
Aventis company profile

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Summary

Business description

Aventis, which merged with Sanofi-Synthelabo in 2004, is a major innovative pharmaceutical corporation. Its core businesses are the discovery, development and marketing of branded prescription drugs, vaccines and animal health products.

- Headquarters: France
- Global presence: over 170 countries
- Primary markets: USA, France, Germany, and Japan
- Employees: approximately 76,000

Aventis key figures for 2003 (in € million)

Sales	17,815
Materials and production costs	5,377
Marketing and administration	6,198
R&D expenditures	2,924
Operating income	3,670
Net profit	1,901

Since 2002, Aventis has divested its agribusiness division and other non-core activities. The company focuses on seven high-potential strategic products, including Allegra/Telfast (allergies), Lovenox/Clexane (thrombosis), Taxotere (oncology), and Delix/Tritace (hypertension). These four drugs generated global sales above €1 billion each. Aventis Pasteur, the vaccines division of Aventis, is also a key contributor to the business success of the company.

Aventis produces several products of special importance to developing countries, including:

- Vaccines for developing countries
- Pentamidine, melarsoprol and eflornithine, against sleeping sickness
- Glucantime, against leishmaniasis
- Tuberculosis drugs

Corporate Social Responsibility (CSR)

CSR refers to the responsibility of a company for the social, ecological and economic

impacts of its operations. In 2003, Aventis adopted a new Sustainability Policy. This forms the overarching CSR policy of the company and brings together the policy elements for various individual CSR issues. Aventis has set up a new CSR management structure and reports elaborately on CSR performance in its annual Sustainability Reports. The company is clearly in a process of adopting a more integral CSR approach. Recent criticism concerning Aventis' CSR performance includes inappropriate drug promotion and price fixing.

Aventis supports the World Trade Organization (WTO) agreement on intellectual property protection, including the safeguards to secure access to medicines in the case of urgent public health needs. Yet Aventis is also in favour of stronger patent protection, which might limit access to medicines in poor countries. The company follows a constructive approach for the pricing of vaccines by offering them at differential prices for UNICEF tenders. Furthermore, it has several R&D programmes on vaccines of special relevance to developing countries. However, it does not describe any special commitments or explicit targets (for example in terms of R&D investment) for R&D on diseases that mainly affect poor countries.

Global Public-Private Initiatives (GPPIs)

GPPIs bring together different partners to address health problems in poor countries. Aventis participates in a variety of GPPIs, including:

- Global Polio Eradication Initiative (GPEI)
- WHO Programme to Eliminate Sleeping Sickness (WPSS)
- Global Alliance for Vaccines and Immunization (GAVI)
- Paediatric Dengue Vaccine Initiative (PDVI)
- Dengue Vaccine Project (DVP)

- Stop TB Partnership (Stop TB)
- TB Free

Aventis also funds a variety of smaller initiatives.

The GPEI was started in 1988 with the aim of global polio eradication by 2000 through large-scale vaccination campaigns. When it was realized that this target would not be reached and the World Health Organization (WHO) strongly increased the amount of vaccinations, funds were falling short. Aventis helped with several donations of Oral Polio Vaccine, next to its (much larger) regular supplies at preferential prices. A tripartite Memorandum of Understanding was signed with UNICEF and the WHO for each donation.

The WPESS was started in 2001 when Aventis decided to donate its drugs against sleeping sickness. The WHO and Aventis agreed on a 5-year partnership with three components: drug donations, disease management and control, and R&D. Aventis has committed a total amount of US\$ 25 million to this partnership. The drugs are distributed by Médecins sans Frontières (MSF).

The GAVI was established in 1999 to expand the widespread use of vaccines in developing countries. Aventis was actively involved in the establishment of the GAVI and from 1999 to 2002, Aventis represented the pharmaceutical industry in the GAVI Board. The GAVI has identified three priority diseases: Hepatitis B, *Haemophilus influenza* type b and yellow fever. This focus has been subject to criticism. Aventis is a main supplier of yellow fever vaccines to GAVI, with supplies worth \$34 million for the period 2001-2004. Aventis Pasteur also provides funding for the EPIVAC, a vaccinology training programme in Western Africa that is linked to GAVI.

In 2002, Aventis initiated the TB Free programme to improve the health situation of

people with tuberculosis in South Africa. TB Free is implemented by the Nelson Mandela Foundation in coordination with the South African government. TB Free trains people to support compliance with the complicated 6-month treatment regime of tuberculosis. Teams of Aventis employees are involved in the trainings.

Analysis of GPPI involvement

The business benefits of a GPPI for Aventis vary according to the nature of a the partnership, which can be R&D-oriented (e.g. PDVI) or philanthropic (e.g. WPESS). The value of research-oriented partnerships is in the acceleration of the development of a vaccine. Aventis explains the main company benefits of philanthropic programmes, on the other hand, are an enhanced corporate image and the sense of pride that it creates, which motivates employees.

It is difficult to get a clear overview of Aventis' total contributions to GPPIs. This is partly because of the diverse nature of these contributions, and partly because Aventis does not report aggregate annual figures on the financial and in-kind support it provides. The analysis of Aventis' involvement with various GPPIs shows that the company makes diverse contributions and uses its specific expertise. This supports the rationale for GPPIs, which generally consists of various partners combining their specific expertise.

Lack of transparency about partnership agreements, for example for the WPESS and GPEI, prevents a full external assessment of the conditions of cooperation. The same applies to the establishment of GPPIs, such as GAVI. Furthermore, there may be concerns that responsibilities are transferred from donor governments to companies. This applies to the WPESS, for example, and calls for larger contributions from donor governments.

Contents

Summary	2
List of acronyms	5
Introduction	6
1 General characteristics	7
1.1 Corporate headquarters	7
1.2 A short history	7
1.3 Ownership structure	7
1.4 Merger with Sanofi-Synthélabo	8
1.5 Business profile	9
1.6 Business strategy	10
1.7 Restructuring	12
1.8 Key figures	12
1.9 Medicines of special importance to developing countries	15
2 CSR policy: general	18
2.1 CSR issues in the pharmaceutical sector	18
2.2 Positive and negative publicity	18
2.3 Policies	19
2.4 Implementation and governance	21
2.5 Supply chain responsibilities	21
2.6 Stakeholder involvement	21
2.7 Transparency and reporting	22
2.8 Independent verification	23
2.9 Conclusion	23
3 CSR policy: medicines for developing countries	25
3.1 Patents	25
3.2 Preferential pricing	27
3.3 R&D	29
3.4 Conclusion	29
4 GPPI involvement	31
4.1 Introduction	31
4.2 Global Polio Eradication Initiative (GPEI)	31
4.3 WHO Programme to Eliminate Sleeping Sickness (WPESS)	33
4.4 Global Alliance for Vaccines and Immunization (GAVI)	35
4.5 TB Free	40
5 GPPI policy	43
5.1 The rationale for GPPIs	43
5.2 Management of GPPIs inside the company	44
5.3 GPPI conditions	44
5.4 GPPI strategies	45
5.5 Valuation of drug donations	46
6 Analysis and conclusion on GPPIs	48
Annex 1: Memorandum of Understanding for OPV donations	50

List of acronyms

AAI	Accelerating Access Initiative
CSR	Corporate Social Responsibility
DOTS	Directly Observer Treatment, Short-course
DTP	Diphtheria-tetanus-pertussis
DVP	Dengue Vaccine Project
EHS	Environment, health and safety
GAVI	Global Alliance for Vaccines and Immunisation
GPEI	Global Polio Eradication Initiative
GPPI	Global Public-Private Initiative
IPPPH	Initiative on Public-Private Partnerships for Health
IPV	Inactivated Polio Vaccine
MMR	Measles-mumps-rubella
NGO	Non-Governmental Organization
OPV	Oral Polio Vaccine
PDVI	Paediatric Dengue Vaccine Initiative
PPP	Public-Private Partnership
PhRMA	Pharmaceutical Research and Manufacturers of America
TB	Tuberculosis
TRIPS	Trade-Related aspects of Intellectual Property rights
UNICEF	United Nations Children's Fund
USTR	United States Trade Representative
WBCSD	World Business Council on Sustainable Development
WHO	World Health Organization
WPSS	WHO Programme to Eliminate Sleeping Sickness
WTO	World Trade Organization

Introduction

This report forms part of a broader research project on the role of companies in public-private partnerships (PPPs). Such collaborations have become an increasingly important way to stimulate sustainable development. The research project aims to contribute to a better understanding of the rationale, functioning and effectiveness of these partnerships.

This report focuses Global Public-Private Initiatives (GPPIs) for healthcare in developing countries. These GPPIs are a specific type of public-private partnerships. The report assesses company contributions and the rationale for industry involvement with GPPIs. It does not evaluate outcomes or effectiveness, nor does it deal with the governance and functioning of the partnerships in much detail. These issues are addressed in separate reports, focusing on four specific initiatives (GPEI, GAELF, RBM Partnership, Stop TB). Field studies on the implementation of these programmes in developing countries form part of the broader research project.

This company profile analyses Aventis, a large pharmaceutical corporation that has recently merged with Sanofi-Synthelabo, and its involvement in GPPIs. The report consists of three parts:

1. a description of the business of the company (chapter 1);
2. an analysis of its corporate social responsibility (CSR) policies (chapters 2-3);
3. a discussion of its role in GPPIs and the contributions to these partnerships (chapters 4-6).

This integral approach allows to relate Aventis' involvement with GPPIs to the core-business of the company and to broader company strategies and policies.

It should be emphasized that a company's support for PPPs (or GPPIs) is not the same as its CSR performance. PPPs and CSR should be clearly distinguished. CSR, as defined in the report, covers a broad range of issues that are all directly related to the core-business of a company (environmental issues, labour conditions, access to medicines, competition policy, etc.). CSR performance therefore primarily depends on how a corporation manages its core-business. In certain cases, PPPs may be directly related to the business operations of a company and address issues that can reasonably be considered a responsibility of the company. There will then be a link between PPPs and (a specific area of) CSR performance. However, in other cases PPPs may be completely unrelated to a company's core-business, especially when company contributions consist of cash donations only. Such initiatives are not linked with CSR at all and can be classified as corporate philanthropy or charity.

Finally, it should be noted that the report focuses on a few large GPPIs that were selected because of their relevance for the broader research project. This company profile does not provide a complete overview of the PPPs supported by Aventis.

1 General characteristics

1.1 Corporate headquarters

Aventis S.A.
Espace Européen de l'Entreprise
16, avenue de l'Europe
67917 Strasbourg
FRANCE
Phone: +33 388991100
Website: <http://www.aventis.com>

1.2 A short history

- In 1985, the Mériex Institute acquires Pasteur Production, the vaccine production branch of the Institut Pasteur, and creates Pasteur Vaccins.
- In 1989, the Mériex Institute acquires the Connaught Laboratories in Canada and creates Pasteur Mériex Serums & Vaccins.
- In 1994, Pasteur Mériex Sérums & Vaccins becomes a wholly owned subsidiary of the French company Rhône-Poulenc and is later renamed Pasteur Mériex Connaught.
- In 1995, the German company Hoechst acquires Marion Merrell Dow (formerly Marion Laboratories), which is later combined with Roussel-Uclaf and the pharmaceutical activities of Hoechst to create Hoechst Marion Roussel.
- In 1999, Rhône-Poulenc and Hoechst unite their life sciences activities in a single company, which takes on the name Aventis. Within this group, Pasteur Mériex Connaught changes its name to Aventis Pasteur.¹
- In 2002, Aventis sells Aventis Cropscience to Bayer and Aventis Animal Health to CVC Capital Partners.
- In March 2003, Aventis sells Aventis Behring and its subsidiaries to CSL.²
- In July 2004, the smaller French pharmaceutical company Sanofi-Synthélabo takes over Aventis.

1.3 Ownership structure

Aventis used to be a publicly traded company, listed on the Paris, New York and Frankfurt Stock Exchanges with ticker symbol AVE. Its largest shareholder was the Kuwaiti Petroleum Corporation, controlled by Kuwaiti royal family, which had a 13,5% stake in Aventis.³ In

¹ <http://www.aventis.com>; <http://www.aventispasteur.com>.

² Aventis Form 20-F Report 2003.

³ Aventis Form 20-F Report 2003.

July 2004 Aventis is to be taken over by the smaller French pharmaceutical company Sanofi-Synthélabo.

The prescription drugs and vaccine businesses of Aventis operate through subsidiaries in nearly 100 countries. Daughter companies in main national markets are listed below.⁴

Major market	Pharmaceutical daughter company
USA	Aventis Pharmaceuticals Inc.
France	Aventis Pharma S.A.
Germany	Aventis Pharma Deutschland GmbH
Japan	Aventis Pharma (Japan) Ltd.

1.4 Merger with Sanofi-Synthélabo

In January 2004 the smaller French pharmaceutical company Sanofi-Synthélabo offered a hostile takeover bid of 47 billion euro for Aventis. Aventis first sought to defend itself and approached the Swiss firm Novartis for friendly merger talks, in reaction to the Sanofi-Synthélabo offer. However, the French government favoured the creation of a national pharmaceuticals champion. It therefore strongly backed the takeover by Sanofi and opposed a merger with Novartis.

In April 2004 Aventis accepted an enhanced bid from Sanofi-Synthélabo of 55 billion euro. Jean-François Dehecq, CEO of Sanofi, becomes the chief executive of the new combination. The former CEO of Aventis, Igor Landau, leaves the group with a severance pay of 12 million euro and share options worth several millions more. The merger will give Sanofi access to Aventis' strong selling networks in the US. However, the deal with Aventis was also motivated by the risk that Sanofi would be taken over itself by a larger international competitor. There will be no forced layoffs following the merger. The public buying offer was closed on 30 July 2004.

The main four therapeutic areas of Sanofi-Synthélabo are cardiovascular/thrombosis, central nervous system, oncology and internal medicine. It produces also generics and over-the-counter medicines.⁵ As there is a large overlap between the main therapeutic areas of Sanofi and Aventis, the merger increases corporate concentration. In an effort to head off problems with the US Trade Commission, Sanofi has already agreed to sell two heart disease drugs and a manufacturing plant to GSK.⁶

This remainder of this report describes the company Aventis only, and not Sanofi-Synthélabo.

⁴ Aventis 2002 Sustainability Report, p4.

⁵ <http://www.sanofi-synthelabo.com>.

⁶ Financial Times (May 6, 2004). p 23, Sanofi expects a June close.

1.5 Business profile

Aventis is one of the world's leading pharmaceutical corporations. Its core businesses are the discovery, development and marketing of innovative products in the fields of prescription drugs, vaccines and animal health. These are branded products developed by the company itself.

Aventis has a commercial presence in some 85 countries and sells its products in over 170. Major manufacturing and R&D sites of Aventis are located in each of its four primary markets: the USA, France, Germany and Japan. In Europe, other leading markets for Aventis are Italy, Spain and the United Kingdom. These main manufacturing sites are listed below. Smaller facilities are located in Spain, Italy, Turkey, Slovakia, Korea, and India, among others.

Major manufacturing sites	Major R&D sites
<ul style="list-style-type: none"> • Bridgewater, New Jersey, USA • Paris, France • Frankfurt, Germany • Tokyo, Japan 	<ul style="list-style-type: none"> • Bridgewater, New Jersey, USA • Vitry-sur-Seine, France • Frankfurt, Germany • Kawagoe, Japan

Aventis has a number of high-potential core strategic products. These are the following:

Aventis strategic brands	
<ul style="list-style-type: none"> • Allegra/Telfast (allergies) • Lovenox/Clexane (thrombosis) • Taxotere (oncology) • Delix/Tritace (hypertension) 	<ul style="list-style-type: none"> • Actonel (osteoporosis) • Lantus (diabetes) • Ketek (respiratory tract infections)

Of the strategic brands, Allegra/Telfast, Lovenox/Clexane, Taxotere and Delix/Tritace are so-called blockbusters, generating global sales well above US\$ 1 billion each. The patents of Aventis' products Lovenox and Allegra are currently being challenged. The loss of patent protection on these important products could have a considerable negative impact on the business of the corporation.

Aventis has ongoing R&D collaborations with private companies as well as public organizations and research institutes. Furthermore, Aventis participates in the following joint-ventures in the field of its core-business:⁷

⁷ These are main joint ventures only. Aventis has other joint ventures in China through its Chinese holding company, for instance. Aventis Form 20-F Report 2003, p184.

Core-business joint ventures

• Merial (animal health)	50% Aventis, 50% Merck & Co.
• Aventis Pasteur - MSD (vaccines)	50% Aventis, 50% Merck & Co.
• Diabel (pharmaceuticals)	50% Aventis, 50% Pfizer
• MCM Vaccine Company (vaccines)	50% Aventis, 50% Merck & Co.

Aventis Pasteur MSD operates Aventis' vaccine business in 19 countries in Western Europe. The corporation also has a minority participation in three non core-business joint ventures: DyStar (35% share), Rhodia (15%) and Wacker (49%). These are textile dyes and chemical businesses.⁸

The company has formed many partnerships to co-promote or co-market certain products in specific geographic areas. Unlike joint-ventures, these are contractual arrangements with other companies that do not establish a new and legally independent business entity. Some major business partnerships include agreements with Procter & Gamble for the drug Actonel, with Teva Pharmaceuticals for Copaxone, with Yakult for Campto, and with Daiichi for Tavanic.⁹

The vaccines business is a key contributor to the success of Aventis. The company has a strong R&D pipeline in vaccines and several new product launches are expected for 2004. Vaccine sales have tripled during the last decade, with strong growth in North America and increasing sales of paediatric combination vaccines, influenza vaccines and adult boosters. Aventis Pasteur is expected to deliver continued solid growth.¹⁰

Aventis is one of the largest pharmaceutical companies of the world with a strong market position. The company has a share of 6% in the world total pharmaceutical market. Aventis is one of the five main competitors in the world vaccine market and Aventis Pasteur MSD is a market leader in Europe with a 37% market share.¹¹

1.6 Business strategy

Aventis is increasing the focus on its core strategic brands and human vaccines. The share of these products in total core-business sales increased from 42% in 2000 to 65% in 2003.¹² The marketing of non-strategic products is being contracted to other companies to further strengthen this focus.

At the same time, Aventis seeks to maximize the potential of its strategic brands by implementing more aggressive commercial strategies to achieve higher product sales. Part

⁸ Aventis Form 20-F Report 2003.

⁹ <http://www.aventis.com>.

¹⁰ Aventis press release (September 26, 2003). Aventis human vaccines set to maintain strong growth.

¹¹; Aventis Form 20-F Report 2003; GSK Annual Report 2003, p61.

¹² Aventis Factsheet 2003.

of this strategy is to continually expand the utility of these products through a process called 'life-cycle management'. This process involves the development of a long-term plan for each drug that takes into account potential opportunities in, among others, the following areas:¹³

- Clinical utility and performance, for example the identification of potential new indications
- New dosage forms, strengths, packaging and dosage administration to support patient compliance
- Formulation improvements
- Proprietary methods and techniques in chemical synthesis
- Combinations with other treatment agents that enhance utility

The company is also increasing its geographic concentration and expanding in the US. The share of this regional market in total core business sales increased from 33% in 2000 to 38% in 2003. A short-term goal of Aventis is to further increase this figure to over 40%.

On the R&D side, Aventis is pursuing a targeted in-licensing and alliance strategy to strengthen its R&D pipeline and add to its in-house R&D efforts. It is increasing collaborations with biotechnology firms and other pharmaceutical companies. At present, Aventis has over 20 ongoing projects to discover, develop and commercialize products in partnership with other companies.¹⁴

Aventis Pasteur, the vaccines division of the company, seeks to optimize production capacities to meet the rising demand for vaccines, which is expected to double by 2010.¹⁵ One of the reasons for this expected increase is the strongly growing demand for flu vaccines in the US, due to increasingly broad government immunization recommendations. The company has been expanding its presence in Asia, especially in China and Japan. It is very active in donors' markets. These refer to the procurement of vaccines by donor organizations like UNICEF for distribution in developing countries and include Global Public-Private Initiatives (GPPIs) on health. Notwithstanding the decline of polio vaccine sales in the US in 2003,¹⁶ the company is expanding Inactivated Polio Vaccine (IPV) production capacity. The demand for this vaccine is expected to grow as the aim of polio eradication comes closer. This is because one of the options for post-eradiction polio control is a switch from OPV to IPV.¹⁷ Furthermore, meningitis vaccine are expected to make a strong contribution to the future growth of vaccine sales. The potential sales of these vaccines could eventually become as high as US\$ 1 billion.¹⁸

¹³ <http://www.roigroup.com/site/C114.asp>.

¹⁴ <http://www.aventis.com> → about Aventis.

¹⁵ <http://www.aventispasteur.com>.

¹⁶ Aventis Factsheet 2003.

¹⁷ However, the associated costs may be prohibitively high for developing countries. See

http://www.phrplus.org/Pubs/Tech004_fin.pdf.

¹⁸ Aventis press release (September 26, 2003). *Aventis human vaccines set to maintain strong growth.*

Aventis Pasteur manages the production of vaccines at the global level and allocates production to the various production sites around the world. This enables the company to diversify supply sources and reduce the risk of supply problems.¹⁹

1.7 Restructuring

Aventis is focussing on its human and animal health core-business and divesting other activities. In 2002, the company sold its agribusiness division Aventis CropScience to Bayer, and Aventis Animal Health to CVC Capital Partners.²⁰ On 31 March 2004 Aventis completed the divestment of Aventis Behring and its subsidiaries, a global leader in the therapeutic protein industry, to CSL. Aventis intends to complete the disposal of remaining non-core business interests by the end of 2004.²¹ As described earlier, Aventis is to merge with Sanofi-Synthélabo in July 2004.

Over the past few years, Aventis has developed new vaccine production sites in the low-cost countries China, Thailand, and Argentina. The diversification of manufacturing locations has been one of the reasons for these new sites.

1.8 Key figures

Below an overview of key figures of the corporation is provided. The figures include the non-core businesses that were divested over the past years and can therefore not be very well compared between different years. For continued operations only, thus excluding Aventis Behring, in 2003 sales were Euro 16.841 million and net income was Euro 2.218 million (Aventis Behring made a loss). Note that net profit margins for recent years are high. Excluding Aventis Behring, net profits amounted to 13% of sales, for example. Such a margin is more or less average for the pharmaceutical sector.²² Note that marketing and administration expenses are much higher than R&D investment, which is common among large pharmaceutical companies. They also surpassed production costs in 2002 and 2003.

¹⁹ <http://www.aventispasteur.com>.

²⁰ Aventis Form 20-F Report 2003.

²¹ Aventis Factsheet 2003.

²² See SOMO (2004). *Sector profile of the pharmaceutical industry*.

Aventis Key figures for total businessess (in million Euro).

	2003	2002	2001	2000	1999
Sales	17,815	20,622	22,941	22,304	20,452
Materials and production costs	5,377	6,578	7,943	8,286	8,155
Marketing and administration	6,198	6,705	7,178	7,219	6,536
R&D expenditures	2,924	3,420	3,481	3,291	3,040
Operating income	3,670	2,830	3,639	3,789	3,019
Net income	1,901	2,091	1,505	1,126	691

Source: Annual and Form 20-F report, various years.

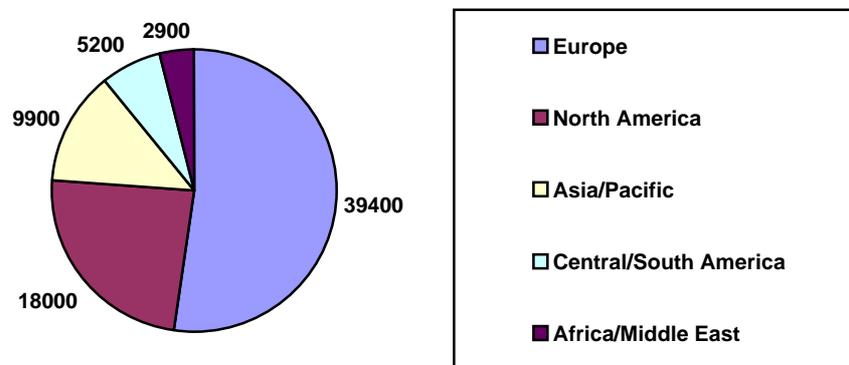
The number of Aventis employees for main divisions is shown in the overview below. The large decrease in work force size from 2001 to 2002 was caused by the divestment of Aventis CropScience and Aventis Animal Nutrition. In 2003 the category 'other activities' included some 6000 employees of Aventis Behring. Hence, Aventis has some 70.000 employees left as of mid-2004. These include a strong global sales force of nearly 20,000 employees, of which 4,400 in the US. A diagram provides a break-up of employees per region as well, and shows that Aventis has considerable staff presence in developing countries.

Employees by division at year-end (rounded figures).

Division	2003	2002	2001	2000	1999
Prescription drugs	60,900	62,400	59,900	61,400	n/a
Human vaccines	7,900	7,900	6,500	6,000	n/a
Other activities	6,800	7,600	25,100	35,100	n/a
Total	75,600	77,900	91,500	102,500	n/a

Source: Annual and Form 20-F report, various years.

Employees per region at 31 December 2003 (rounded figures).



Source: <http://www.aventis.com>.

The following overview shows a break-up of core-business sales per region. The regions distinguished in the reports changed from 2002 to 2003. The different shares do not add

up to 100% due to rounding and a separate Bulk & Toll Manufacturing category that is distinguished in Aventis' reports. Some differences in regional shares, like the sharp decrease of sales in Japan over the past five years, are a result of the divestment of non-core businesses that were geographically concentrated. Although Aventis has a strong presence in Europe and the US, it has substantial operations in all markets, including developing countries.²³

Core-business sales per region (share of total).

Region	2003	2002	2001	2000	1999
USA and Canada	38 %	43 %	41 %	35 %	30 %
France	13 %	14 %	14 %	14 %	16 %
Germany	6 %	6 %	7 %	7 %	8 %
Other Europe, excl. Eastern Europe	n/a	13 %	13 %	12 %	14 %
Latin America	n/a	6 %	8 %	8 %	7 %
Japan	5 %	5 %	6 %	7 %	9 %
Rest of the world	n/a	12 %	11 %	12 %	12 %

Source: Annual and Form 20-F report, various years, and calculations by SOMO.

In 2003, Aventis Pasteur realised 52% of its sales in the USA and Canada, 28% in Western Europe through Aventis Pasteur MSD and approximately 20% in other regions.²⁴ Hence, the sales of vaccines are much more concentrated in the high-income markets of the US and Western Europe than the sales of Aventis as a whole. The largest among the other regions are Latin America, Eastern Europe and the Middle East. China and Japan represent important vaccine markets for Aventis too.²⁵

A break-up of the total sales and operating income by division is provided below. The break-up by division was reported differently before 2001 because of the different company structure before the divestment of various businesses. Human vaccines do not include the Aventis Pasteur MSD joint venture. Vaccines sales show quick and regular growth over the past 5 years.

Comparing sales and operating income, it follows that the gross profit margin for vaccines is much higher than for prescription drugs. In 2003 these figures were approximately 27% and 22%, respectively. The vaccine business is very attractive for Aventis.²⁶ Yet the company also comments that the market for vaccines is more volatile and return on investment is more difficult to forecast than for prescription drugs. Furthermore, the

²³ See SOMO (2004). *Sector profile of the pharmaceutical industry*. When compared to the sizes of different regional markets, the presence of Aventis is relatively low in the US and Japan, and relatively high in Europe and other markets.

²⁴ Aventis Form 20-F Report 2003, p23.

²⁵ <http://www.aventispasteur.com>.

²⁶ Aventis press release (September 26, 2003). Aventis human vaccines set to maintain strong growth.

production process is more complicated and continued investments are required to comply with quality standards. The higher profit margins for vaccines reflect these costs.²⁷

Total sales and operating income by division (in mln Euro, and share of total for 2003).

	2003 share	2003	2002	2001	2000	1999
Sales by division						
Prescription drugs	85 %	15,190	16,026	15,168	13,871	12,266
Human vaccines	9 %	1,621	1,580	1,425	1,091	818
Corporate & Other	6 %	1,002	3,066	6,439	7,342	7,458
Total	100 %	17,815	20,622	22,941	22,304	20,452
Operating income by division						
Prescription drugs	90 %	3,313	3,326	2,864	n/a	n/a
Human vaccines	13 %	465	540	367	n/a	n/a
Corporate & Other	-3 %	-108	-1,036	-408	n/a	n/a
Total	100 %	3,670	2,830	3,639	3,789	3,019

Source: Annual and Form 20-F report, various years, and calculations by SOMO.

The overview below shows the Aventis' sales of main therapeutic categories.

Aventis prescription drug sales per category (in mln Euro, and share of total for 2003).

Therapeutic category	2003 share	2003	2002	2001	2000	1999
Cardiology/Thrombosis	23 %	3,521	3,435	3,325	3,193	n/a
Respiratory/Allergy	15 %	2,317	2,794	2,575	2,055	n/a
Metabolism/Diabetes	13 %	1,977	1,978	1,761	1,648	n/a
Oncology	12 %	1,835	1,743	1,494	1,176	n/a
Central Nervous System	10 %	1,521	1,530	1,448	1,374	n/a
Anti-Infectives	9 %	1,368	1,560	1,546	1,690	n/a
Arthritis/Osteoporosis	5 %	812	799	677	582	n/a
Other	12 %	1,839	2,187	2,342	2,153	n/a
Total	100%	15,190	16,026	15,168	13,871	12,266

Source: Aventis Annual Reports and Form 20-F Annual and Sustainability Reports, several years, and calculations by SOMO.

1.9 Medicines of special importance to developing countries

Aventis Pasteur produces a wide range of vaccines. Many of these are of special importance to developing countries. A complete list of diseases for which Aventis currently produces vaccines is provided below.

²⁷ Communication with S. Gilchrist, June 21, 2004.

Bacterial vaccines	Viral vaccines
<ul style="list-style-type: none"> • Cholera • Diphtheria • Haemophilus Influenzae type b • Meningococcus meningitis • Pertussis (whooping cough) • Pneumococcal infections • Tetanus • Tuberculosis (TB) • Typhoid fever 	<ul style="list-style-type: none"> • Chickenpox • Hepatitis A • Hepatitis B • Influenza • Japanese encephalitis • Measles • Mumps • Poliomyelitis (polio) • Rabies • Rubella • Yellow fever

The vaccines nowadays used in high income countries are often of a different type than those used in developing countries. For example, high income countries use acellular pertussis vaccines, a measles-mumps-rubella (MMR) vaccine combination and Inactivated Polio Vaccine (IPV) for regular vaccinations. Developing countries, on the other hand, use wholecell pertussis vaccines, measles alone instead of MMR, and Oral Polio Vaccine (OPV).²⁸ Aventis produces both the vaccine types for high income countries and for developing countries. It is the main manufacturer in the world of various vaccines, including IPV, influenza and yellow fever vaccines.

Apart from vaccines, Aventis products of special importance to developing countries include the drugs pentamidine, melarsoprol and eflornithine against sleeping sickness, glucantime against leishmaniasis and various drugs (fixed-dose combinations) for the treatment of tuberculosis (TB).

The United Nations Children's Fund (UNICEF) procures vaccines and medicines for use in the developing world through tenders for prequalified suppliers. UNICEF also handles the procurement for the Global Alliance for Vaccines and Immunisation (GAVI) and some World Health Organization (WHO) programmes. The contracts awarded through these tenders give some information on the type and amount of vaccines and medicines a company supplies to UNICEF and to partnerships such as the Global Alliance for Vaccines and Immunization (GAVI). An overview of the most recent UNICEF contracts awarded to Aventis is provided below.

²⁸ For more information on the different types of vaccines, see See SOMO (2004). *Sector profile of the pharmaceutical industry*.

UNICEF Supply Division, Aventis Contract Awards 2001 - April 2004.

Awarding date	Commodity	Value (US\$)	Division
April 2004	Diphtheria-tetanus-pertussis (DTP) vaccine	18.660.000	Aventis Pasteur, France
April 2004	Yellow Fever Vaccine	32.478.000	Aventis Pasteur, France
December 2003	Inactivated Polio Vaccine (IPV) - single dose	616.000	Aventis Pasteur, France
July 2003	Anti-Malarials	267.713	Aventis Pharma Intl.
April 2003	DTP-Haemophilus influenzae b (HIB) vaccine, lyophilized	88.128	Aventis Pasteur, France
January 2003	Hepatitis B, Measles-Mumps-Rubella (MMR), Measles-Rubella (MR) vaccines	660.000	Aventis Pasteur, France
February 2002	Meningitis vaccine	3.555.000	Aventis Pasteur, France
January 2002	Meningitis vaccine	3.555.000	Aventis Pasteur, France
April 2001	Rabies vaccine	741.200	Aventis Pasteur, France
August 2001	Oral Polio Vaccine (OPV) - 20	18.984.000	Aventis Pasteur, France

Source: http://www.unicef.org/supply/index_12/141.html.²⁹

²⁹ The annual report of the UNICEF Supply Division mentions total vaccines/biologicals purchases of \$2.933.708 from Aventis Pasteur Canada and \$37.054.702 from Aventis Pasteur France in 2002. The explanation for the difference with the figures in the table might be that some contracts are long term arrangements for up to 3 years (e.g. the contract for OPV supplies), so that the value of actual purchases in a certain year does not correspond with the value of contracts awarded in that year.

See http://www.unicef.org/supply/supply_division_annual_report2002.pdf.

2 CSR policy: general

2.1 CSR issues in the pharmaceutical sector

The MVO-Platform, a coalition of Dutch civil society organizations and trade unions, understand by Corporate Social Responsibility (CSR) *'a process in which corporations take responsibility for the social, ecological and economic consequences of their actions - throughout their product and service delivery chain - making themselves accountable, and engaging in a dialogue with all those involved.'*³⁰

Some of the CSR issues that may be considered most important for the pharmaceutical sector are related to access to medicines in developing countries. These include the following:

- Industry lobbying for intellectual property protection
- Pricing policy for medicines
- R&D for developing countries' diseases
- Drugs donations policy
- Participation in Global Public-Private Initiatives (GPIs) on health

These issues will be dealt with in the next chapters.

Apart from access to medicines, other critical CSR issues in the pharmaceutical sector are the following:

- Drugs safety
- Drug promotion and advertising
- Clinical trials
- Indigenous knowledge
- Bribery, corruption and fraud
- Workplace health, safety and environment

For a discussion of these issues, see the *Sector profile of the pharmaceutical industry* by SOMO.

2.2 Positive and negative publicity

Positive and negative publicity on CSR performance is helpful to get an impression of the strong and weak aspects of a company's CSR performance. The selection below mentions some main issues only.

On the positive side, Aventis has been recognized and listed as a good employer by several organizations. Furthermore, it has received awards for good environmental and safety

³⁰ MVO Platform (2003). CSR Frame of Reference.

performance. The company is also listed in several responsible investment indexes, including the FTSE4Good Europe Index and Dow Jones Sustainability World Index (DJSI).

Recent negative publicity on various CSR issues includes the following.

- In November 2003, the Food and Drug Administration (FDA), the regulatory authority in the US, sent Aventis an official warning to stop disseminating misleading promotional material for its blockbuster drug Taxotere. Promotional materials had stated misleading effectiveness claims and omitted important safety information. Aventis had not taken action yet after a first warning from the FDA on this practices in December 2002.³¹
- In 2003, Aventis reached a settlement involving a payment of US\$ 178 million for inflation of the price of methionine in the US. This was a compensation to customers of its former Animal Nutrition division for excessive prices charged during the period 1985-2000.³²
- In 2002, the European Commission imposed a fine of almost 3 million Euro to Aventis for fixing the price of methylglucamine between 1990 and 1999, in collaboration with Merck KGaA.³³
- In 2001, the European Commission imposed a fine of 5 million Euro for fixing the price of vitamins. The original fine of 462 million Euro was dramatically reduced because of the full cooperation of the company in the investigations.³⁴
- In 2001, the agribusiness division of Aventis (which was later divested) came under fire because the genetically modified corn it produced was only approved for animal products, but turned up in human food products.³⁵
- In 2000, Aventis was found to be growing genetically modified sugar beet in the UK without permission.³⁶

2.3 Policies

The vision of Aventis is *'To create and sustain value by being recognized as a pharmaceutical industry leader - valued by patients and healthcare providers, sought after as an employer, and respected by the scientific community and by our competitors.'*³⁷ It is building a company culture based on the following values, to support the company's core business objective:³⁸

³¹ Star-Telegraph.com (1 February 2004). *Onslaught of drugs ads overwhelms FDA.*

³² AOF (7 April 2003). *Entente sur le prix de la methionine. Aventis verse 178 M\$.*

³³ Merck KGaA is a German company and should not be confused with the US-based Merck & Co., Inc.

³⁴ Les Echos (27 November 2002). *Aventis condamné à une amande de 2,85 mE pour entente.*

³⁵ Boston Globe (15 June 2001). *UN: Aventis Accused of Breaking Global Compact.*

<http://www.corpwatch.org/article.php?id=72>.

³⁶ Environment News Service (10 October 2000). *UK: Aventis admits growing unauthorized GM seed.*

<http://www.corpwatch.org/article.php?id=508>.

³⁷ Aventis 2002 Sustainability Report, p13.

³⁸ Aventis 2002 Sustainability Report, p13.

- Respect for people
- Integrity
- Sense of Urgency
- Networking
- Creativity
- Empowerment
- Courage

The new Aventis Sustainability Policy is related to the company's vision and values. It forms the overarching CSR policy of Aventis and brings together the policy elements for various individual CSR issues.

The Aventis Sustainability Policy consists of the following parts:³⁹

- Sustainable Healthcare Policy
- Employee Related Policies
- Compliance Policy and other Legal Policies
- Finance Policy
- Environmental, Health and Safety (EHS) Policy
- Purchasing Policies

The Compliance Policy consists of a set of guidelines for employee behaviour and contains internal procedures and general considerations on issues related to legal compliance. These include business integrity, free competition, disclosure of financial information, non-discrimination, and environment, health and safety standards.⁴⁰

Aventis has a 2001-2006 improvements programme for environment, health and safety, called '*A journey to EHS excellence*'. Through this programme, Aventis seeks to carry out risk assessments for all its workplaces and reduce workplace accidents and environmental emissions. Furthermore, the company has planned to install an external EHS advisory board and obtain ISO 14001 certification for all its operational sites and management system. ISO 14001 is a standard for environmental management of the International Standard Organization (ISO) and involves external auditing and certification. Aventis says it applies a precautionary approach in product development and manufacturing.⁴¹ This means that environmental processes are not considered safe unless scientific evidence is available. Aventis retains responsibility for certain environmental damage caused in the past by divested subsidiaries of the company.⁴²

³⁹ Aventis 2003 Sustainability Report, p7.

⁴⁰ Aventis (n.d.). *Business Ethics and Legal Standards: Compliance Policy*. Available at <http://www.aventis.com/main/framework/filesserver.asp?id=758973532326669913>.

⁴¹ Aventis 2002 Sustainability Report, p9.

⁴² Aventis 2003 Sustainability Report, p54.

Regarding employment policies, Aventis says it supports a constructive dialogue with employees and their representatives. Employee satisfaction is measured in through an annual survey.⁴³

Aventis is a signatory to the UN Global Compact.⁴⁴ The Global Compact is a voluntary initiative that seeks to foster dialogue between companies and their stakeholders and to promote good corporate citizenship. The partners of the initiative commit themselves to nine principles on basic human rights, labour standards and environmental practices, but the Global Compact is in the first place a learning forum.⁴⁵

2.4 Implementation and governance

In 2003 the Aventis Responsibility Council (ARC) was established. This is a new executive-level management committee that supervises the Aventis Sustainability Policy. It still has to communicate this policy to all employees of Aventis. Furthermore, the company has a Global Compliance Officer dealing with compliance issues. This officer is supported by a number of cross-functional compliance committees for various CSR issues, including the following:⁴⁶

- Global Quality and Compliance Board, focussing on manufacturing standards
- Corporate Safety Board, dealing with the safety of medicines
- Environmental Health and Safety Review Committee, supervising the management of these issues
- Global Privacy Office, ensuring compliance with data protection requirements

2.5 Supply chain responsibilities

Aventis has established a Supply Chain Charter to clarify business processes and responsibilities in its supply chain. The company seeks long-term relationships with strategic suppliers.⁴⁷ Aventis states that it strives to ensure compliance with ethical business standards and core labour standards of the International Labour Organization (ILO) through its relationships with suppliers.⁴⁸ The company is also addressing EHS issues throughout the supply chain. However, it was not found how Aventis monitors and enforces compliance with ethical, labour and EHS standards.

2.6 Stakeholder involvement

⁴³ Aventis 2002 Sustainability Report, p28.

⁴⁴ Aventis 2002 Sustainability Report, p8.

⁴⁵ <http://www.unglobalcompact.org/Portal/Default.asp>.

⁴⁶ Aventis 2002 Sustainability Report, p7, 12-3; <http://www.aventis.com>.

⁴⁷ Aventis 2002 Sustainability Report, p18.

⁴⁸ Aventis 2003 Sustainability Report, p21-22.

Aventis explicitly recognizes the following stakeholders: ⁴⁹

- Patients
- Healthcare professionals and customers
- Third-party payers
- Regulators and government officials
- Shareholders and investor groups
- Non-governmental organizations (NGOs)
- Neighbourhoods and local communities
- Board members
- Employees
- Retirees
- Suppliers and contractors
- Industry peers
- The scientific community
- Universities and educators

The company has a stakeholder dialogue programme consisting of different internal and external projects. A major stakeholder project, largely driven by Aventis, has been a stakeholder dialogue on intellectual property rights and biotechnology. This project took place in 2001-2002 and was hosted by the World Business Council on Sustainable Development (WBCSD).⁵⁰ In 2002, Aventis initiated a broader Stakeholder Review and Consultation Process. This process is intended to provide stakeholders with an opportunity to influence company policies and to provide the company with a better understanding of stakeholder expectations.⁵¹ The outcomes of this process are not yet clear.

2.7 Transparency and reporting

Aventis publishes separate annual Sustainability Reports for its core-business. The format of these reports follows the reporting guidelines of the Global Reporting Initiative (GRI). The GRI has developed a set of globally applicable, voluntary reporting guidelines on economic, social and environmental performance.⁵² The reports of Aventis contain a GRI content reference that indicates on which pages information on a GRI reporting element can be found.⁵³

⁴⁹ Aventis 2002 Sustainability Report, p15.

⁵⁰ Aventis 2002 Sustainability Report, p15; see also WBCSD (July 2003). *Intellectual property rights in biotechnology and healthcare: results of a stakeholder dialogue*. Available at <http://www.wbcd.org/includes/getTarget.asp?type=d&id=MTQwNA>.

⁵¹ Aventis 2002 Sustainability Report, p15.

⁵² See <http://www.globalreporting.org>.

⁵³ Aventis 2002 & 2003 Annual Sustainability Reports.

Aventis provides detailed quantitative information on environmental performance, including energy and water consumption, waste generation and various kinds of air and wastewater emissions.

The 2002 report contained specific data on employment practices of the Aventis parent company only, covering some 200 employees. The 2003 report contained more detailed data on the 10 major countries, covering 75% of the workforce of Aventis. These countries are the US, Canada, France, Germany, Japan, the UK, Spain, Brazil, Mexico and Italy. The data include average working hours, employee wastage, training and benefits coverage for each country. For France, data are again more detailed and extend to reasons of departures, types of contracts and average salary.⁵⁴

On sustainable healthcare policy and access to medicines in developing countries, the reports provide do not provide a similar comprehensive account. Some general information is given on company policies, but the focus is on a large selection of highlights and case studies.

2.8 Independent verification

Statements in the 2002 Sustainability Report of Aventis were verified by two external auditors, PricewaterhouseCoopers and Gerling Risiko Consulting. The 2003 Sustainability Report was verified by PricewaterhouseCoopers alone. In both cases, the scope of the verification was confined to EHS data, EHS management systems and employment practices only.⁵⁵ This suggests that independent external verification of other aspects of Aventis' CSR performance does not take place.

The verification of the Sustainability reports is a standard procedure which, according to Dutch NGOs, cannot be regarded as 'independent verification', because of the contractual relationship between Aventis and PricewaterhouseCoopers. In the CSR Frame of Reference, a document created by Dutch civil society organizations and trade unions organised in a national CSR platform, 'independent verification' is described as verification carried out by organizations not linked to the company in question, and with the full trust of the stakeholders involved.⁵⁶ Such organizations could be independent analysts, NGOs or trade unions, for example.

2.9 Conclusion

Comparing Aventis' Sustainability Policy with the CSR Frame of Reference of Dutch civil society organizations and trade unions,⁵⁷ the policy at large covers a broad range of CSR

⁵⁴ Aventis 2002 Sustainability Report, p30; Aventis 2003 Sustainability Report, p445.

⁵⁵ Aventis 2002 Sustainability Report, p48; Aventis 2003 Sustainability Report, p64.

⁵⁶ MVO Platform (2003). CSR Frame of Reference.

⁵⁷ MVO Platform (2003). CSR Frame of Reference.

issues. This overarching policy is still relatively new and indicates that Aventis is in a process of adopting a more integral CSR approach. The Compliance Policy of Aventis, which comes closest to a code of conduct, does not cover all CSR issues. For example, it does not include several core labour standards or a section on consumer protection. It has now become part of a larger CSR approach.

Apart from access to medicines, the focus of Aventis' CSR approach is on legal compliance issues, EHS and employment relations. The choice of supported international standards in part reflects this focus. Additional support for a broader CSR standard, such as the guidelines for multinational enterprises of the Organization for Economic Cooperation and Development (OECD), might strengthen the credibility of the new overarching CSR policy.

Aventis reports elaborately on its CSR performance through annual Sustainability Reports. The GRI table of contents allows to quickly find specific information and transparency increased over the past years, for instance on employment conditions. However, further improvements are possible as equally detailed information about employment conditions in countries such as Korea and India were still lacking.

Although the CSR performance of the company is good on some issues, like EHS improvements in core-business facilities, the negative publicity mentioned above suggests that Aventis does not always implement its standards properly. This applies especially to commercial practices. In principle the endorsement of generally accepted international standards is positive, because it helps to establish a bottom line for CSR performance. Yet the unethical behaviour of Aventis Cropscience (currently not part of Aventis anymore) has raised doubts about the significance of Aventis' commitment to the Global Compact. Hence, the company is advancing with regard to CSR policies, information disclosure and other operational issues, but still has a negative track record to clear with regard to CSR performance.

3 CSR policy: medicines for developing countries

3.1 Patents

As a branded drugs producer, Aventis considers respect for intellectual property protection essential. *'Without exclusivity provided by patents and data protection, the private investment necessary for the development of new medicines could not be justified and patients would be deprived of the necessary innovations (...).'*⁵⁸ Yet Aventis also recognizes that different perspectives exist on intellectual property protection. A general policy of Aventis on patent flexibility could not be found. The company is said to be experimenting with licensing prescription drugs for generic production in developing countries.⁵⁹

For vaccines, in most cases Aventis does not consider licensing production to a local producer a feasible option. In contrast to pharmaceuticals, it is very complicated to set up a new production facility because of the complexity of vaccine manufacturing. As Aventis explains:

*'Countries must have independent and competent National Regulatory Authorities, the local producers must be producing under conditions of Good Manufacturing Practices (GMP), staff must be experienced and trained, assurance must [be] given of the same quality of vaccine from the local producer, and WTO agreements must be respected. For these reasons, transfers of technology must always be assessed for feasibility on a case-by-case basis. (...) There is a low probability that technology transfer will result in less expensive and more innovative products. Examples of truly successful technology transfer are rare.'*⁶⁰

In a few instances, though, Aventis has agreed to transfer technology for licensed production. According to company, in these specific cases there is a sound rationale, considering the realities of the local market, and good value can be derived for all stakeholders.⁶¹

Aventis spearheaded a project run by the WBSCD to explore controversial issues in the field of intellectual property rights (IPRs). The general outcomes of the project include some interesting statements and are quoted below.⁶²

⁵⁸ Aventis 2003 Sustainability report, p17.

⁵⁹ M. Hunter (2003). *Report of a meeting organized by INSEAD business school and the IPPPH*. Paris, France, 30 June - 1 July 2003.

⁶⁰ Communication with S. Gilchrist, 17 September 2003.

⁶¹ Communication with S. Gilchrist, 13 May 2003.

⁶² WBSCD (July 2003). Intellectual property rights in biotechnology and healthcare: results of a stakeholder dialogue. Available at <http://www.wbcsd.org/includes/getTarget.asp?type=d&id=MTQwNA>.

- A balance might be represented by the following three statements. However, this balance was not supported by all participants.

'1) Any sustainable solution to the conflict between IPRs and access to medicines should combine respect for human rights, the acknowledgement of property rights, and it should be compatible with R&D.

2) If there is a conflict, public health has primacy over IPRs.

3) Companies are economic agents and as such have a right to be profit oriented, but have a responsibility to act ethically and respect human rights. A right to compensation for innovation must be acknowledged. In particular, the human right to health does not apply to private products (medicines), but to the information required for manufacturing medicines as implied in the states' right to grant compulsory licenses.⁶³

- *'The participants did not agree on the interpretation of the 'exceptional nature' of compulsory licensing and on the adequacy and reach of parallel imports.⁶⁴*
- *'There was a broad consensus that companies have a moral duty to help those in need, and to promote better access to medicines for the poor. Participants did not agree, however, that such a duty could be framed in terms of human rights.'* Furthermore, *'as states have to integrate respect for the common good into their IPR legislation, companies have to accept the safeguards of TRIPS and abstain from any lobbying for TRIPS-plus legislation, which undermines the use of the safeguards.⁶⁵*

Aventis has joined the consensus on the three statements quoted under the first bullet point.

On the compulsory licensing issue, addressed under the second and third bullet, Aventis agrees with the WTO Ministerial Declaration on Intellectual Property and Public Health ('Doha Declaration' of November 2001), and with the agreement of 30 August 2003 implementing Article 6 of this Declaration. Both these agreements recognize the validity of compulsory licensing under specific circumstances.

Aventis is a member of the Pharmaceutical Research and Manufacturers of America (PhRMA), and this organization advocates a 'TRIPS-plus' agenda.⁶⁶ 'TRIPS-plus' lobbying pushes developing countries to offer intellectual property protection beyond TRIPS requirements. Aventis is in favour of a continuous improvement of intellectual property rights standards. However, the company would not support 'TRIPS-plus' legislations that

⁶³ WBCSD *ibid.*, p28.

⁶⁴ WBCSD *ibid.*, p29.

⁶⁵ WBCSD *ibid.*, p30.

⁶⁶ Oxfam briefing paper 56 (November 2003). *Robbing the poor to pay the rich?*

would undermine the use of the safeguards, such as compulsory licensing, included into the TRIPS agreement. In this respect, Aventis provided the following statement:

*'The TRIPS agreement is a minimum standard, accepted by all WTO members. This minimum does not prevent some members [that is, countries] to go beyond and to provide a better standard of intellectual property (IP) protection for their inventors. IP laws in the US or the European Union are already "TRIPS-plus" and we wish more WTO member states to join this improved standard. However, we limit our support to "TRIPS-Plus" legislations to measures that would not prevent countries to use the safeguards granted in the TRIPS agreement itself. The recent Free Trade Agreement between the USA and Morocco is an example of "TRIPS-Plus" which explicitly recognize Morocco the right to use compulsory licensing in case of public health crisis, according to the TRIPS agreement and the Doha Declaration.'*⁶⁷

3.2 Preferential pricing⁶⁸

Aventis Pasteur supports a policy of tiered pricing of vaccines on the condition that parallel trade controls exist. Tiered pricing of vaccines is limited to a few international buyers and poor governments, where there are well defined medical needs. The type of vaccines to which tiered pricing applies, depends on what international buyers and poor governments wish to purchase.⁶⁹

Since the 1970s, Aventis Pasteur has provided vaccines to UNICEF at differential prices,⁷⁰ which cover manufacturing costs only. This is a common approach among global vaccine manufacturers.⁷¹ Hence, differential pricing for vaccine supplies to GPPIs like the GPEI (which are also procured by UNICEF) was not initiated specifically for these GPPIs, but an already established practice. UNICEF procures vaccines through tenders and prefers to use a range of suppliers. Aventis searches to supply as much of the required vaccines as its production capacity allows. The company is not under any binding obligation to offer differential prices to UNICEF, but does so on a purely voluntary basis as has always been Aventis' policy. Because of the tender procedures, it would be impossible to publicly disclose these offers in advance. After the tender, the awarded contracts are made public by UNICEF.⁷²

Another large procurement agent, which also uses tenders for vaccine procurement, is the Pan-American Health Organization (PAHO). In general, the differential prices offered to the PAHO are a little higher than those offered to UNICEF. This is partly because of the much smaller volumes and partly because of the categories of differential prices which

⁶⁷ Communication with A. Aumonier, 14 September 2004.

⁶⁸ This section is largely based on an interview with S. Gilchrist, 13 May 2004.

⁶⁹ Communication with S. Gilchrist, 17 September 2003.

⁷⁰ Aventis 2003 Sustainability report, p33.

⁷¹ Communication with S. Gilchrist, 21 June 2004.

⁷² See http://www.unicef.org/supply/index_12/141.html.

Aventis applies. Differential prices for drugs for distribution in the poorest countries are set at a lower level than those for other developing countries. Aventis uses the World Bank division of countries into an A, B, C and D category. The poorest countries are in the A and B categories and have a GDP per capita of less than US\$ 1.000.

In all cases, Aventis tries to recover its R&D costs in high income markets. This implies that failure to generate sufficient return on investment from high income markets will in the long run have a negative impact on the company's ability to develop vaccines for at developing countries.⁷³ For newly developed medicines the principle is not different and Aventis will try to compensate for lower-priced supplies to developing countries through sales in high income countries.

Aventis perceives that differential pricing of new vaccines becomes more difficult now, because the vaccines that are used in developing countries are no longer the same as those that are used in high income countries. For instance, polio immunization campaigns in developing countries use Oral Polio Vaccine (OPV), while regular immunization in high income countries uses Inactivated Polio Vaccine (IPV). UNICEF is now almost the exclusive buyer of OPV. As a consequence, the sales of a vaccine to developing countries can no longer be subsidized by the sale of the same vaccine in high income countries.

Regarding its AIDS vaccine in phase III trials, Aventis comments that it is still too early to say how access to this vaccine would be provided for developing countries. However, it is expected that differential pricing will be applied. The company is now in discussion with the Thai government on a regulatory framework to make the vaccine eventually available. According to Aventis, AIDS does not fit existing business models. In contrast to past introductions of new medicines, the majority of supplies would go to developing countries right after the introduction. It would therefore be impossible to fully recover R&D costs.

The pricing policy described above applies to vaccines. The position of Aventis on differential pricing of prescription drugs is quite similar, but it could not be found how it this policy is implemented. Aventis' statement reads as follows:

*'Aventis believes that adjusting medicine prices to the economic capacity of the different markets to bear these prices is for the mutual benefit of both producers and consumers. However, one has to make sure that low prices benefit to patients who have limited means to pay, not to intermediaries who would only make business in buying at low prices in certain countries or in privileged distribution channels and sell them back on wealthy markets. Differential pricing has to go along with protected distribution systems and strict limitation of parallel trade. When this is possible, Aventis is in favour of practicing differential pricing.'*⁷⁴

⁷³ Communication with S. Gilchrist, 21 June 2004.

⁷⁴ Communication with A. Aumonier, 14 September 2004.

3.3 R&D

At the beginning of 2004, Aventis has over 30 human drug and vaccine candidates in preclinical development, over 40 candidates in early-stage development and 14 in late-stage.⁷⁵ These include vaccine candidates for cancer, meningococcal meningitis and dengue (all phase 1), SARS (phase I or II), RSV (Respiratory Syncytial Virus) (phase II), and prophylactic and therapeutic vaccines for HIV/AIDS (phase II and III, respectively).⁷⁶ Clinical trials for the prophylactic HIV/AIDS vaccine are currently being carried out in Thailand and will finish in 2006 or 2007. Some of the R&D programmes are carried out through partnerships, like the Paediatric Dengue Vaccine Initiative (PDVI) and Dengue Vaccine Project (DVP). The HIV/AIDS vaccine is being developed in partnership with VaxGen.

Although some of the R&D programmes of Aventis are of special relevance for developing countries, the company does not describe any special commitments or explicit targets (for example in terms of R&D expenditures) for R&D on diseases that mainly affect these countries. It is also remarkable that Aventis has not been developing better alternatives for the drugs against sleeping sickness it currently donates to the WPESS.

3.4 Conclusion

Aventis' central role in the WBCSD project shows that the company is willing to discuss the problems associated with intellectual property protection and explore alternative intellectual property regimes. By providing additional information for this report, Aventis also shows transparency about its position on patent protection. The support of the company for the safeguards in the TRIPS agreements is positive and shows that Aventis recognizes the need to balance intellectual property protection with public health concerns. However, the company's position in favour of other aspects of 'TRIPS-plus' legislation might limit access to medicines in developing countries.

With regard to pricing policies for vaccines, Aventis follows a constructive approach. The differential prices of vaccines for procurement by UNICEF and the PAHO are substantially lower and apparently Aventis uses objective criteria for eligibility, although these are not fully disclosed. Due to the procurement of vaccines through tenders Aventis is not able to publish preferential pricing offers in advance, but the company could still increase transparency by publishing a list of all vaccines on which it has applied preferential prices in retrospect, for example. It is not known for which prescription drugs preferential pricing is applied.

Some of the R&D programmes of Aventis are of special relevance for developing countries. However, the company does not describe any special commitments or explicit targets (for

⁷⁵ Aventis Form 20-F Report 2003.

⁷⁶ <http://www.aventispasteur.com>.

example in terms of R&D expenditures) for R&D on diseases that mainly affect these countries. Aventis has several R&D programmes on vaccines relevant for developing countries and participates in R&D partnerships for such vaccines. The research did not find comparable information on R&D for prescription drugs.

4 GPPI involvement

4.1 Introduction

Aventis participates in the following Global Public-Private Initiatives (GPPIs) specifically aimed at healthcare in developing countries, that are registered at the Initiative on Public-Private Partnerships for Health (IPPPH):⁷⁷

- Global Polio Eradication Initiative (GPEI)
- WHO Programme to Eliminate Sleeping Sickness (WPSS)
- Global Alliance for Vaccines and Immunization (GAVI)
- Paediatric Dengue Vaccine Initiative (PDVI)
- Dengue Vaccine Project (DVP)
- Stop TB Partnership (Stop TB)

Aventis also supports the TB Free programme in South Africa, a partnership with the Nelson Mandela Foundation that might also be regarded a GPPI. In addition, Aventis funds a variety of smaller initiatives like the Aventis Tropical Disease Centre (CADT) and a separate programme against leishmaniasis in São Vicente Ferrer, both in Brazil. The report does not cover these local partnerships.

The two dengue projects mentioned above are R&D collaborations. The GPEI, WPSS, GAVI and TB Free are the four major partnerships of Aventis aimed at enhancing access to medicines and strengthening local health infrastructure. These GPPIs and will be described in more detail. Stop TB is a partnership with a global coordinating function. Aventis does not play a major role in it, and it will be shortly mentioned only in the section on TB Free.

4.2 Global Polio Eradication Initiative (GPEI)

Background and donation strategy

When the GPEI was started in 1988, the WHO aimed at the global eradication of polio by 2000 through large-scale vaccination campaigns. However, in the late 1990s it realized that this target would not be reached. The WHO then sought to double the amount of vaccinations. As funds for this sudden large increase were not available, the WHO asked for product donations.

The WHO proposed to the company a specific region with limited resources, to which it could donate a part of its production. It happens that the WHO receives many specifically ear-marked contributions from donors. Donors may require, for example, that their funds are used in countries where sufficient infrastructure is available for the distribution of the vaccine. As a consequence, the WHO identified 5 African conflict countries to receive

⁷⁷ <http://www.ippph.org>

donations from Aventis. Together these countries needed 50 million doses for a period of three years. Although some flexibility was allowed in the use of the donation, the five countries had intense National Immunization Day activities at the time of the donation and all vaccine was actually used by those countries targeted.⁷⁸

During the peak years 1999-2001, Aventis sold 275-300 million doses annually to UNICEF at preferential prices in addition to the donation of 50 million doses for these three years. The total quantity of global OPV administration amounted to about 2 billions of doses a year, which was at maximum global production capacity. In 2001, nearly 2 billion doses of OPV were administered during national and sub-national immunization days.⁷⁹ OPV administration in 2002 was at a comparable level. Some 1.3 billion doses of these were procured through tenders by the central Supply Division of UNICEF, for a total of US\$ 107 million. Hence, UNICEF purchases the vaccine at approximately \$0.08 per dose. Another 500 million doses were purchased locally by the UNICEF India Country Office.⁸⁰

Although the donation of 50 million doses was a rather small share of total OPV administration, Aventis Pasteur points out it was a significant amount when compared to its own annual sales of the 300 million doses. Aventis' total OPV donations since 1997 now amount to 120 million vaccine doses.⁸¹ The WHO approached other pharmaceutical companies for donations too, and some of them agreed to make donations, although in smaller quantities than Aventis Pasteur.⁸² Chiron, for example, provided 20 million free doses of OPV between 1997 and 1998 and donated another 9.5 million doses in 2002. GlaxoSmithKline has also made OPV donations.⁸³

Conditions for the donations

Aventis signed a tripartite Memorandum of Understanding (MoU) for the GPEI with the WHO and UNICEF for each donation. The company does not publicly release the agreement,⁸⁴ but the public policy manager of Aventis Pasteur was willing to explain the contents of the most recent agreement.⁸⁵ These can be found in Annex 1. Adherence to the agreement is monitored by the other partners.

Governance of the GPEI

⁷⁸ Interview with S. Gilchrist, May 13, 2004.

⁷⁹ WHO (29 March 2002). *Progress towards the global eradication of poliomyelitis, 2001*. In: Weekly epidemiological record, 17(13), 98-107.

⁸⁰ See http://www.unicef.org/supply/supply_division_annual_report2002.pdf.

⁸¹ <http://www.aventis.com>.

⁸² Interview with S. Gilchrist, May 13, 2004.

⁸³ http://www.chiron-vaccine.com/company/4_570.php; GPEI Strategic Plan 2004-2008, p37.

⁸⁴ Communication with S. Gilchrist, June 21, 2004.

⁸⁵ Interview with S. Gilchrist, May 13, 2004.

Although Aventis is a partner in the GPEI, it has not been involved in the design of the partnership strategy. Aventis states that this is not the role of the company. The company explains that its role has been one of a vaccine provider, and that its participation in the GPEI has helped to ensure better planning with respect to the actual vaccine needs, as these needs change in the course of progress towards polio eradication. Aventis adds that it has a role in advocacy as well; the company engaged in a social mobilization campaign to raise public awareness of the eradication campaign.

4.3 WHO Programme to Eliminate Sleeping Sickness (WPSS)⁸⁶

Background and WPSS design

There exist four drugs for the treatment of sleeping sickness (African trypanomiasis). One of these drugs, eflornithine, was developed by Marion Merrell, one of the Aventis' mother companies in the 1980's in collaboration with the WHO. It was one of the very few medicines for neglected diseases developed in the past decades. When Rhône-Poulenc and Hoechst merged in 1999 to form Aventis, the combined portfolio included three of the four available medicines: pentamidine, melarsoprol and eflornithine. The fourth medicine, suramin sodium, is producer by Bayer. This medicine is only used to treat the less common, faster developing type of the disease (*T. b. rhodesiense*).

Thus, the merger effectively eliminated competition for the supply of sleeping sickness drugs, creating a monopoly position that brought a large responsibility for Aventis. Rhône-Poulenc had already a long-standing donation programme of Pentamidine to the WHO. Building on this programme, Aventis decided after the merger to donate all three drugs.

In the case of the WPSS, Aventis considered product donations the most appropriate strategy to provide the medicines at this stage of the elimination of sleeping sickness. Differential pricing was not an option, because there does not exist a market for the medicines outside developing countries. The company did not seek for an external donor organization to buy the medicines either. When the WPSS comes to an end in 2006, the company will again consider what kind of approach will be most appropriate to continue the cooperation. This could be continued donations, differential pricing or another option, depending on changing contexts and adjusted to the needs at that moment.

Aventis stresses that the maintaining of manufacturing capacity for these drugs is more important than the financial sustainability of the programme, as this capacity cannot be easily replaced. Aventis has contracted the manufacturing of the drugs to external producers, but remains responsible for production. This is in accordance with normal business practices in the pharmaceutical sector. At present Aventis is arranging for the transfer of the relevant manufacturing technology in developing countries.

⁸⁶ This section is largely based on an interview with A. Aumonier, 3 June 2004.

As the WHO expressed the need for a broader programme beyond drug donations, including support for the distribution of the medicines as well as greater R&D efforts for new medicines and treatments, Aventis and the WHO then agreed on a 5-year partnership with three components: drug donations, disease management and control, and R&D. Aventis has committed a total amount of US\$ 25 million for this partnership.

The WPESS was started in 2001. In 2002 Bayer also became a WPESS partner. Bayer agreed to restart the production of suramin and nifurtimox⁸⁷ and donate these drugs. In addition, Bristol-Myers Squibb donated the bulk material for the production of the eflornithine provided by Aventis to WHO during the first year of their partnership.⁸⁸

Conditions of the partnership

Aventis Pharma AG, the global pharmaceuticals division of the company, signed a agreement with WHO for the WPESS. This agreement is not publicly disclosed. Aventis made a commitment to donate the drugs for a period of 5 years. The company is also providing cash funding to the WPESS during this period. The donations are made in accordance with the WHO guidelines on drug donations. Every six months, the WHO makes adjusted forecasts for medicine requirements for the next 12 months, which Aventis uses for the planning of its production. The drugs are distributed by Médecins sans Frontières (MSF).

Governance of the WPESS

The commercial sector partners are not represented on the Steering Committee of the WPESS. Inside Aventis, the director of international public affairs coordinates all aspects of WPESS and is the final responsible for the programme. He works closely together with the WHO officer that coordinates the WPESS at the WHO.

Description of company contributions

The total drug donations of Aventis have an estimated value of US\$ 12.5 million. This value is based on initial forecasts of the drug manufacturing cost, not wholesale value. This does not include the value of the raw material provided by Bristol-Myers Squibb to Aventis (estimated at US\$ 3.6 million by BMS).⁸⁹ Part of Aventis' production costs qualify for a tax break.⁹⁰ As of 15 April 2004, Aventis had provided 180,000 vials of eflornithine, 340,500

⁸⁷ Apparently this fifth drug is also used against sleeping sickness. On the WHO list of essential medicines, it is listed as a treatment for American trypanomiasis. See WHO (April 2003). *Essential medicines: WHO Model List, 13th edition*.

Explanatory Notes

⁸⁸ <http://www.ippph.org>.

⁸⁹ It is not known on which basis Bristol Myers Squibb has valued its donation. Apparently the value of US\$ 3.6 million is higher than the total manufacturing cost of the drug.

⁹⁰ WHO (2002). WHO Programme to Eliminate Sleeping Sickness: Building a Global Alliance.

vials of pentamidine and 665,000 vials of melarsoprol.⁹¹ In addition, Aventis makes contributions for two WHO programs (disease management and control program and R&D for new treatments program) for an estimated amount of 12,5 million for the period 2001-2006.

Other WPESS donors are now considering to join the disease control programmes, and the demonstrated results of the programme attract new partners. For disease management and control, the Gates Foundation has committed US\$ 15 million. These funds will be used to develop diagnostics.

Company benefits

The WPESS does not yield any financial benefits for Aventis. However, the company still considers this partnership a win-win situation. Many of Aventis' programmes with a philanthropic nature are initiated by local subsidiaries. Therefore these actions are hardly visible. The WPESS, in contrast, is not a local initiative but a corporate programme. Its high profile offered an opportunity to illustrate the public health commitments of Aventis and to create a positive identity for the merged company. This element of the company's reputation is important for the public at large as well as for employees. It gives the latter an opportunity to work for something else than financial profits only. Aventis stresses that its high public profile was not a reason to initiate the programme, though. The company explains that the WPESS had absolutely no visibility when it was first started.

4.4 Global Alliance for Vaccines and Immunization (GAVI)⁹²

Background

GAVI has evolved from the Children's Vaccine Initiative (CVI), which was an outcome of the World Summit for Children in September 1990. The goal of that partnership was to promote global vaccination and it was funded by the WHO, The World Bank, UNICEF, UNDP and the Rockefeller Foundation.⁹³ After disagreement between these five organizations on the role of the CVI, it was dissolved in 1999 and it was agreed that another initiative would replace it. Thus the GAVI was established, and the newly started Gates Foundation created the Vaccine Fund of US\$ 750 million to support it. As Aventis had already been cooperating on the CVI, Aventis Pasteur participated in the discussions that founded the GAVI and in the design of the new partnership.

Industry commitments

The pharmaceutical industry, as a whole, has made five commitments to GAVI:

⁹¹ <http://www.aventis.com>.

⁹² This section is largely based on an interview with S. Gilchrist, May 13, 2004.

⁹³ <http://www.who.int/archives/inf-pr-1997/en/pr97-78.html>.

- To supply high quality vaccines
- To support training and education in developing countries
- To continue R&D on vaccines for developing countries
- To support advocacy and awareness raising
- To continue to develop technologies to facilitate administration and distribution of vaccines

Each industry partner decides on its own approach. Apart from the general industry commitments and the Guiding Principles of GAVI, commitments of partners may be recorded in Board meetings and other partners' meetings. However, there does not exist a Memorandum of Understanding or other formal agreement that specifies the commitment and responsibilities of partners to GAVI.⁹⁴

Aventis points out that GAVI is an alliance rather than a partnership. It is not an organization. Aventis explains that an alliance *'regroups all of the necessary partners, from both private and public sectors, needed to achieve its goals. (...) each member plays a unique role in the alliance, such that without an alliance the attainment of specific goals would be more difficult or timely.'*⁹⁵ It considers that one of the advantages of working in an alliance is that all partners continue to play the roles of each of the respective organisations. Hence, there would be no need for a formal agreement specifying the commitment and responsibilities of partners to GAVI.

Governance of GAVI

The chairman and CEO of Aventis Pasteur had a seat in the 12 member board from the start of GAVI in 1999 to 2002. After that, the president of Wyeth took over the board seat for the industry representative, and in 2003 it passed on to the president of Chiron. The pharmaceutical industry partners coordinate their position among themselves and speak as a group. Because the vaccine industry was involved in GAVI right from the beginning, it has never been a question whether the industry should be represented in the board. Aventis itself perceives its central role in the partnership as the result of an evolution. In the past the role of Aventis used to be more limited and more focussed on the supply of vaccines. This still applies to older GPPIs, such as the GPEI. The larger role of the industry is considered an advantage to the partnership, preventing logistical and distributional problems as described below.

Although it is not always successful in defending its position, Aventis actively contributes to shaping the structure of GAVI and its strategies. Aventis considers that one of the main contributions of the vaccine industry has been to better educate GAVI partners, such as

⁹⁴ Communication with S. Gilchrist, 21 June 2004.

⁹⁵ Communication with S. Gilchrist, 17 September 2004. Note that GAVI is sometimes referred to as a partnership too, and the two words are used often interchangeably. On the GAVI website, for example, it reads *'It is an historic alliance (...)'* as well as *'A new type of public-private partnership, GAVI brings together (...)'*. See <http://www.vaccinealliance.org>.

UNICEF, on all aspects of vaccine production. These include the duration of production cycles, industrial constraints, and the regulatory environment in which the industry operates. In contrast to past practices, UNICEF now forecasts future vaccine needs and contracts their production on a 3-year basis, which fits better with the time-scale that pharmaceutical companies need for the production of large quantities of vaccines.

In addition, unlike with the CVI, GAVI has resources to allocate to the reinforcement of national health systems. The vaccine industry strongly supported the inclusion of infrastructure strengthening and training and education for healthcare workers in developing countries in the initiative. These concern issues like the maintenance of inventories and cold chains (permanent refrigeration of vaccines from production to delivery). One of the important goals of GAVI is to reduce the wastage rates of vaccines resulting from poor planning from as much as 75% to less than 15% for the newly introduced vaccines.

Targeted diseases

Aventis encouraged GAVI to focus on the three diseases *Haemophilus influenzae* type b, Hepatitis B and yellow fever. Apparently these diseases were identified by GAVI partners, including the WHO and World Bank. The *Haemophilus influenzae* type b and Hepatitis B vaccines had already been very successful in high income countries, but the major burden of these diseases would be in developing countries. According to GAVI estimates, these diseases cause approximately 450,000 and 520,000 deaths per year, respectively.⁹⁶ Yellow fever, the third priority disease, was not discussed at the proto-board meeting in July 1999.⁹⁷ However, it was formally adopted as a priority disease together with *Haemophilus influenzae* type b and Hepatitis B at the first board meeting of GAVI in October 1999.⁹⁸ Yellow fever vaccines had been recommended, where prevalent, since 1985, but no sustained programme for the delivery of this vaccine was in place yet. Yellow fever causes approximately 30,000 deaths per year. According to Aventis, a focus on these three under-used vaccines was therefore a logical choice and would have a major impact. Regarding more traditional vaccines, GAVI has asked and obtained some support for other initiatives as well, including polio and measles control activities.

⁹⁶ The approximate annual death toll of some other infectious diseases may be helpful to put these figures into context: 5,000 for diphtheria, 300,000 for tetanus and for pertussis, 500,000 for rotavirus, 750,000 for measles, and 1.6 million for pneumococcus infections. Data from

http://www.vaccinealliance.org/home/General_Information/Immunization_informa, years not specified. The World Health Report 2004 gives figures for 2002 for some of these diseases too. In some cases figures are comparable, in others WHO figures are up to 30% lower. Note that the death toll of Hepatitis B is contested, though. See e.g. V. Taneja (29 April 2002). *Silence of WHO is deafening*. In: BMJ, <http://www.bmj.com/cgi/eletters/324/7343/974/a>.

⁹⁷ GAVI (1999). Meeting of the Proto-Board. Seattle, Washington, 12-13 July 1999.

⁹⁸ GAVI (1999). First Board Meeting. New York, 28 October 1999.

Aventis is itself one of the four producers in the world for yellow fever vaccines.⁹⁹ It has the largest production capacity and is the main supplier of this vaccine to GAVI. In April 2004 it received a US\$ 34 million contract from UNICEF for yellow fever vaccines supplies.¹⁰⁰ These sales are at differential prices like other supplies to UNICEF. According to Aventis, GAVI does not request or receive any vaccine donations.¹⁰¹

Criticism on GAVI

On several occasions, the focus of GAVI on the introduction of relatively expensive vaccines has been criticized. According to some, the selected diseases would not have the highest priority from a public health point of view. It has been suggested that the burden of Hepatitis B in India has been misrepresented at 200,000 deaths per year, whereas the figure may be as low as 5,000, and that natural immunity against *Haemophilus influenzae* type b exists in India and Turkey. Hence, it is argued that the benefits of these two vaccines have been overestimated.¹⁰²

As of July 2004, five-year support from GAVI to 70 developing countries for new and under-used vaccines, including new combination vaccines, was estimated at US\$ 654 million. This sum does not include the support for the development of new vaccines and is additional to US\$ 337 million of five-year commitments for basic immunization services support plus US\$ 86 million over three years for injection safety.¹⁰³ Some have been argued that the massive resources available for the introduction of under-used vaccines would be better used in other ways and that more priority should be given to the strengthening of health infrastructure in developing countries.¹⁰⁴ Aventis questioned this criticism and explained that new combination vaccines could not be attracting attention away from UNICEF's regular Expanded Programme on Immunization (EPI):

*'GAVI's purpose is to provide needed vaccines to all children (...). WHO and UNICEF are full partners and supporters of GAVI. In order to qualify for support from GAVI, countries must show that they are improving vaccination coverage with the regular EPI vaccines.'*¹⁰⁵

⁹⁹ http://www.childrensvaccine.org/html/v_yellow_vac.htm, a source from the CVI, mentions 3 manufacturers of yellow fever vaccines only. Communication with S. Gilchrist, 17 September 2003, suggests four manufacturers according to the WHO.

¹⁰⁰ http://www.unicef.org/supply/index_12/141.html.

¹⁰¹ However, Merck & Co did commit to make a donation of 5 million doses of hepatitis B vaccines to the GAVI for the period 2000-2004. See <http://www.anrpt2000.com/16.htm>.

¹⁰² V. Taneja (29 April 2002). *Silence of WHO is deafening*. In: BMJ, see <http://www.bmj.com>; J. M. Puliyeel (21 February 2004). *Plea to restore public funding for vaccine development*. The Lancet, vol. 363; R. K. Ohja e.a. (8 February 2002). *Vaccine promotion is circumventing market forces*. In: BMJ, see <http://www.bmj.com>.

¹⁰³ http://www.vaccinealliance.org/home/Support_to_Country/Country_Status/index.php.

¹⁰⁴ M. Starling, R. Brugha, G. Walt, A. Heaton & R. Keith (2002). *New products into old systems: The GAVI from a country perspective*. London: Save the Children; G. Yamey (23 November 2002). *WHO in 2002: Faltering steps towards partnerships*. In: BMJ, 325, 1236-1240.

¹⁰⁵ Communication with S. Gilchrist, 17 September 2004.

The financial sustainability of GAVI has been another source of concern. The newly introduced vaccines are now delivered free of charge, but the current funding commitments are for a period of five years only. The governments of developing countries will not be able to support the use of the vaccines themselves. Therefore some consider the programme unsustainable.¹⁰⁶ GAVI has been addressing the of financial sustainability. A special Financing Task Force exists and GAVI requires countries receiving Vaccine Fund grants to prepare a Financial Sustainability Plan. However, a recent study shows that large funding gaps after the end of Vaccine Fund support continue to exist. The two main reasons for this problem are that the high prices of the new vaccines have not come down and that multi-year commitments from bilateral donors are still lacking. The key assumptions that GAVI would drive the prices of the vaccines down and act as a catalyst for further support by partners have not sufficiently borne out.¹⁰⁷

Potential conflicts of interest

Being at the same time a board member deciding which diseases to target and the main supplier for vaccines for one of these diseases, a suggestion of a conflict of interests might exist. However, according to Aventis Pasteur this has never been an issue. Aventis explains that from an industrial point of view, it is helping the public sector, so it does not see any conflicts of interest.

After the launch of GAVI, in 2000, the WHO completed a set of *Guidelines on interaction with commercial enterprises for health outcomes*. These specify that 'in developing relationships with commercial enterprises' 'staff should always consider whether a proposed relationship might involve real or perceived conflicts of interest' and therefore recommend 'a step-by-step evaluation of the commercial enterprise'.¹⁰⁸ Although it is not completely clear how these guidelines were applied, Aventis emphasizes that conflicts of interest have been discussed at GAVI Board meetings. Furthermore, on several occasions partners that may have had a conflict of interests were recused from the discussions in the Board Meetings.¹⁰⁹ The reports of Board Meetings and summaries of teleconferences are all available on the GAVI website.¹¹⁰

Apparently no Board members have ever perceived concerns about conflicts of interest to be an obstacle for the partnership. On the contrary, every actor previously involved with

¹⁰⁶ *Expert meeting 'internationale publiek-private initiatieven in de gezondheidszorg'*. 28 November 2002, Breukelen, The Netherlands; M. Starling, R. Brugha, G. Walt, A. Heaton & R. Keith (2002). *New products into old systems: The GAVI from a country perspective*. London: Save the Children.

¹⁰⁷ M. Kaddar, P. Lydon & R. Levine (2 July 2004). *Financial Challenges of immunization: a look at GAVI*. Bulletin of the WHO, 82, 697-702.

¹⁰⁸ WHO (30 November 2000). *Guidelines on working with the private sector to achieve health outcomes*, annex, p3.

¹⁰⁹ For example, during the discussion on the approval of ADIPs. See GAVI (2002). Ninth GAVI Board Meeting. Dakar, 18-19 November 2002. The reports on the first Board Meetings do not include such information.

¹¹⁰ See http://www.vaccinealliance.org/home/Board/Board_Reports/board_docs.php. Not all reports are equally detailed about the meetings themselves, though.

the CVI was invited to join GAVI. Aventis remarks that criticism on the objectives and functioning of GAVI, as for example voiced in a press release¹¹¹ on a Save the Children report in 2002, seems not to be specifically aimed at the role of the industry and was rejected by all board members.

EPIVAC

Aventis Pasteur supports EPIVAC, a vaccinology training programme in Western Africa that is linked to GAVI. It is a professional course for doctors and medical health managers that aims to strengthen the local healthcare infrastructure. It focuses on the management of the economic, financial and human resources for disease prevention through vaccination, practical aspects of vaccinology, and computation skills. The EPIVAC is implemented by the NGO Association pour l'Aide à la Médecine Préventive (AMP). The programme was developed in partnership with the national governments of the recipient countries, the Universities of Abidjan-Cocody and Paris IX Dauphine, and in collaboration with the WHO, UNICEF and other GAVI partners. Aventis Pasteur provides funding for its first 5 years, from 2002 to 2007. It is expected that 250 district medical health officers will be trained during this period. In 2002, EPIVAC was started in Benin, Burkina Faso, Ivory Coast and Mali. By 2004 it should also be covering Senegal, Cameroon, Gabon, Mauritania, Niger, Central Africa and Togo.¹¹²

Coordination with other training programmes

Other companies and organizations run training programmes in Africa in support of GAVI too. Merck runs the Merck Vaccination Network-Africa (MVN-A) in Kenya and Mali. Some aspects of this programme are similar to EPIVAC. GlaxoSmithKline has a historical focus East Africa and English speaking countries, and the emphasis of its courses is on the use of GlaxoSmithKline products. GlaxoSmithKline is building on its existing infrastructure, whereas Merck funds the project but does not have vaccine businesses in Africa. The WHO has a programme on cold chain management in Egypt and UNICEF and the US-based charity PATH runs training programmes as well. These various efforts are discussed at the WHO's Training Partnerships meetings, which helps to coordinate them. Aventis was the first company to start a training programme linked to GAVI and has been building on its existing infrastructure in Africa. It is historically well-represented in French-speaking Western Africa.¹¹³

4.5 TB Free

Short description

¹¹¹ See F. Fleck (2002). *Children's charity criticises global immunization initiative*. In: BMJ, 324, 129.

¹¹² http://www.aventispasteur.com/index.cfm?FA=OUR_COMMITMENT_2.

¹¹³ Communication with Ms. E. Esber (Merck & Co), 29 June 2004.

In May 2002, Aventis initiated the programme TB Free to improve the health situation of people with TB in South Africa. The programme is implemented by the Nelson Mandela Foundation in coordination with the South African government. The Aventis Foundation will provide 15 million Euro over period of five years. TB Free has been set up as a legally independent, local not-for-profit organization. The goals of TB Free are based on the Global Plan to Stop TB, for instance, the detection of 70% of all new TB cases and the cure of 85% of all detected cases.¹¹⁴ This Global Plan was adopted by the Stop TB Partnership, which has a global coordinating function. Although the TB Free programme follows the framework offered by the Stop TB Partnership, it is operating independently and has its own governance structure.

TB Free strategy

Aventis considered that the price of drugs is not the most important problem for the treatment of TB. Patents on TB drugs have since long expired, there is competition from generic drug manufacturers and prices are relatively low. Compliance with the treatment regime, in contrast, is a major problem. The treatment of TB requires the strict observance of a complicated treatment scheme, involving the use of different drugs during a period of 6 months. In addition to treatment failure, non-compliance increases the risk of drug resistance. Aventis therefore chose not to provide TB drugs for free, but to train people to support treatment compliance.

TB Free will help to improve the detection and treatment rates through implementing Patient Compliance Projects and the so-called Directly Observer Treatment, Short-course (DOTS) strategy approved by the WHO. At present there is on average one DOTS supporter, who ensures treatment compliance by directly observing it, for every 25 patients in South Africa. In the end there should be one supporter for every two patients. It is foreseen that 9 TB expert centres will be established, one in every province. Teams of Aventis employees will be involved in the trainings. The courses do not focus on the use of Aventis products, but on TB treatments in general.¹¹⁵

Choice of target country

Aventis decided that a country-based strategy would be more appropriate than a worldwide programme. South Africa was chosen as the beneficiary country for several reasons.

- It is one of the countries most affected by TB.
- There was a demand from the country itself.
- A reliable local partner was available, the Nelson Mandela Foundation.
- Aventis staff is well present in South Africa.

¹¹⁴ http://www.aventis-foundation.org/_en/keyprojects/civilsociety/tbfree/index.html;
<http://www.aventis.com>;

¹¹⁵ Interview with A. Aumonier, 3 June 2004.

Aventis explains that the TB Free may be replicated in other countries if the experiences with the programme are positive.

5 GPPI policy

5.1 The rationale for GPPIs

Aventis' corporate Director of International Public Affairs states for access to medicines in developing countries cooperation between different stakeholders is essential. The access problem includes issues like infrastructure, and the corporation considers itself as part of the solution only. Thus, the rationale for GPPIs would be evident.¹¹⁶

GPPIs tend to naturally evolve, as companies and organizations work on the same issue. Aventis does not have a policy to initiate partnerships or to identify partners. Instead, partners become naturally involved.¹¹⁷

Aventis does not see its role in partnerships as a substitute for government efforts. The company responds to the needs it perceives, but at the same time it constantly reminds governments of their responsibilities. Aventis searches to address the potential crowding out of local government efforts by actively involving the public sector in developing countries in GPPIs.¹¹⁸

The business benefits of a GPPI vary according to the nature of a the partnership, which can be R&D-oriented (e.g. PDVI) or philanthropic (e.g. GPEI). The value of research-oriented partnerships is in the acceleration of the development of a vaccine. The main benefits of philanthropic programmes, on the other hand, are an enhanced corporate image and the sense of pride that it creates, which motivates employees. This has been an important benefit of the high-profile WPRESS initiative. As a general rule, Aventis has not been able to determine the financial value of these benefits, but there is a general recognition that the philanthropic activities do yield benefits.¹¹⁹

There might be other business benefits than those mentioned above by Aventis. The vaccine supplies to GAVI generate businesses for Aventis, for example. However, Aventis points out that sales to GAVI are a tiny part of the company's our overall business.¹²⁰ The close involvement of pharmaceutical companies in GPPIs may provide them with important first-hand business information. Some consider it could be useful, for example, to approach countries that will apply for new vaccine supplies in an early stage. Yet Aventis emphasizes that companies are not in a position to influence the choices of governments, so that such benefits do not occur.¹²¹

¹¹⁶ Interview with A. Aumonier, 3 June 2004.

¹¹⁷ Interview with S. Gilchrist, 13 May 2004.

¹¹⁸ Interview with S. Gilchrist, 13 May 2004.

¹¹⁹ Interview with S. Gilchrist, 13 May 2004.

¹²⁰ Communication with S. Gilchrist, 17 September 2004.

¹²¹ Communication with S. Gilchrist, 17 September 2004.

5.2 Management of GPPIs inside the company

Partnerships involving vaccines are managed by Aventis Pasteur, while other types of partnerships are managed by other parts of the company. The management of GPPIs inside Aventis is established on an individual basis, the company does not have a central organ that is responsible for them. As a general rule, a team of people from different departments is involved and the partnership is endorsed by a senior corporate manager. Usually the primary responsibility for R&D-oriented partnerships lies with the R&D department, while that for philanthropical partnerships lies with the corporate public policy group.¹²² Ultimately Aventis programmes are decided at the highest level, the Board of Management. Although it is not always easy to involve the board, its support is considered essential.¹²³

Some typical examples of arrangements for the management of GPPIs are given below.

- In the case of the GPEI, the senior corporate management was requested to formulate the GPPI. The Aventis Pasteur public policy manager is responsible for this partnership. However, it is ultimately managed by a team, composed of people from the marketing, industrial operations, regulatory affairs, communication and legal departments.
- For the Paediatric Dengue Vaccine Initiative (PDVI), staff from the R&D department made a proposal and designed the partnership strategy. This proposal was then approved by the senior management. The research head has a central role in this partnership.
- For GAVI, the Chairman and Chief Executive Officer of Aventis Pasteur (Mr. J. Bertrand) was a board member from 1999 to 2002. Thus, a high corporate management of the Aventis was directly involved with the management of the GPPI.
- For the WPRESS, coordination and final responsibility lies with the corporate Director of International Public Affairs. He works closely together with the WHO officer that coordinates the WPRESS at the WHO.
- Several community initiatives, including partnerships with a more national or local character, are managed by the various company foundations of Aventis. The Germany-based Aventis Foundation (formerly the Hoechst Foundation) is involved with TB Free. For this partnership a new South African not-for-profit organization was created in which the Aventis Foundation is represented. The France-based Institut Aventis Pharma France is involved with a wide range of initiatives, among which a programme against leishmaniasis in São Vicente Ferrer, Brazil.

5.3 GPPI conditions

¹²² Interview with S. Gilchrist, May 13, 2004.

¹²³ M. Hunter (2003). *Report of a meeting organized by INSEAD business school and the IPPPH*. Paris, France, 30 June - 1 July 2003.

As GPPIs tend to naturally evolve, Aventis does not have a set of minimum conditions which partnerships or potential partners have to meet. These are established on a case by case basis. The negotiations about a partnership culminate in an agreement.¹²⁴ These agreements are not publicly disclosed.

5.4 GPPI strategies

Aventis Pasteur decides about GPPI strategies for each partnership individually. Commitments are made for defined periods of time, which should be understood from the outset of a GPPI. However, according to Aventis programmes can still be sustainable if a programme can be replaced by a 'second generation' initiative or if other partners will take over.¹²⁵

Unlike preferential pricing, donations of vaccines are not a standard practice. Aventis Pasteur believes that donations are not a sustainable long term solution, because countries would become dependent on such donations. This would be an undesirable outcome for these countries as well as for the company. The donations to the GPEI are a special case because the WHO sought to quickly expand immunization campaigns without an accompanying increase in donor funding. No donations are made to GAVI. For this partnership, public sector representatives agreed that donations would not be sustainable.¹²⁶

In exceptional circumstances like natural disasters and emergencies, though, Aventis donates vaccines from existing inventories whenever it can. It seems that for pharmaceuticals a similar approach is followed as for vaccines and donations are made on a case-by case basis. This is illustrated by the donations to the WPESS.

A non-exhaustive overview of emergency donations for the period 1999-2003 is given below. The product value of these donations has been estimated on the basis of average UNICEF procurement prices. Using this method, it follows that the total value of emergency donations in the past five years was approximately US\$ 3 million. The wholesale value of these products in high income countries, which is usually stated in the communications of pharmaceutical companies, would be several times higher. The valuation of product donations is further described in the next section.

¹²⁴ Interview with S. Gilchrist, May 13, 2004.

¹²⁵ M. Hunter (2003). *Report of a meeting organized by INSEAD business school and the IPPPH*. Paris, France, 30 June - 1 July 2003.

¹²⁶ That is, according to Aventis. Merck & Co made a donation of 5 million doses of hepatitis B vaccines to the GAVI for the period 2000-2004. See <http://www.anrpt2000.com/16.htm>.

Aventis emergency drug donations 1999-2003.

Date	Country	Vaccine	Quantity (doses)	Procurement value (US\$) ¹²⁷
September 2003	Philippines	diphtheria-tetanus-pertussis (DTP)	561,390	45,500
April 2003	Philippines	DTP	148,840	12,100
February 2003	North Korea	DTP	464,020	37,600
April 2002	Burkina Faso	Menomune (meningitis)	25,000	n/a
March 2002	Cuba	Vaxigrip (flu)	800,000	n/a
2001	Ecuador	DTP	150,000	11,700
2001	Cuba	DTP	150,000	11,700
1999	Bosnia	Tetanus toxoid (TT)	6,000	200
1999	Turkey	TT	100,000	3,300
1999	Philippines	Tetanus-diphtheria	140,000	n/a
1999	Venezuela	TT	600,000	19,800
1999	Philippines	TT	4,000,000	132,000

Source : Aventis (April 2004). *Caring for health: Aventis Sustainable Healthcare Projects*; <http://www.aventis.com>.

Aventis makes its donations in accordance with its own set of Donation Guidelines. These contain criteria such as quality standards and a sufficient remaining shelf-life upon delivery.¹²⁸ Aventis explains that its own guidelines are in accordance with the WHO Guidelines for Drug Donations.¹²⁹

5.5 Valuation of drug donations

The valuation of drug donations for tax purposes is important, because in some cases the tax exemptions granted for drugs donations may cost the US government even more than the procurement of preferentially priced drugs or generics.¹³⁰ In general, donations of Aventis are expenses that are written off and do not qualify for tax exemptions,¹³¹ so this problem does not occur.

Communication on the value of vaccine donations is another issue, which is usually not linked to valuation for tax purposes. Aventis reports that this issue is sometimes complicated. The OPV donations to the GPEI provide a good example. In 1999 an initial donation of 50 million vaccines was agreed. Negotiations on the valuation of this contribution between WHO and Aventis took several months, because of the large range of

¹²⁷ Estimated product value at average UNICEF procurement prices. V&B SAGE (June 2001). Divergence of products for public sector immunization programmes. See <http://smain.synergynewmedia.co.uk/gavi/vaccinealliance/reference/ppt/sage136.ppt>.

¹²⁸ Aventis 2002 Sustainability Report, p 26.

¹²⁹ See WHO (Revised 1999). *Guidelines for Drug Donations*.

¹³⁰ A. Guilloux (October 2000). Hidden price tags: disease-specific drugs donations, costs and alternatives. MSF.

¹³¹ Statement of the CFO of Aventis Pasteur, mentioned in communication with S. Gilchrist, May 15, 2004.

different prices. UNICEF purchases the vaccine at approximately \$0.08 per dose, while its sales value in high income markets is between \$1-2. Aventis initially took the position that communication on the donation should be at the value to the company, which would be the high market price. As Aventis wrote: *'We felt that it was only fair that this should be recognised by the recipients of the donation. We were concerned that otherwise the value of the 50 million doses would be trivialised, and would not be recognised by the public for its true value in any other market.'*¹³² Yet the WHO insisted that the value of the donation to the organization was not more than \$4 million. In the end, the WHO and Aventis agreed in a Memorandum of Understanding that Aventis would not attribute a financial value to it in its communications.¹³³

As far as the WPSS is concerned, Aventis values the donated drugs at their manufacturing cost.

¹³² Communication with S. Gilchrist, June 21, 2004.

¹³³ Interview with S. Gilchrist, 13 May 2004.

6 Analysis and conclusion on GPPIs

The nature of Aventis' contributions to different GPPIs indicates that the company makes diverse contributions, follows a flexible approach and uses its specific expertise. For example, contributions to the WPESS involve maintaining production capacity for sleeping sickness drugs, to GAVI partners the company provides logistical skills, and TB Free gets support from local Aventis staff. This means that the role of the company could not be fulfilled in the same way by another partner and supports the rationale for GPPIs. The rationale for GPPIs is based on the complementarities of the resources contributed by different partners. Aventis recognizes that product donations should only be given in exceptional cases. The donations to the WPESS seem to be at odd with this reasoning. Aventis explains these have been decided under the consideration that the situation of sleeping sickness was an 'exceptional case'.

Donor government funding for medicine procurement at preferential prices may have advantages over medicine donations by companies, for instance because it allows developing countries more autonomy to set their own public health priorities.¹³⁴ To some extent the need to make product donations arises from a general lack of donor funds, as the GPEI clearly illustrates. It is positive that Aventis sought a sustainable solution for OPV supplies to the GPEI. In the case of WPESS drug procurement funded by external donors was not even considered, because no donor funds were available. This suggests that responsibilities may be transferred from donor governments to the company.

Recognition of its contributions to GPPIs, by employees and society at large, is of value to Aventis. This is indicated by the negotiations on the communicated value of OPV donations to the GPEI and by the benefits of the company's commitment to the WPESS.

Tax exemptions do not seem to play a major role in Aventis' programmes. This is illustrated by the OPV donations, which did not qualify for a tax break. The presence or absence of tax benefits is hardly addressed in public communications. This is a pity, because it makes it difficult for outsiders to assess the costs and benefits of donations. The absence of tax exemptions could also enhance the public image of the corporation. The company was willing to provide some information on the issue for the report, though.

Different GPPIs in which Aventis is a partner gradually evolved. This has the advantage over partnerships initiated and designed by a company that it strongly reduces the risks associated with supply-driven programmes, for example that they do not fully reflect the priorities of the beneficiary governments and populations. On the other hand, the gradual involvement of a GPPI is at the same time not conducive to a formal agreement on the terms of collaboration, nor to the screening of commercial partners. Aventis points out that such an agreement is not always necessary.

¹³⁴ See SOMO (2004). *Sector profile of the pharmaceutical industry*.

In the case of the GAVI, the roles and responsibilities of industry partners are not well-defined due to the lack of a formal agreement. The partners themselves might not see this as a problem, though, and Aventis points out that the GAVI is an alliance rather than a partnership. For other researched GPPIs in which Aventis participates such agreements do exist. This is positive, because it clarifies commitments and interests. However, transparency about these issues is lacking because the agreements between partners are not disclosed. The explanation of the latest Aventis-WHO-UNICEF agreement for OPV donations provides some insight in the agreed conditions of collaboration, which are quite reasonable. Yet without the full disclosure of such agreements, it remains difficult for outsiders to assess the conditions and the responsibilities that have been agreed.

Aventis is an important partner in the GAVI. Aventis participated in the GAVI Board discussions on the selection of priority diseases, while it is the main supplier for yellow fever vaccines, one of the prioritized diseases. A suggestion of a conflict of interests might have existed. According to the company this has been addressed adequately and has never been a source of concern. GAVI partners have benefited from the close cooperation with pharmaceutical companies, because it provided them with expertise on vaccine production. Regarding the financial sustainability of the use of new vaccines, introduced by GAVI, this is still insecure.

Aventis has a clear policy for dealing with beneficiary countries' governments. TB Free and EPIVAC provide examples of efforts to integrate partnerships into the local health infrastructure and to strengthen it. This benefits the recipient countries. It was not clear whether integration of these initiatives with other GPPIs is also sought. If integration between different GPPIs operating in the same countries and using the same health infrastructure is lacking, this might reduce the efficiency of the partnerships.

It is difficult to get a clear overview of Aventis' total contributions to GPPIs. This is partly because of the diverse nature of these contributions, and partly because Aventis does not report aggregate annual figures on the financial and in-kind support it provides. The analysis of Aventis' involvement with the GPPIs studied in this report shows that the company has been making valuable contributions and that a sound rationale for GPPIs is usually present. On the other hand, it also indicates that there is scope for improvement with respect to the transparency about total contributions, partnership agreements and the establishment of partnerships (and alliances). Furthermore, there may be concerns that responsibilities are transferred from donor governments to the company, but the root of this problem lies of course with donor governments.

Annex 1: Memorandum of Understanding for OPV donations

Contents of the most recent Memorandum of Understanding (MoU) for the GPEI between Aventis, the WHO and UNICEF.¹³⁵

- The MoU specifies that Aventis Pasteur agrees to donate a certain amount of OPV to WHO/UNICEF, and specifies the period of the donation and its use. The last agreement, for example, dates from 2002 and mentions that quantity of 30 million doses, to be used between 2002 and 2005. The donation will be used in the five selected countries if appropriate. (This last phrase has been formulated to allow for flexibility regarding the use of the donation in other countries, if for some reason less than 30 million doses are administered in the selected countries).
- It specifies that the donations will be delivered free of charge, sets delivery times, etc.
- It identifies one person as the responsible manager for the GPEI at Aventis: the public policy manager of Aventis Pasteur.
- It contains a detailed clause on public communications, which includes restrictions on external communications, contains standard messages, specifies the use of logos and brand names, etc.
- It allows for the name of the sponsor to be visible on the medicine donation packages, as a form of recognition for its the contribution.
- It has an annex which specifies the time-schedule of the donations. In the last agreement, the donation of 30 million doses is spread over four years, in which 2.5, 14.5, 6.5 and 5.5 million doses will be delivered, respectively.

¹³⁵ Interview with S. Gilchrist, May 13, 2004.

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