



European
Vaccine
Manufacturers



For further information please contact:

European Vaccine Manufacturers (EVM)

a specialized group of EFPIA

Rue du Trône 108/Troonstraat 108

B-1050 Brussels

Belgium

Web: www.evm-vaccines.org Email: info@evm-vaccines.org

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Vaccines: a strategic industry
for Europe

Vaccines: a strategic industry for Europe



1. Highly innovative
2. A European based industry
3. Essential for public health
4. Strategic support for continued success

Definitions

The European Vaccine Manufacturers (EVM) collected data included in this publication from the 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: reference to the 'industry' in this brochure refers to the data collected from these major producers only; other data are taken from various sources.

The data relate to 2004 and are expressed in million Euros (€) or in doses (each antigen corresponds to one dose: combination vaccines containing more than one antigen correspond to more than one dose).

Europe includes the 25 EU Member States (which excludes Bulgaria and Romania) and the EFTA members (i.e. Iceland, Liechtenstein, Norway and Switzerland).

Vaccine manufacturers represent an important and distinct subsection of the pharmaceutical industry. While sharing some features, 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 the bulk 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.

Europe develops and produces most of the world's vaccines, however in terms of revenues North America represents the largest vaccines marketplace. Strategic support is required to ensure the continued success of this key European industry.

Vaccines: a highly innovative industry

- Innovative new vaccines are set to transform public health
- Vaccine R&D is one of the most productive in the pharmaceutical industry
- €1.4 billion was invested in R&D in 2004: a significant proportion of total revenues (22.5%)

Source: EVM survey

Following many years of investment a number of new vaccines are nearing the marketplace, with the potential to protect against a range of diseases for which no vaccine currently exists.

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

New vaccines from investment in innovation

Today/short-term

Meningococcal conjugate (ACYW135)

Pneumococcal conjugate

Papilloma virus (cervical cancer)

Rotavirus (gastroenteritis)

Herpes Zoster (shingles)

Influenza pandemic (prototype)

Influenza pre-pandemic

Influenza cell-culture derived

Enterotoxigenic Escherichia coli (diarrhoea)

Middle/long-term

Neisseria meningitidis B

Staphylococcus aureus

Influenza (next generation)

Human immunodeficiency virus (HIV)

Dengue fever

Cytomegalovirus (CMV)

Malaria

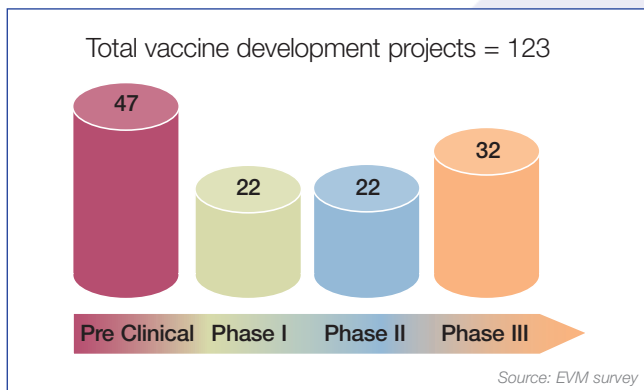
Therapeutics (cancer)

As a result of the industry's ongoing investment in new technologies a range of innovative new vaccines are now available, and others may become available in both the short- and longer-term.

These new vaccines target a number of infections that are responsible for much disease and death, such as cervical cancer caused by human papilloma virus and gastroenteritis due to rotavirus.

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

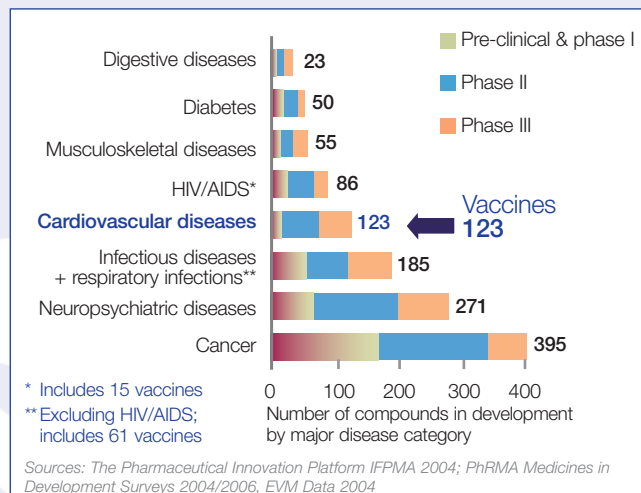
Strong investment at every stage of development



The development of vaccines is a lengthy, complex and costly biological process. It involves 4 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.

The combination of industry investment over a number of years and the application of revolutionary biotechnology has resulted in a strong pipeline of new vaccines in development.

One of the strongest pipelines of potential new products



While vaccines account for a small proportion of the overall pharmaceutical industry (less than 2%), in terms of R&D it is particularly productive.

Data show that of the major disease categories benefiting from significant research investment, if taken separately vaccines would rank fourth along with cardiovascular diseases.

One of the highest levels of R&D investment

Total sales	€6,250.3m
Industry R&D investment	€1,287.6m
Investment from partnerships	€121.7m
<i>Investment from private funds</i>	€89.4m
<i>Investment from public funds</i>	€32.3m
Total R&D expenditure	€1,409.3m (22.5% of sales)

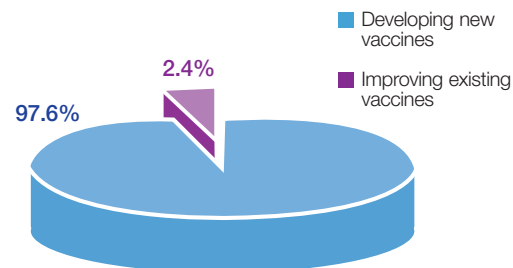
Investment excludes capital expenditure except when it relates to specific R&D projects

Source: EVM survey

As a highly innovative sector, vaccine industry R&D investment accounts for a significant proportion of its sales.

While direct comparisons across different industries are difficult to quantify, the pharmaceutical industry, which is often considered to invest heavily in research, spent 17.6% of its revenues on R&D while major vaccine manufacturers invested a substantially higher proportion (22.5%).

Nearly 100% of research investment is spent on new vaccines



New vaccines include unregistered antigens and new products, such as the combination of registered antigens/new technologies

Source: EVM survey

Data from the major industrialised countries' vaccine manufacturers show that research is not focused on 'me-too' vaccines.

Almost all R&D in the industry is focused on developing innovative vaccines, whether new antigens (the active ingredient in vaccines) or new combination vaccines or the incorporation of new vaccine technologies.

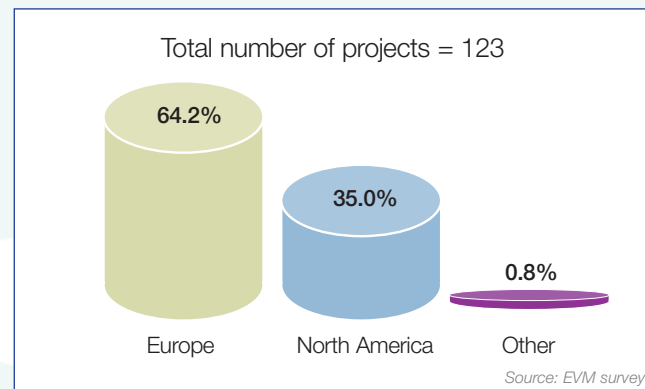
Vaccines: a European based industry

- Vaccines represent a strategic knowledge-based industry for Europe
- $\frac{2}{3}$ of vaccine R&D is based in Europe
- 90% of vaccine production is in Europe
- $\frac{2}{3}$ of vaccine employees are in Europe
- **although** only $\frac{1}{3}$ of the market is in Europe

Data from the EVM survey show that Europe benefits strategically from the vaccine industry. Major vaccine manufacturers focus the majority of their activities in Europe, including most of their R&D investment and employment.

North America accounts for a significantly larger proportion of the global vaccines market than Europe (46% vs 33% respectively). Europe should maintain a favourable environment for continued investment.

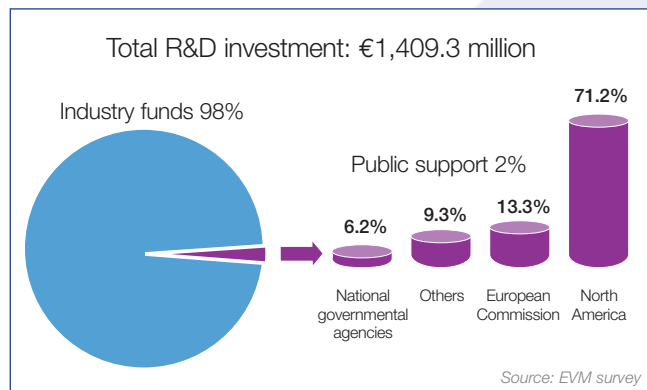
Europe benefits from the majority of R&D investment



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

Of the 123 vaccine projects in development nearly two-thirds are based in Europe (79 programmes), which is nearly double the total for North America (43).

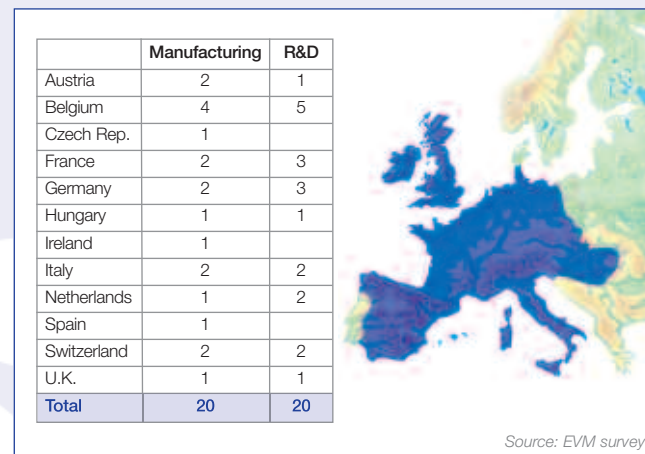
Nearly 100% of R&D investment comes from industry



Significant investment in vaccines boosts Europe's high-tech economy. Of this investment almost all comes from manufacturers, while a very small proportion comes from the public purse.

Of the 2% of R&D investment from public sources the vast majority comes from North America, and US agencies in particular. European Commission programmes accounted for approximately 0.3% of total vaccine research.

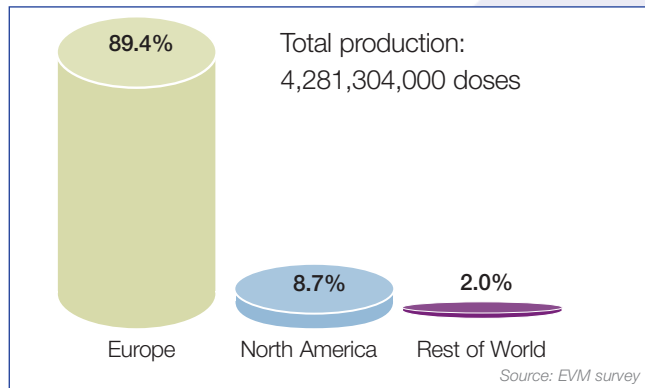
Europe has a strong network of vaccine facilities



Data show that Europe is the heart of the global vaccine industry. As a result, the continent, and in particular the European Union, has a strong network of facilities.

Of the major manufacturers' 40 vaccine facilities in Europe half are focused on production, with the other half home to R&D innovation.

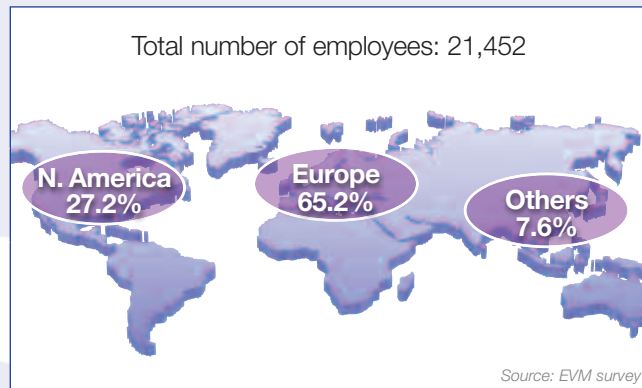
The vast majority of vaccine doses are manufactured in Europe



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

Major vaccine producers manufacture approximately 4.3 billion doses per year, of which 3.8 billion are produced in Europe.

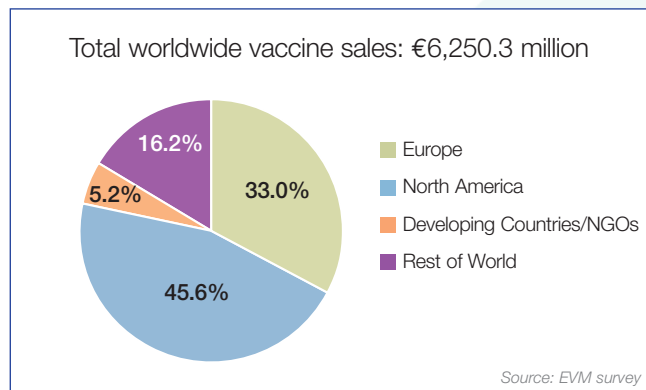
Most vaccine industry employees are based in Europe



As a high-tech sector with a strong record of investment, the vaccine industry provides high quality employment.

Europe is at the heart of the vaccines industry. Major industrialised countries' vaccine manufacturers employ more than 21,000 people and about $\frac{2}{3}$ of these are working in Europe.

But Europe accounts for just one third of vaccine sales



Despite Europe enjoying the benefits of significant vaccine investment, production and employment, it accounts for a disproportionately small segment of global sales.

Although North America provides the largest public investment in vaccine R&D and the biggest marketplace in the world, Europe remains at the heart of the vaccine industry.

Vaccines: essential for public health

- Vaccines are one of the most important health investments available
- Saving lives, protecting individuals & communities
- Insuring against unpredictable diseases (flu pandemic, bioterrorism)
- Protection worldwide: $\frac{2}{3}$ of vaccine exports go to developing countries

Vaccines have transformed public health, protecting against a range of infectious diseases. WHO estimates that immunization has saved huge numbers of lives, amounting to approximately 2 million in 2002 alone, while since 1988 5 million people have avoided paralysis by polio*.

Health systems around the world need to 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 focused on global provision, working closely with governments and humanitarian agencies around the world.

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

Protecting individuals: protecting communities

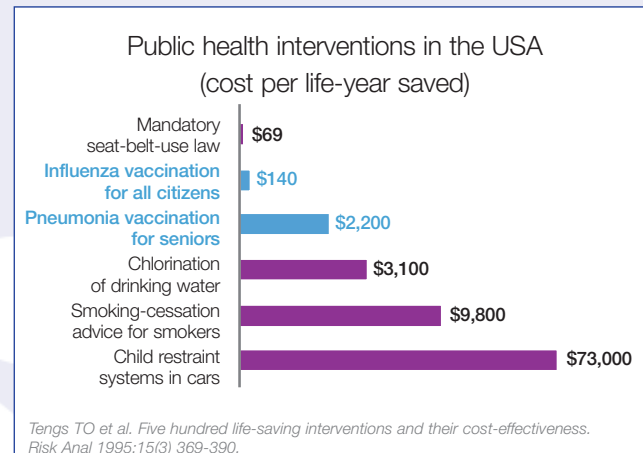
	Peak of European cases (1998-2004)	European cases 2004	Reduction
Rubella	1,661,722	263,582	84%
Mumps	1,038,942	248,685	76%
Hepatitis B	207,439	47,046	77%
Pertussis	184,904	39,757	78%
Measles	624,847	28,789	95%
Diphtheria	54,645	688	99%
Hib	2,391	229	90%
Polio	1,008	0	100%
Total	3,775,898	628,766	83%

Source: WHO Europe, September 2005: Cases of vaccine-preventable diseases in the WHO European region

Consistent wide-spread use of vaccines can achieve remarkable public health results. By protecting individuals, whole communities benefit from the dramatic reduction and even elimination of certain diseases.

Through effective vaccine use smallpox was eradicated in the late 1970s and WHO declared Europe polio free in 2002.

Vaccines are one of the most important health investments available



Vaccines not only save lives, but are also one of the most cost-effective health interventions available. Data from the US show that vaccination can prove highly cost-efficient in comparison with other commonly implemented public health interventions.

WHO acknowledges that by preventing illness vaccines make significant savings in terms of productivity, earning capacity and access to education.

Vaccination programmes must be extended

- Immunization saves **>2 million lives** a year
- **>100 million infants** are immunized each year
- In 1974 **<5%** of infants were immunized against 6 key diseases – this is now nearly **75%**
- Immunization rates have risen globally **but** have decreased in some countries

Source: WHO

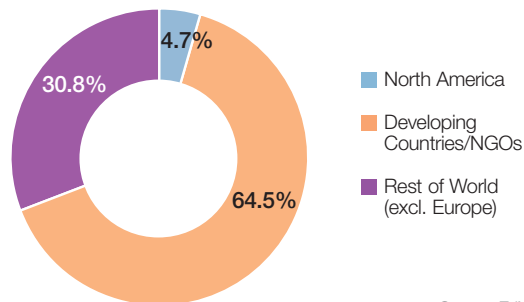
Governments and international agencies have driven up immunization rates around the world, saving significant numbers of lives.

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 rates decreasing in some countries vaccination programmes must continue to be expanded.

Global protection: 2/3 of vaccine exports go to developing countries

Total vaccine exports: 3,614,622,000 doses



Source: EVM survey

Major vaccine manufacturers export over 80% of their total production to protect people around the world. Of this nearly two thirds is exported to developing countries, particularly oral polio vaccine which is produced in Europe.

These countries are largely supplied via humanitarian groups and supranational organizations such as UNICEF. The vaccines are provided at reduced prices and represent just 5.2% of vaccine manufacturers' sales.

Vaccines: strategic support for continued success

- **High level support needed to maintain a key industry**
- **Need supportive climate and long-term vision for industry investment**
 - **Research** – innovative new technologies to address global health issues including pandemics
 - **Development** – expertise and management of large-scale studies
 - **Manufacturing** – high-quality know-how for long production cycles
- **Need to recognise value of immunization and importance of new vaccines to improve health of all EU citizens**
 - **Improve access** to new vaccines through optimized recommendation processes and appropriate funding for vaccination programmes
 - **Increase coverage** for all recommended vaccines

While Europe is at the heart of the vaccine industry, strategic support is required at the highest level to ensure this remains the case.

With the long-term commitment required for ongoing vaccine investment, it is important that Europe provides a supportive climate to ensure the continued success of its industry.

Driving up immunization rates across Europe is essential to further enhance public health, and place disease prevention at the core of healthcare. In addition, funding should recognise the importance and cost-efficiency of immunization, reflecting the true value of both existing and new vaccines.

Europe's industry lies at the heart of vaccination worldwide

- **Protecting individuals and communities around the world**
- **Investing for the future**
- **Supporting Europe's economy** – fostering innovation through high technology investment
- **Offering Europe a key asset that needs strategic support for continued success**