European Vaccine Manufacturers

Worldwide Major Vaccine Manufacturers in Figures

Edition 2004

Summary

The European Vaccine Manufacturers Association has conducted a survey with a view to assessing economic indicators amongst major worldwide vaccine manufacturers, which represent about 85% of worldwide vaccine sales. These companies collectively supply almost all the vaccines in Europe and USA and the majority used in the rest of the world. Regional and local manufacturers, which represent about 15% of vaccine sales, are not covered by the survey.

The survey shows that Europe has an innovative vaccine industry with international commitments but that the largest market value is in North America, which is compromising Europe's leadership in the future.

The key points were:

- In 2002, these companies produced 3.9 billion vaccine doses. About 90% of this production originates from Europe.
- North America was the largest market by value, accounting for 50% of sales. Europe represented about 30%.
- Exports amounted to 2.8 billion doses (72% of total production). Of the doses exported, over half (52%) were destined for humanitarian aid agencies.
- R&D investment is, on average, 24% of sales. As of December 2002, there were a total of 139 R&D projects on stream. About 2/3 of these projects were located in Europe.
- The major worldwide vaccine manufacturers employed more than 18,000 people in 2002. About 2/3 of these were working in Europe.

Vaccine Manufacturers which took part in the Survey

Vaccine Manufacturers:

- Aventis Pasteur
- Aventis Pasteur MSD
- Baxter
- Berna Biotech
- Chiron Vaccines
- GlaxoSmithKline Biologicals
- Merck & Co
- Solvay Pharmaceuticals
- Wyeth Vaccines

Data do not take into account regional and local manufacturers, which represent about 15% of vaccine sales. Data were processed in order to avoid any double counting.

Nine major international vaccine companies took part in the survey. These companies supply almost all the vaccines used in Europe and the vast majority used in the rest of the world.

Preliminary Remarks

Survey process:

- Questionnaire sent on 1st December 2003
- 100% response
- All data relate to year 2002.
  (Data expressed in million euros (€), or in doses)

Breakdown of Europe:

- **EU-15 + EFTA** (Iceland, Liechtenstein, Norway, Switzerland)
- **EU-10 acceding countries**

For the purposes of the survey, one dose corresponds to one antigen:

- **Example 1:** Trivalent Polio OPV (Oral Poliovirus Vaccine) = 1 dose;
  Diphtheria Tetanus Pertussis (DTP) = 3 doses
- **Example 2:** DTP = 1 vaccine

Questionnaire - Key Items

Sales:

- Breakdown by main regions (US, Europe, Rest of the world)

R&D:

- Percentage of sales + location
- Origin of funds + number of projects (pre-clinical, I, II, III)

Production:

- Number of doses + location

Exports:

- Number of doses + destination

Employment:

- Number (by main functions) + location

The objective of the survey was to provide general statistical information on the vaccine industry and the context in which it operates. The questionnaire was focused on main indicators in order to reduce the burden on respondents.

Data were treated in confidence. Individual data are not disclosed.

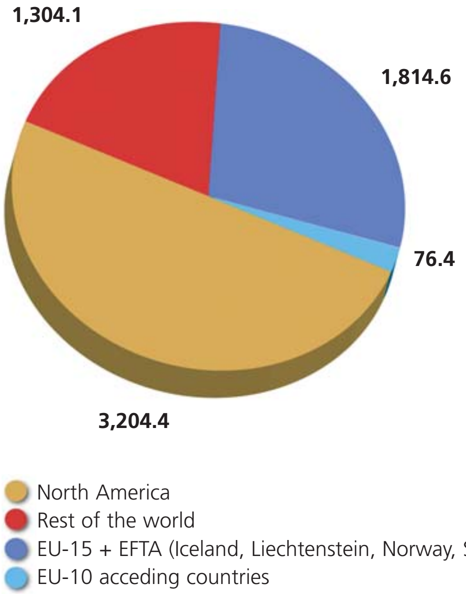
Key Data on Worldwide Major Vaccine Manufacturers

TOTAL	Year 2002
Production (1,000 doses)	3,901,845
Exports (1,000 doses)	2,833,316
Sales (in € million)	6,399.4
R&D expenditure (in € million)	1,521.2
Number of R&D projects (as of 31 December 2002)	139
R&D/Sales (in %)	23.8
Employment (units)	18,216
R&D employment (units)	3,729

This table summarises the main results of the survey:

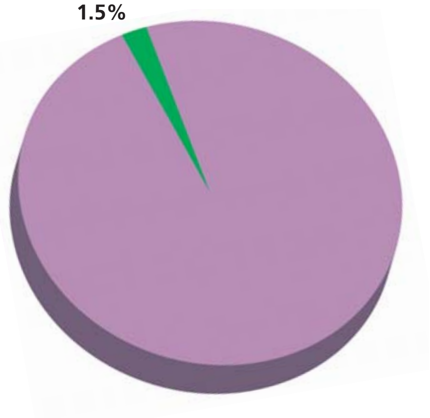
- Vaccines production by major international vaccine companies in 2002 amounted to over 3.9 billion doses, of which 2.8 billion doses (i.e., 72.6%) were sold outside Europe.
- In terms of market value, major international vaccine companies sales represented 6,399.4 M€.
- As a whole, the vaccine industry invested 1,521.2 M€ in R&D (about 23.8% of sales). In 2002, the vaccine industry directly employed about 18,200 people, of which 20.5% were working in R&D.

Worldwide Major Vaccine Manufacturers Market Value: €6,399.4 Million



The value of vaccines sales amounted to €6,400 million in 2002. In terms of market value, North America was the leading market.

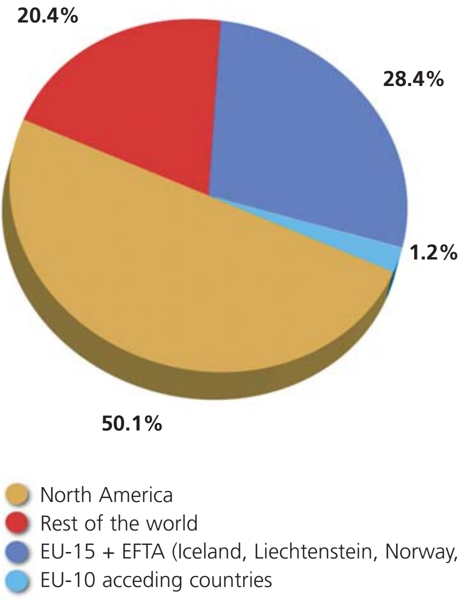
The Vaccine Market accounted for Less than 2% of the Total Pharmaceutical Market in 2002



Rest of the Pharmaceutical market
Vaccines

Compared to worldwide pharmaceutical sales (which amounted to €423.5 billion at ex-factory prices in 2002), vaccines for human use constitute a small market segment since they represent only 1.5% of the world pharmaceutical consumption.

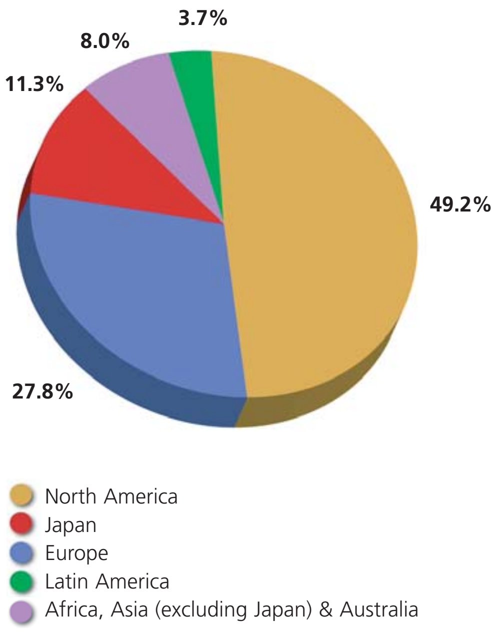
North America represents Half of the World Vaccine Market Value



In terms of market sales, North America was the leading market in 2002, accounting for half of the value of worldwide vaccine sales (50.1%) whilst Europe (25 Member States + EFTA countries) accounted for less than one third (29.6%).

Worldwide Pharmaceutical Market Value 2003

The Breakdown of Vaccines Market by Main Regions Shows a Similar Pattern to the Pharmaceutical Market

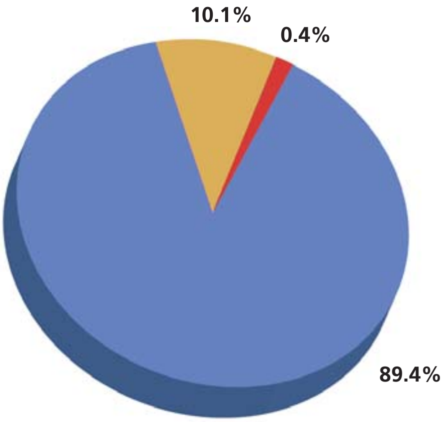


Source: IMS World Review 2004

The world pharmaceutical market was worth an estimated €412,290 million ($466,300 million) at ex-factory prices in 2003. The breakdown of vaccines sales by main geographical regions shows a similar pattern to the pharmaceutical sales: North America represents about 50% of the worldwide market sales.

The Majority of Vaccine Doses are produced in Europe

Production of doses breakdown by main regions (in %)



- North America
- EU-25 + EFTA (Iceland, Liechtenstein, Norway, Switzerland)
- Rest of the world

Europe is the main manufacturing location for human-use vaccines. About 90% of the total production of the worldwide vaccine manufacturers originates from Europe in 2002.

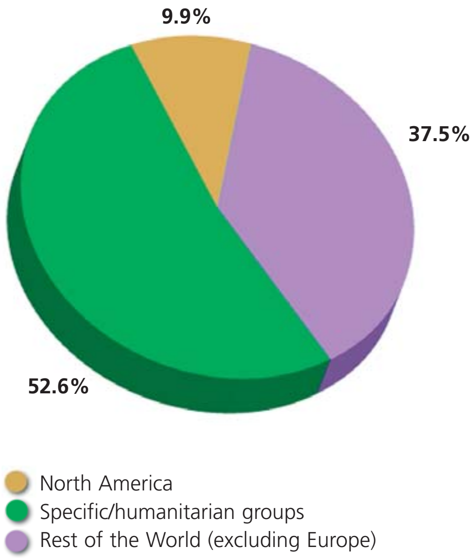
Manufacturing and R&D Sites Number & Location in Europe

	MANUFACTURING	R&D
Austria	2	
Belgium	3	1
Czech Republic	1	
France	3	2
Germany	2	2
Hungary	1	
Italy	2	2
Netherlands	1	2
Spain	1	
Switzerland	2	2
TOTAL	18	11

Major international vaccine companies altogether had 18 manufacturing sites and 11 R&D sites based in Europe in 2002.

Exports represent 72% of Production - Half of the exported Doses go to Humanitarian Agencies

Total exports of doses: 2,833,316,000



About 2.8 billion doses (i.e., 72.6% of the total production) are exported.

Developing countries, which are mainly supplied through humanitarian or aid agencies (e.g., UNICEF, WHO, etc.), accounted for the bulk of vaccines exports. This high volume is linked to the oral polio vaccine which is produced in Europe. Countries other than North America (and Europe) accounted for 37.5%.

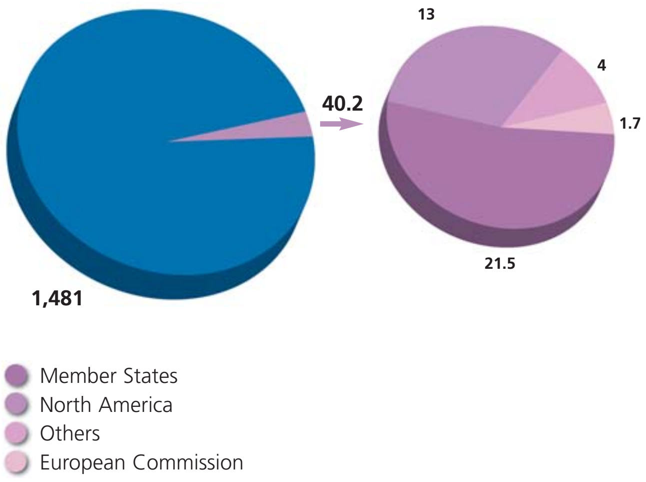
The Vaccine Industry invested about 24% of its Sales in R&D

R&D expenditure (€ million)	
1. Total internal R&D investment	1,357.5
2. Total investment in partnership	163.7
2.a Investment by private funds	(123.5)
2.b Investment by public funds	(40.2)
Total R&D expenditure (1+2)	**1,521.2**

The vaccine industry invested about 23.8% of its sales in R&D in 2002, as compared to 19.4% for the pharmaceutical industry. With respect to the total amount invested by major international vaccine companies in R&D, about €163.7 million (i.e., 10.8%) were spent in partnership (private + public).

Public Funds represent a Small Share of R&D Investment (in €)

R&D investment - Origin of R&D funds (€ million)



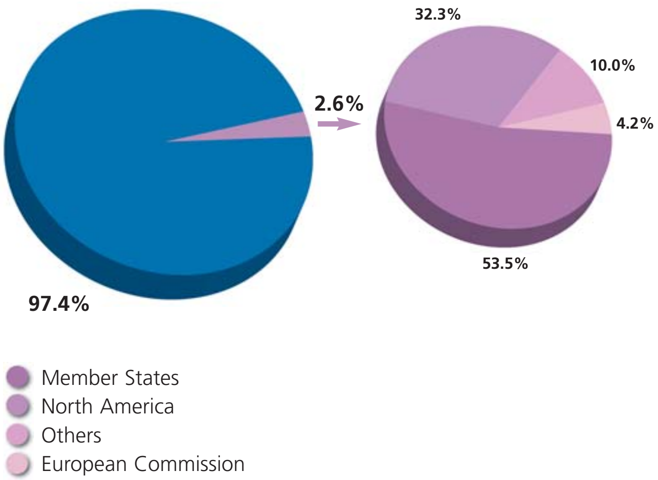
In 2002 major international vaccine companies invested about €1.5 billion in R&D.

In 2002 R&D expenditures made by vaccine manufacturers were almost entirely financed from companies' own resources (€1,357.5 million* out of a total of €1,521.2 million, i.e., 89.2%). In addition, €123.5 million comes from private investment. The amount of R&D spending financed through external public funds was small (about €40 million in 2002). Only €1.7 million originated from the European Commission's R&D budget.

* See Table on page 13

About 97% of R&D Investment is sourced from Private Funds

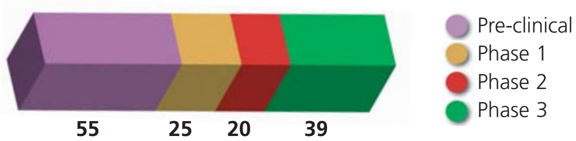
R&D expenditure - Origin of R&D funds (%)



About 97% of R&D investment comes from private funds (own vaccine company resources and private partnership). Only 2.6% of R&D expenditures were financed through external public funds, mainly from EU Member States' Governmental Agencies. Of this, the share financed through the European Commission's R&D funds/programmes was rather small (about 4.2%).

Vaccines are a Highly Innovative Sector

Total number of projects = 139



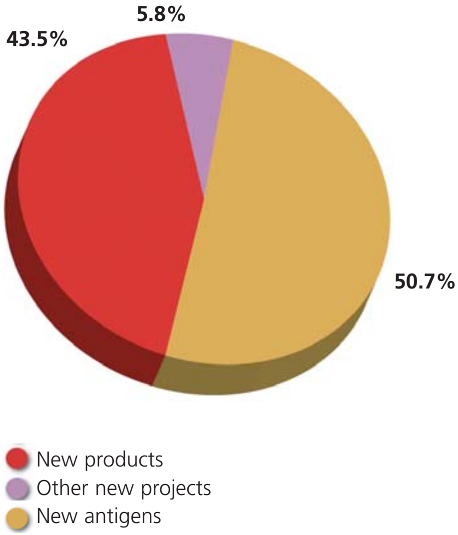
The number of R&D projects (from pre-clinical stage to Phase III development) by major international vaccine manufacturers amounted to a total of 139 as of 31 December 2002.

The breakdown of projects by R&D phases was as follows:

- pre-clinical stage: 55 projects (39.6% of the total number)
- Phase I: 25 projects (18.0%)
- Phase II: 20 projects (14.4%)
- Phase III: 39 projects (28.0%).

By comparison, IMS Health data (source: R&D Focus) shows that a total of 32 vaccine projects were in Phase III development in 2003. If therapeutic areas are listed according to the number of projects under development, vaccines were in 4th position behind cancer (82), cardiovascular/hyperlipidemia (47), viral infections/HIV (38), but ahead of arthritis/pain (30), bacterial infections/mycosis (27), thrombosis/stroke (22), and others such as diabetes, allergy/asthma, anxiety/depression, etc.

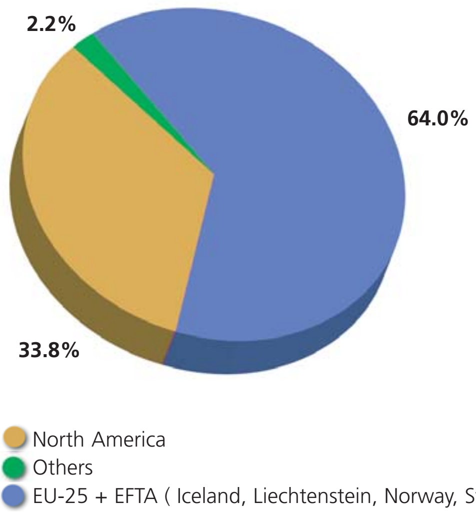
Number of R&D Projects by Main Categories



About half of the projects in R&D by major international vaccine companies at the end of 2002 related to new antigens, i.e., antigens that were not registered and marketed in any markets, in comparison to 43.5% for new products (i.e., new process technologies and/or combination of registered/marketed antigens).

About 2/3 of the R&D Projects are located in Europe

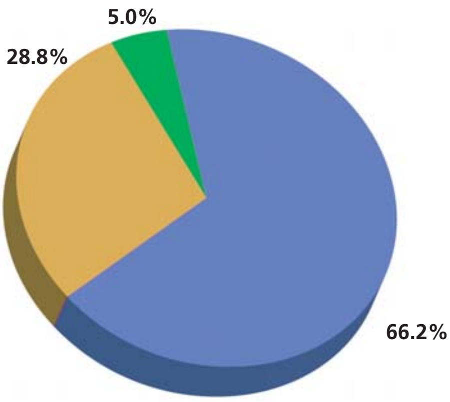
Location of R&D Projects



About two thirds of the total number of R&D projects were located in Europe (Europe: 89 projects; North America: 47 projects; Other countries: 3 projects).

About 2/3 of Worldwide Major Vaccine Manufacturers Employees are located in Europe

Total number of employees: 18,216

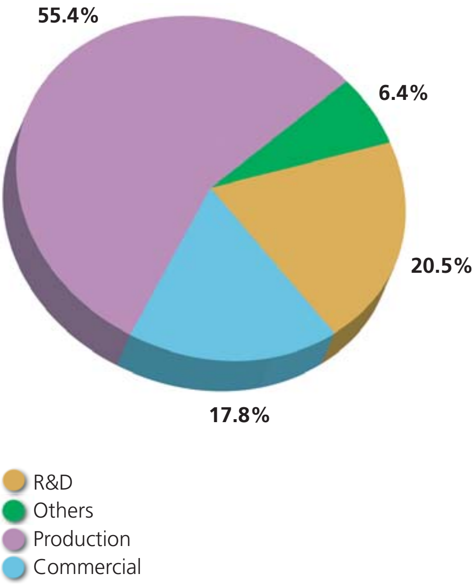


North America
Others
EU-25 + EFTA (Iceland, Liechtenstein, Norway, Switzerland)

Major worldwide vaccine manufacturers employed about 18,200 people in 2002, of which about two thirds were working in manufacturing and research & development units in Europe.

About 3/4 of Employees work in Production and R&D

Total number of employees: 18,216



Data show that the percentage of employees by main functions could be estimated as follows:

- 55.4% in production-related activities (including quality control and distribution);
- 20.5% in R&D (compared to 17.1% in the pharmaceutical industry);
- 17.8% in sales and information;
- 6.4% in other functions (including administration).

A specialised group within EFPIA

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