European
Vaccine
Manufacturers

The vaccine industry's contribution to health and welfare in Europe

Contents

Vaccine manufacturers represent an important and distinct subsection of the pharmaceutical industry. While sharing some features with its pharmaceutical counterpart, such as high levels of investment in innovative new products, the vaccine industry differs in a number of ways. Most notable is its concentration of resources in Europe and the disproportionately positive impact it has on improving public health through disease prevention.

With Europe home to most of the world's vaccine production, the majority of vaccine R&D and the largest proportion of vaccine companies' employees, the industry is a key contributor to the region's economy.

Vaccines are essential for public health, and protect individuals and communities, both within and outside Europe, against established and newly-emerging diseases. Consequently, vaccination is one of the most effective public health interventions, contributing to health and welfare worldwide.

Investing in innovation

Following many years of investment, a number of new vaccines have recently reached the market and several others are close behind. These vaccines have the potential to protect against a range of diseases for which previously no vaccine existed.

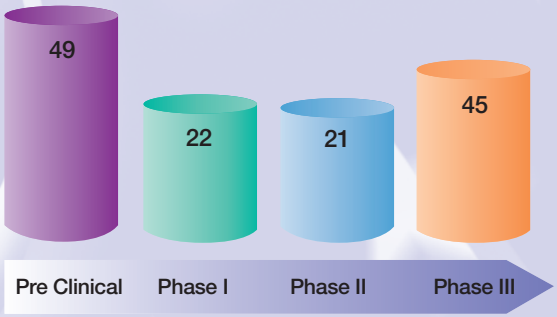
Importantly, virtually all of the vaccine industry's R&D investment is focused on developing innovative new products. This is resulting in a number of new vaccines that have the potential to drive significant further improvements in public health.

Vaccine development requires significant investment

Developing vaccines is a lengthy, complex and costly process. It involves four stages: firstly the pre-clinical phase, followed by three stages of testing in humans, which involve increasing numbers of subjects as the vaccine progresses through the trials. When these stages are successfully completed, the data are filed with regulatory authorities who then decide if the vaccine can be used in their territories.

Undertaking this development process requires the commitment of significant resources. Through the combination of continued investment over many years and the application of revolutionary biotechnology, the industry has put in place a strong pipeline of new vaccines. As a result, the number of projects in the final stage of testing has increased by 15% since 2002, rising from 39 in that year to 45 in 2006.

Total vaccine development projects = 137

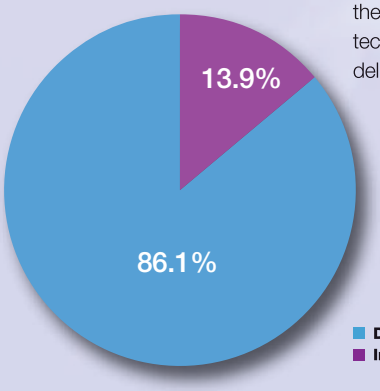


Source: EVM data 2006

Over 85% of R&D projects involve new vaccines

Data from major manufacturers show that industry research is focused on new vaccines rather than 'me-too' products.

As a consequence, almost all of industry's R&D is focused on developing innovative vaccines, whether new antigens (the active ingredients in vaccines), new combination vaccines or the incorporation of new technologies, such as novel delivery systems



Developing new vaccines
Improving existing vaccines

Source: EVM data 2006

New vaccines include unregistered antigens, new products (such as the combination of registered antigens) or the use of new technologies with existing antigens (such as new delivery systems)

New vaccines from investment in innovation

As a result of industry's ongoing investment in R&D, several new vaccines have been licensed recently or are at an advanced stage of development.

Among the illnesses targeted by these vaccines are rotavirus diarrhoea, pneumococcal disease and cervical cancer caused by the human papilloma virus. The major potential these vaccines offer for controlling infectious diseases has been publicly acknowledged by WHO†.

As industry continues to invest in the development pipeline, ongoing scientific innovations may result in vaccines against major infections such as HIV and malaria, as well as those that treat disease, including cancers, as illustrated in the table below.

†WHO Fact sheet number 289, 2006

Recently licensed...
- Pneumococcal conjugate
- Human papilloma virus (cervical cancer)
- Rotavirus (gastroenteritis)
- Herpes zoster (shingles)
- Influenza – cell-culture derived
- Vibrio cholerae (cholera)

In the pipeline...
- Influenza pre-pandemic
- Influenza pandemic*
- Meningococcal conjugate ACYW135
- Enterotoxigenic escherichia coli (diarrhoea)

The future...
- Neisseria meningitidis B
- Staphylococcus aureus
- Influenza**
- Human immunodeficiency virus
- Dengue fever virus
- Cytomegalovirus
- Plasmodium falciparum (malaria)
- Mycobacterium tuberculosis
- Therapeutics for cancer, autoimmunity and allergy

TIME

*Prototype vaccines have received approval
**Including universal influenza vaccines and DNA-based vaccines

Source: EVM data March 2008 based on EU authorisations

Investing in innovation
Key facts

- Innovative vaccines offer major public health benefits by protecting against a continually growing range of infectious diseases
- Vaccine industry R&D is highly productive with 137 projects in development
- Industry invested €1.8 billion in R&D in 2006: a significant proportion (18.4%) of total revenues
- Sustained R&D effort is essential to meet current and future public health challenges

Source: EVM data 2006

Contributing to Europe's knowledge-based economy

Data gathered from major manufacturers show that Europe benefits strategically from the vaccine industry. These major producers conduct the majority of their activities in Europe, including most of their R&D, manufacturing and employment.

Although their activities are concentrated in Europe, major vaccine manufacturers are global leaders, successfully exporting their products around the world.

This global competitiveness, combined with the high-tech nature of the vaccine industry, represents a key contribution to the European knowledge-based economy.

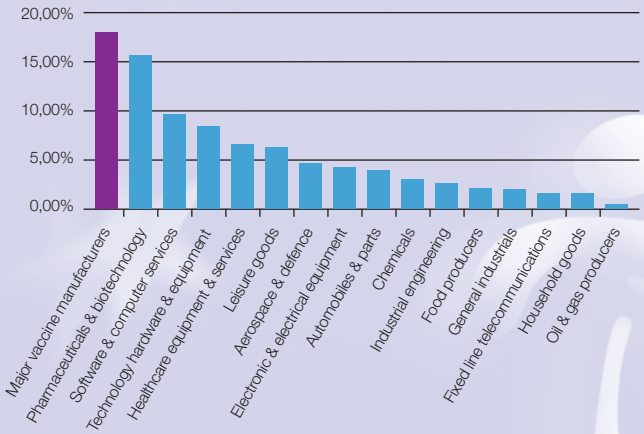
The vaccine industry has the highest R&D intensity in Europe

R&D investment is at the core of vaccine development. Indeed, vaccine manufacturers invest a much higher share of their revenues in research and development than all the other major industrial sectors in Europe.

Through its intense and sustained R&D investment the vaccine industry boosts Europe's science base.

R&D is a high-risk, high-cost activity, and nearly all investment in the field is provided by producers. Public sector support for new vaccine projects undertaken by industry amounts to 3% of the total invested.

R&D intensity: major vaccine manufacturers vs top 15 sectors in the EU



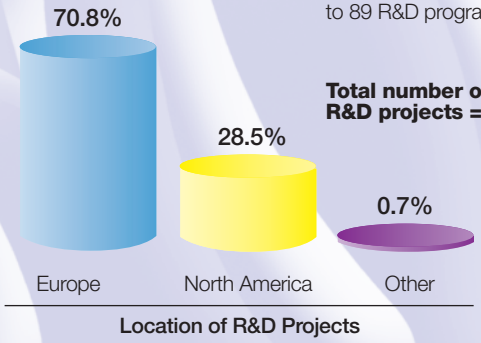
Sources: EVM data 2006; EU 2007 Industrial R&D Investment Scoreboard, European Commission (2006 data)

Europe benefits from the majority of vaccine industry R&D investment

Vaccine manufacturers invest heavily in Europe developing new and innovative products, and thereby supporting the region's knowledge economy.

Of the 137 vaccine projects in development, over two-thirds are based in Europe (97), more than double the total for North America (39). The number of European projects has increased by nearly 10% since 2002, when Europe was home to 89 R&D programmes.

Total number of R&D projects = 137



Source: EVM data 2006

Europe benefits from strong industrial infrastructure

Europe is at the heart of the global vaccine industry and as a result the continent, and in particular the European Union, benefits from a strong industrial infrastructure.

Of the major manufacturers' 42 vaccine facilities located in Europe, 20 are focused on production while 22 are home to R&D innovation.

	Manufacturing facilities	R&D centres
Austria	**2**	**2**
Belgium	**4**	**5**
Czech Republic	**1**	**–**
France	**2**	**3**
Germany	**2**	**2**
Hungary	**1**	**1**
Ireland	**1**	**–**
Italy	**1**	**2**
Netherlands	**1**	**3**
Spain	**1**	**–**
Sweden	**1**	**1**
Switzerland	**2**	**2**
U.K.	**1**	**1**
TOTAL	**20**	**22**

Source: EVM data 2006

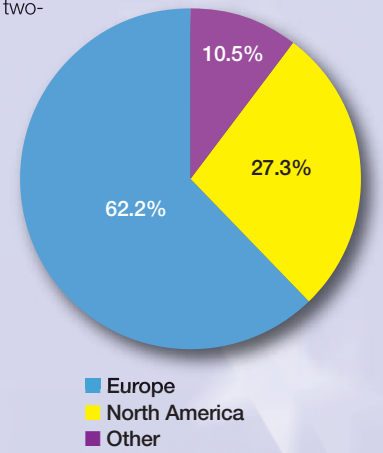
The majority of vaccine industry employees are based in Europe

As a high-technology sector with a strong record of investment, the vaccine industry provides quality employment across a range of disciplines.

Major industrialised countries' vaccine manufacturers employ more than 28,000 people globally, and with Europe at the heart of the industry nearly two-thirds of these work in the region.

The number of European employees has increased by over 45% since 2002, rising from just over 12,000 to more than 17,600 in 2006.

Total number of employees: 28,380



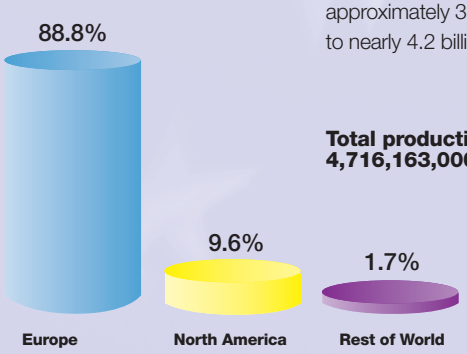
Source: EVM data 2006

Major vaccine manufacturers' production is concentrated in Europe

In addition to its heavy investment in European R&D, vaccine manufacturers also undertake the vast majority of their production in Europe.

Of the 4.7 billion doses produced annually by major vaccine manufacturers, nearly 90% is manufactured in Europe. Since 2002, European vaccine production has increased by 20%, rising from approximately 3.5 billion doses to nearly 4.2 billion in 2006.

Total production: 4,716,163,000 doses



Source: EVM data 2006

European vaccine production is an export success story

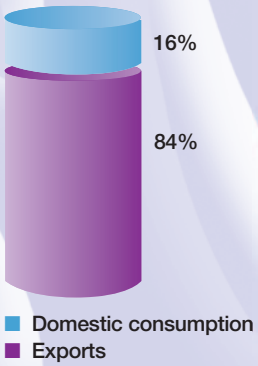
The European-based vaccine industry is a global leader, exporting 84% of its total production. This export success clearly highlights the industry's competitiveness and its contribution to Europe's economy.

Vaccine exports from Europe help improve public health around the world. Developing countries receive approximately half of these exports, in particular oral polio vaccine which is produced in large quantities in Europe.

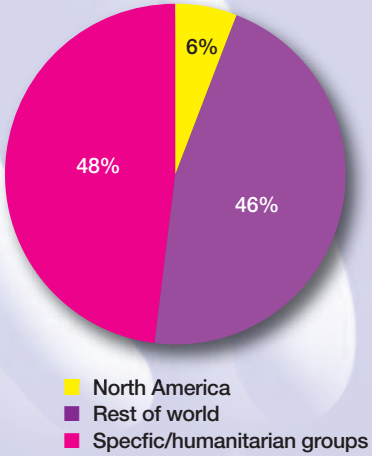
The industry supplies vaccines to developing countries largely through humanitarian groups and supranational organizations such as UNICEF. These vaccines are provided at reduced prices, and consequently represent just 3.5% of vaccine manufacturers' sales.

Total vaccine exports from Europe: 3,501,290,000 doses

Distribution of European production



Destination of exports from Europe



Source: EVM data 2006

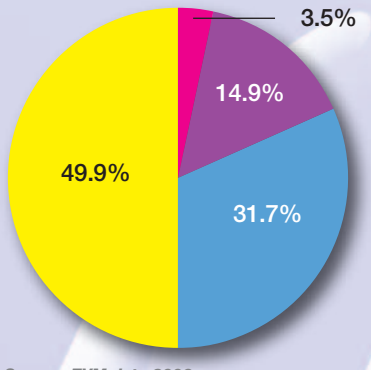
Europe's vaccine industry is competitive with a strong position on global markets

The competitiveness of major vaccine manufacturers is reflected by their strong position on worldwide markets, with Europe accounting for only one-third of global sales.

Although developing countries receive half of the vaccine industry's exports from Europe, they account for only 3.5% of manufacturers' sales as they are supplied largely via humanitarian groups at reduced prices.

North America is the leading market for the vaccine industry, with the region accounting for 50% of total sales.

Total worldwide vaccine industry sales: €9,722.2 million



Source: EVM data 2006

- Europe
- North America
- Specfic/humanitarian groups
- Rest of world

Contributing to Europe's knowledge-based economy

Key facts

- The vaccine industry has the highest R&D intensity in Europe
- 70% of vaccine R&D is based in the region
- 90% of major vaccine manufacturers' production is in Europe
- 60% of vaccine employees are based in the region
- Vaccines represent a highly competitive industry
- Strong vaccine exports from the continent protect health worldwide

The vaccine industry makes a significant contribution to Europe's economy and the region's knowledge base. With the majority of R&D, production and employment based in the region, the vaccine industry represents a strategically important asset for Europe.

Protecting and improving public health worldwide

"Immunization is a cost-effective and life-saving intervention which prevents needless suffering through sickness, disability and deaths. It benefits all people – not only through improvements in health and life expectancy but also through its social and economic impact at the global, national and community level."

WHO Global Immunization Vision and Strategy - Strategic Framework (2006-2015)

Vaccines have transformed public health, protecting people around the world against a range of infectious diseases. Immunization saves huge numbers of lives: WHO estimates approximately 3 million each year*. Since 1988, 5 million people have avoided paralysis caused by polio**.

Vaccine innovations developed over recent years offer individuals and communities the possibility of protection against an increasing number of diseases. For instance, new vaccines against human papilloma virus, rotavirus and pneumococcal infection can save additional lives every year.

Consequently, health systems around the world need to continue to drive vaccination forward, as immunization represents one of the most cost-effective health interventions available**.

***WHO Europe Fact Sheet EURO/07/05**
WHO fact sheet 288 'Immunization against diseases of public health importance'

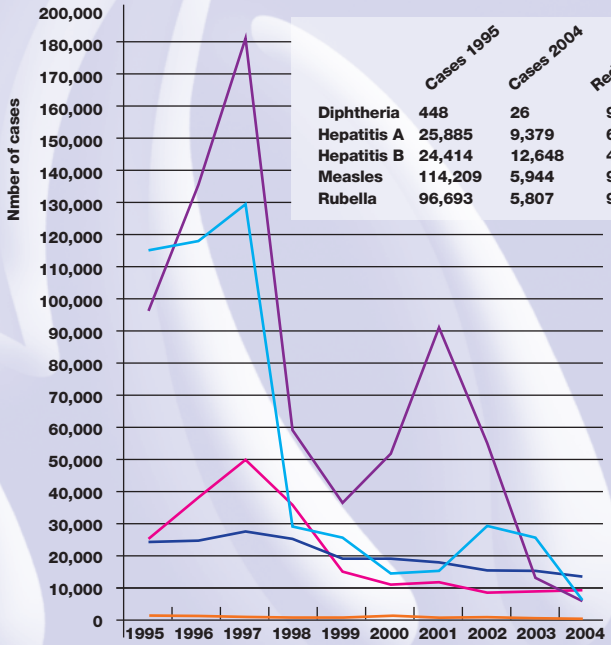
Protecting individuals: protecting communities

Consistent wide-spread use of vaccines can achieve remarkable public health results. By protecting individuals, whole communities can benefit from the dramatic reduction and even elimination of certain diseases. With sufficiently wide-spread vaccination even those who are not immunized can be protected via 'herd immunity'.

In recent decades vaccines have had a highly positive impact. Through effective vaccine use smallpox was eradicated in the late 1970s and WHO declared Europe polio free in 2002.

Consequently, to consistently improve public health around the world, comprehensive vaccine programmes must continue to be expanded.

Reduction in vaccine-preventable diseases in the EU and EEA/EFTA 1994-2004



	Cases 1995	Cases 2004	Reduction 1994-2004
Diphtheria	448	26	94%
Hepatitis A	25,885	9,379	64%
Hepatitis B	24,414	12,648	48%
Measles	114,209	5,944	95%
Rubella	96,693	5,807	94%

■ Diphtheria ■ Hepatitis A ■ Hepatitis B ■ Measles ■ Rubella

Source: ECDC. Reported number of cases in the EU and EEA/EFTA Member States (1994-2004), p 28, Annual Epidemiological Report 2007

Improving health and quality of life

Vaccination protects both individuals and society against significant disease and cost burdens (cost of disease treatment, lost earnings etc)

- Pneumococcal conjugate vaccination of European infants could prevent approximately 800 cases of meningitis each year (avoiding 160 deaths and 240 cases of serious disability)
- Vaccination against human papilloma virus could protect against up to 70% of the 33,000 cases of cervical cancer that cause 15,000 deaths in Europe each year
- Rotavirus vaccination of European infants could prevent up to 90% of severe cases of a disease that results in 700,000 doctor visits and 87,000 hospitalisations each year

Source: EVM Briefing Sheets available at www.evm-vaccines.org

Vaccines have saved millions of lives, and achieved major public health successes, such as the eradication of polio in many parts of the world and of smallpox across the entire globe.

Sustained industry innovation now offers the possibility of protection against a wider range of diseases than in the past, as demonstrated by the recent introduction of human papilloma virus, pneumococcal and rotavirus vaccines. These vaccines not only save lives, but also improve welfare and quality of life, by reducing hospitalisations and the disabilities caused by infection.

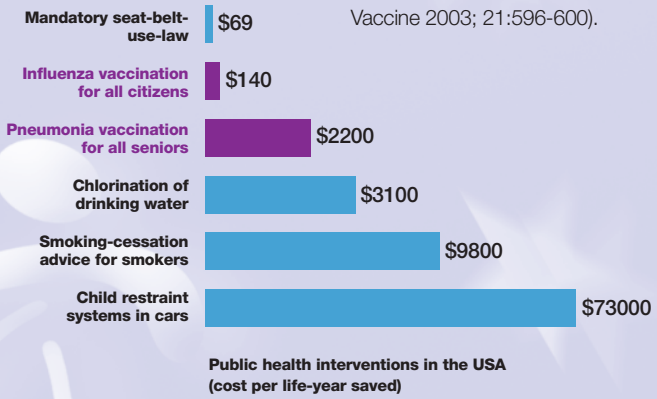
As a result, uptake of these new vaccines could dramatically reduce the burden of disease for individuals and society as a whole.

Vaccines are one of the most important health investments available

While immunization programmes require support and adequate funding, the associated prevention of mortality and morbidity provides long-term cost savings, increased productivity and economic growth.

Vaccines are the most cost-effective medical intervention available. In addition, data from the US show that vaccination is also highly cost-efficient when compared with other public health interventions.

Vaccination can provide significant savings by avoiding the direct health costs associated with treating disease as well as the indirect costs caused through lost productivity. In 2003, vaccines were responsible for direct societal savings of US$10 billion (Source: Ehreth. The global value of vaccination. Vaccine 2003; 21:596-600).



Tengs TO et al. Five hundred life-saving interventions and their cost-effectiveness. Risk Anal 1995;15(3) 369-390.

'Vaccination greatly reduces disease, disability and inequity worldwide'*

Vaccination offers multiple benefits*:

- Controlling disease
- Saving health-care and other costs for society
- Preventing the development of antibiotic resistance
- Allowing safe travel and mobility
- Protecting against bioterrorism
- Providing economic growth

**WHO (2008). Vaccination greatly reduces disease, disability and inequity worldwide. Bulletin of the World Health Organization Volume 86 N°2 81-160, 2008*

The benefits of vaccination are not limited to disease control and health-care savings. WHO recognises a number of broader advantages that accrue from immunization, including economic growth.

However, comprehensive vaccination programmes and supportive policies are crucial to fully realise this potential, and substantially improve the health and welfare of entire populations.

Vaccination programmes must be extended to reap the benefits of immunization

- Vaccines save 3 million lives worldwide each year (source: WHO Europe*)
- Vaccination eradicated polio from the WHO Europe region in 2002
- 1-in-3 Europeans (~130 million) are vaccinated each year (source: EVM estimates)
- Vaccines can now protect against more than 25 diseases
- Vaccines could save 4 - 5 million lives worldwide each year by 2015 (source: WHO**)

**WHO Europe Fact Sheet EURO/07/05*
*** http://www.who.int/immunization/en/#box*

Governments and international agencies have driven up immunization rates around the world, saving significant numbers of lives. WHO's Expanded Programme on Immunization has greatly increased the number of infants protected against polio, diphtheria, tuberculosis, pertussis (whooping cough), measles and tetanus, and newer vaccines such as hepatitis B are increasingly being used.

However, around the world 34 million infants are not immunized, and with uptake decreasing in some countries vaccination programmes must continue to be expanded.

New vaccines offer major opportunities for individuals and communities to protect their health. Increasing the uptake of these vaccines is a challenge that must be taken up by health authorities. Expanding the use of current and future vaccines is vital to exploit the huge potential of immunization, and thereby improve lives across the world.

Protecting and improving public health worldwide

Key facts

- **Vaccines are one of the most important health investments available**
- **Vaccination:**
  - Protects individuals & communities
  - Saves lives
  - Improves quality of life
  - Contributes substantial public health benefits

Vaccines have transformed public health, protecting against a range of infectious diseases. WHO estimates that immunization has saved millions of lives and significant amounts of disability*.

Health systems around the world must continue to drive vaccination forward, as it represents one of the most cost-effective health interventions available*. As part of this drive, vaccine producers are a key partner, working closely with governments and humanitarian agencies around the world.

WHO fact sheet 288 'Immunization against diseases of public health importance'.

Europe's vaccine industry is at the heart of global immunization

- **Investing for the future**
- **Supporting Europe's economy**
- **Fostering innovation through high-technology investment**
- **Protecting individuals and communities around the world**

Definitions

The European Vaccine Manufacturers group (EVM) collected data included in this publication from major industrialised countries' vaccine producers (Baxter, Berna [Crucell], GSK Bio, Merck, Novartis, sanofi pasteur, sanofi pasteur MSD, Solvay and Wyeth), who account for 85% of worldwide vaccine sales. References to the 'industry' in this brochure refer to the data obtained from these major producers only; other data are taken from publicly available sources.

The industry data relate to 2006 (and comparable data from 2002) and are expressed in Euros (€) and in doses (one dose corresponds to one antigen; consequently, combination vaccines containing more than one antigen correspond to more than one dose).

Europe includes the 27 EU Member States and the 4 EFTA members (i.e. Iceland, Liechtenstein, Norway and Switzerland).

For further information please contact

European Vaccine Manufacturers (EVM) a specialised group of EFPIA

Rue du Trône 108/Troonstraat 108
B-1050 Brussels Belgium
info@evm-vaccines.org
www.evm-vaccines.org