainly involved in the manufacture of pharmaceutical products, which developed quite separately from the vaccine sector.

Current market situation

During the last decade, the vaccine sector underwent a transition, most notably characterised by the fact that manufacturing moved from the public sector to private companies. Coinciding with this shift, has been the development of novel generation vaccines, requiring massive investments into research, development and production, and putting the vaccine industry at the cutting edge of biotechnology innovation. Although the number of private vaccine companies increased somewhat during this transition period, their number remains quite small, especially when compared with the magnitude of pharmaceutical companies that developed during the same period.

Today the vaccine market remains very much a public market, still driven in part by specific immunisation needs that are determined by public health authorities at local, national and international levels. During the last ten years, due to escalating costs for vaccine research and development, with new technologies that require scaled-up production and investment in capacity and the growing burden of regulatory compliance, a number of local vaccine producers disappeared or were acquired. While the commercial vaccine market today is small in terms of the overall number of major manufacturers, it is fast growing and competitive; nevertheless, it still represents only 2% of the total pharmaceutical market.

EVM is on the web at:

<http://www.evm-vaccines.org/>

Email: info@evm-vaccines.org

EVM's mission:

- to create a supportive environment for improved vaccine protection and coverage in the interest of the individual and the community;
- to promote vaccine R&D to meet new challenges for innovative vaccine applications against infectious and other types of diseases;
- to foster a favourable policy climate for the vaccine industry to bring new vaccines to the world.

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**Today's vaccine R&D – prevention and therapy**

Despite the relatively small number of manufacturers serving global vaccine needs, vaccine R&D has reached its highest level ever, with over 400 new vaccine projects ongoing worldwide. With the acceleration of new vaccine development not only for preventive but also for therapeutic applications (e.g., HIV/AIDS and cancer, among others), the vaccine market is expected to at least double within the next decade.

The European regulatory environment

Before a vaccine candidate can even be considered for development, many years of applied research are necessary to determine which components will be needed to develop the future vaccine. While innovation has become one of the key drivers to growth of the vaccine market, the complicated manufacturing process (because organisms do not always grow or respond in a predictable manner), quality control, quality assurance, testing, and regulatory framework, require increasingly stringent criteria for which vaccine research, development, clinical testing and licensing can be carried out. New vaccines as biopharmaceutical products have an average development period of twelve years from preclinical development (2-4 years), clinical testing (approximately 5-7 years), to vaccine registration period (about 2-3 years).

Since 1995, biotechnological vaccines or innovative vaccines may be licensed through the centralised procedure by the European Agency for the Evaluation of Medicinal Products (EMA) and community-marketing authorisations are granted for the 15 EU countries.

Vaccines not eligible for registration by the EMA, are licensed by national regulatory authorities according to the mutual recognition procedure (MRP).

Whatever the registration procedure, these biological products cannot be commercialised before they have been tested by an official medicines control laboratory (OMCL) according to specific guidelines on batch release established by the European Directorate for the Quality of Medicines (EDQM).

EVM priorities and the EU agenda

EVM is committed

- to working closely with EU and national authorities in the Community Influenza Preparedness Plan to ensure timely supply of vaccine in the event of an influenza pandemic. See the following on the EVM website:

[EVM Briefing Sheet: Halting the influenza pandemic](#)
[Special Topics – Influenza Pandemic](#)

- to supporting the European Commission's initiative in creating a European Centre for Disease Prevention and Control, recognising that such a Centre will play a key role in improving public health strategies to better identify, monitor and control infectious diseases. See the following on the EVM website:

EVM Position Paper: [EVM views on the European Centre for Disease Prevention and Control](#)

EVM Press Release: [EVM welcomes Commission initiative to create a European Centre for Disease Prevention and Control](#)

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EVM is a specialised group within the [European Federation of Pharmaceutical Industries and Associations \(EFPIA\)](#)