Global Alliance to Eliminate Lymphatic Filariasis

Partnership profile

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Contents

List of acronyms

AFESD	Arab Fund for Economic and Social Development
APOC	African Programme for Onchocerciasis Control
CCC	GSK/WHO Collaborating Coordination Committee
DEC	Diethylcarbamazine citrate
EMEC	Expanded Mectizan Expert Committee
GAELF	Global Alliance to Eliminate Lymphatic Filariasis
GCP	Global Community Partnership (of GlaxoSmithKline)
GPPI	Global Public-Private Initiative
GSK	GlaxoSmithKline
IPPPH	Initiative on Public-Private Partnerships for Health
LF	Lymphatic filariasis
MDA	Mass Drug Administration
MDP	Merck Mectizan Donation Programme
NGDO	Non-Governmental Development Organization
NGO	Non-Governmental Organization
PELF	Programme to Eliminate Lymphatic Filariasis
PRSP	Poverty Reduction Strategy Papers
RCG	Representative Contact Group
RPRG	Regional Programme Review Groups
TAG	Technical Advisory Group
UNICEF	United Nations Children's Fund
WHO	World Health 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 describes and analyses the Global Alliance to Eliminate Lymphatic Filariasis (GAELF), a Global Public-Private Initiative (GPPIs) for health. GPPIs are a specific type of public-private partnerships. The report focuses on the role of pharmaceutical industry partners in the operations and governance of the GAELF. It does not evaluate outcomes or effectiveness in much detail, nor does it provide an analysis of each company's approach to GPPIs for healthcare in general. These issues are addressed in separate reports by SOMO, including three reports on individual companies (Aventis, GlaxoSmithKline, Merck & Co).[1] These reports relate their involvement with GPPIs to the core-business of the companies and to broader company strategies and policies for corporate social responsibility. Field studies on the implementation of the GPPIs in developing countries, conducted by partner organizations of WEMOS, form part of the broader research project.[2]

[1] See http://www.somo.nl.

[2] At the release of this report, the reports of the field studies were still being edited. When they are finished, they will be placed on the WEMOS website, http://www.wemos.nl.

1 Short description of the GAELF

In 1997, the World Health Assembly (WHA) called for the elimination of lymphatic filariasis (LF).[3] LF, also known as 'elephantiasis', is a disease caused by parasitic worms that can cause permanent disability. Worldwide, 120 million people in 183 countries are infected by the disease, and 40 million are severely incapacitated by it.

The strategy to interrupt transmission of LF is mass drug administration (MDA) to the entire population that is at risk of infection, for a period of at least 5 years. This period corresponds to the reproductive lifespan of the parasite. There exist three drugs that can be used as a treatment for LF: Albendazole, Mectizan (ivermectin), and Diethylcarbamazine citrate (DEC). They need to be administered only once a year for this purpose. The combination of two different drugs enhances the effectiveness of the treatment. The WHO recommends a combination of Albendazole and DEC, except for countries where onchocerciasis (river blindness) is also endemic. In these areas, DEC cannot be used because it causes severe complications, and a combination of Albendazole and Ivermectin is recommended instead.[4]

Occasionally, DEC-fortified salt is also used to prevent LF. In that case the treatment regimen consists of the daily intake of DEC-fortified salt during a period of 1 year. This strategy is only applicable when all salt supplies in a country can be controlled.

The Global Alliance to Eliminate Lymphatic Filariasis (GAELF) emerged from a forum in which different organizations reviewed existing activities for the elimination of LF.[5] Several ministries of health in endemic countries, donor governments and international organizations were involved in an early stage. In 1998, the pharmaceutical corporation GlaxoSmithKline (GSK)[6] agreed to donate as much of its drug Albendazole as required for the LF programme of the World Health Organization (WHO).

Subsequently, in 1999 Merck & Co expanded its existing donation programme of the drug Mectizan, for onchocerciasis (river blindness), to include the treatment of LF in African countries where LF and onchocerciasis are both endemic.[7] Similar to GSK, Merck has committed to provide its drug free of charge for as long as required. Although linked to the GAELF, these donations take place through a separate GPPI, the Merck Mectizan Donation Program (MDP). The MDP and the GAELF should not be confused. The MDP is a company donation programme, whereas the GAELF is an umbrella organization. In contrast to the MDP, the GAELF does not implement national programmes itself, but this is done by the various partners.

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[3] Resolution WHA50.29.
[4] GAELF website, http://www.filariasis.org/index.pl?iid=1743. Accessed in September 2004.
[5] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[6] By that time SmithKline Beecham, which later merged with Glaxo Wellcome to form GSK.
[7] IPPPH website, http://www.ippph.org. Accessed in Septermber 2004.

Starting with the cooperation between GSK and the WHO in 1998, a coalition of different organizations and companies working together gradually evolved. The GAELF was officially founded at a meeting in Santiago de Compostela, Spain, in May 2000. The mission of the GAELF is '*to bring together a diverse group of private and public health partners to support the Programme to Eliminate Lymphatic Filariasis (PELF) by mobilizing political, financial and technical resources to ensure success*'. The Global Programme to Eliminate LF, implemented by the various members of the alliance, is designed to interrupt transmission of infection, and to alleviate and prevent the suffering and disability caused by the disease.[8]

Based on this Global Programme, each endemic country formulates its own PELF. These national programmes should approach the elimination of LF '*as the focal point of a broadly beneficial public health intervention organized through existing or strengthened national health infrastructures*'.[9] Thus, the programme stresses integration with national programmes, especially those with a community-based approach.[10] Field studies indicate that PELFs do not always strengthen existing health systems, though.[11] The alliance currently operates in 34 countries.[12]

[8] GAELF Joint Mission Statement, as communicated on 17 October 2003.
[9] *The Programme to Eliminate Lymphatic Filariasis* (slide presentation). See GAELF website, http://www.filariasis.org/index.pl?iid=2498. Accessed in September 2004.
[10] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[11] G. Onyango Nyamor (2004). *A case study report on Global Public Private Initiatives (GPPI) with specific reference to Global Alliance for Elimination of Lymphatic Filariasis (GAELF) in Kenya.* TICH.
[12] IPPPH website, http://www.ippph.org. Accessed in September 2004.

2 Partnership policy

2.1 Partners involved

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Main partners of the GAELF include:

- The WHO
- GSK
- Merck (Merck participates in the GAELF through the MDP, which is a separate GPPI, but not a separate legal entity)[13]
- UNICEF
- The Liverpool School of Tropical Medicine
- Emory University, Atlanta, USA
- The Arab Fund for Economic and Social Development (AFESD)
- The Gates Foundation
- The World Bank
- International development agencies (donor governments)
- Ministries of health of the endemic countries

2.2 Roles of partners

The GAELF itself provides the following description of different partners' roles: [14]

- ***Endemic countries*** lead the Global Alliance by implementing the strategy, identifying operational research needs and monitoring and evaluating progress.

- ***Donors*** pledge funds to support the implementation of national LF elimination programmes.

- ***Drug companies*** provide free drugs for mass drug administration campaigns, promote advocacy, support academia and facilitate programme development

- ***Academia*** strengthen the scientific basis, test new tools and strategies and carry out operational research.

- ***Non-Governmental Development Organizations (NGDOs)*** complement the efforts of the national ministries of health in implementing different components of the programmes within their specific competence and scope.

[13] Communication with B. Colatrella on 24 May, 26 May & 4 June 2004.
[14] GAELF website, http://www.filariasis.org/index.pl?iid=2380. Accessed in September 2004.

- The ***WHO*** provides expertise to support national programmes in preparing national plans, mapping disease distribution, training health personnel both in drug distribution and disability prevention and control activities, social mobilization, and monitoring and evaluation.

2.3 Contributions from Merck[15]

This section provides a description of the contributions of Merck to the MDP, because Merck participates in the GAELF through the MDP. It should be noted that this programme targets onchocerciasis (river blindness) as well as LF. The MDP started in 1987 and operates also in countries where LF is not endemic.

Merck has committed to provide Mectizan, its drug against onchocerciasis and LF for free as long as needed until these diseases are eliminated as public health problems. At present the MDP covers 60.000 communities and reaches more than 30 million people annually in 34 countries in Africa, Latin America and Yemen in the Middle East. By some the MDP has been recognized as a model for GPPIs for addressing health issues in the developing world.[16]

As the MDP is not an independent legal entity, the Mectizan donations are made directly by Merck to its partners (not by the MDP). The costs of the MDP, including R&D of the drug, are supported by the overall operations of Merck.

To date, more than 1 billion Mectizan tablets have been donated for onchocerciasis and LF, and over 300 million treatments have been delivered. The dosing of Mectizan is based on height or weight, and the average dose is three 3-mg tablets. Most of the donated medicines have reached the target groups. Logistical problems have not seriously impeded the delivery and distribution of Mectizan.

For public reporting purposes, the Mectizan donations are valued at $1.50 per tablet. This is the US wholesale price, not the production cost. In 2002, Mectizan donations were worth US$ 249 million.[17] The company pays for all shipping and clearance costs associated with the delivery of the drug, which amounts to approximately $300,000 annually. Merck also provides support to the programme by funding the Expanded Mectizan Expert Committee (EMEC) and the MDP secretariat at a cost of approximately $2 million annually, and by funding educational activities associated with the programme. For the first 14 years of the programme, Merck employed a full-time medical director and an assistant for the MDP as

[15] This sections is largely based on communication with B. Colatrella on May 24, May 26, June 4 & June 25, 2004.
[16] Business Wire (December 5, 2003). *US Commerce Secretary hunours Merck for Excellence in Corporate Stewardship*.
[17] Merck Annual Report 2002.

well. The annual operational costs of the program will probably continue to grow, as the LF component of the MDP expands.

At present, the MDP and other GAELF partners operate together in the following eight countries: Benin, Burkina Faso, Ghana, Nigeria, Tanzania, Togo, Uganda and Yemen. Merck explains that due to the geographical overlap of the diseases in Africa, the GAELF has benefited greatly from the infrastructure established by the delivery of Mectizan for onchocerciasis control. The GAELF also supports programmes in 26 countries where onchocerciasis does not occur, mainly in South and Southeast Asia and the Pacific. In these countries Mectizan is not required and Merck is not involved.

Apart from the 8 countries where the LF and onchocerciasis programmes run concurrently, the MDP operates in 21 other endemic and 2 non-endemic countries in Africa and 6 in Latin America for the prevention of onchocerciasis.[18] Lymphatic filariasis also occurs in most of these countries. They are not covered by the GAELF yet, but this is because the GAELF is still a relatively new initiative. The intention is to expanded the efforts for LF elimination to these countries too.

2.4 Contributions from GlaxoSmithKline[19]

The GAELF is GSK's flagship community programme. Unlike Merck, GSK signed a Memorandum of Understanding (MoU) with the WHO for the donations. The Albendazole is donated to the WHO and at country level, the drug is administrated through national programmes. Inside GSK, the GAELF and other partnerships of with philanthropic nature are managed by the Global Community Partnership (GCP) department.

94 million Albendazole tablets were donated in 2003, valued at US$ 18 million (£11 mln) at wholesale acquisition cost. In addition, GSK contributed grants of approximately US$ 1.5 million (£1 mln) and staff and expertise to the partnership. Albendazole supplies since the start of GAELF amount to 240 million treatments. The total quantity of required Albendazole for 20 years is estimated at 6 billion tablets, with an associated wholesale value of roughly US$ 1 billion.[20]

GSK also supports fundraising for the GAELF by trying to bring in new donors. In North America, there exists a high-profile committee for fundraising for the GAELF, which includes executives of GSK and other pharmaceutical companies. Hence, the GAELF

[18] GAELF website, http://www.filariasis.org and MDP website, http://www.mectizan.org. Accessed in September 2004.
[19] This section is largely based on an Interview with J. Frain, Vice President of GSK Global Community Partnerships department, 1 June 2004.
[20] GSK (2004), Facing the Challenge: Two years on; GSK Annual Report 2003.

Secretariat perceives that pharmaceutical industry partners have an important role in advocacy.[21]

GSK considers that it is ultimately the responsibility of developing countries governments to provide healthcare and to allocate funds to it. The company is aware that GPPIs clearly entail a risk of draining resources away from other healthcare programmes. It therefore prefers GPPIs to be country-led and considers the GAELF to be an example of this, because countries have to submit proposals for national programmes.

2.5 Funding of the partnership

External funding

Total LF programme costs are expected to rise from nearly $30 million in 2003 to $50 million in 2005 and will continue to rise in this pace for several years on. Most of these funds are required for implementation of LF programmes in Africa and South East Asia. These programme costs are external funding requirements only, excluding drug donations. Domestic resources allocated by Ministries of Health of the endemic countries, such as health centre staff, transport and management costs, are not included either and are probably higher than external funding.[22]

Currently available external support is falling far short of the required amounts, leaving a financing gap of $20 million in 2003, which may increase to $40 million in 2005.[23] At the moment the GAELF is experiencing a real financial crisis. Funds for national programmes are hardly available.[24] In a field study in Kenya, a PELF manager indicated that he frequently had to look himself for additional funding. As a consequence, the programme sometimes had to be suspended.[25]

Drug donations and company grants

Drug donations and other contributions from GSK and Merck make up an important part of the financing of the GAELF. GSK's donations in 2003 are valued at US$ 18 million. This amount is expected to double in 2004. In 2002, total Mectizan donations (including for onchocerciasis as well as for LF) were valued at US$ 249 million at US wholesale value.[26] Drug requirement estimates indicate that the LF component of Mectizan donations in 2003

[21] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[22] WHO (September 1999). *Building Partnerships for Lymphatic Filariasis: Strategic Plan September 1999.* WHO/FIL/99.198.
[23] WHO (2003). *GAELF Strategic Plan 2003-2005: Challenges of Scaling up.* CDS/CPE/CEE/2003.39.
[24] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[25] G. Onyango Nyamor (2004). *A case study report on Global Public Private Initiatives (GPPI) with specific reference to Global Alliance for Elimination of Lymphatic Filariasis (GAELF) in Kenya.* TICH.
[26] Merck Annual Report 2002.

would have an associated value of $120-130 million.[27] Adding drug donations and organizational support of both companies, total contributions in 2003 were valued over $140 million.

Funding from the Gates Foundation

The first major funding from external sources (other than Merck and GSK) came in February 2001, when the Gates Foundation committed $20 million for a period of five years. This sum was intended to accelerate the implementation of GAELF up to May-June 2006, when the next meeting of the Global Alliance will be held. The current administration of the Gates Foundation is interested in supporting R&D, but not in broad-based providing country support. Support for other aspects of PELF implementation has to be mobilized from other sources.

The GAELF obtained funds from the Gates Foundation for clinical monitoring programmes and other operational research, with the aim to demonstrate that the mass drug administration strategy is effective to interrupt transmission. The Gates grant is used in 8 countries only. It supports activities of several organizations, including the Liverpool and Emory universities and the WHO. Each organization has its own programme. The funding from the Gates Foundation is now entering its last year, but the clinical monitoring experiment has not yet been completed. Mass drug administration is required for at least 5 subsequent years and most countries are somewhere in the middle of the implementation period. Therefore, new support for operational research is also required.

Domestic resources

Where possible, the GAELF seeks to mobilize domestic resources. In Ghana and Tanzania, it has been successful in securing full support for LF elimination from the national health budget. In these countries, the elimination of LF is linked to the Heavily Indebted Poor Countries (HIPC) Initiative for debt reduction, and included in national Poverty Reduction Strategy Papers (PRSPs). [28]

However, full domestic support is not possible in all countries. A country like Burkina Faso is unable to sustain its own PELF. In such cases other sources of funding are sought. Companies, from different sectors, are one potential source. The Dutch mobile phone company Celtel contributed US$ 30,000 for PELF implementation in Burkina Faso, for example.[29]

Organizational support

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[27] WHO 2003. *GAELF Strategic polan 2003-2005: Challenges of scaling up*. This document mentions an estimated requirement of 84 million doses of Mectizan in 2003. worth $126 million at wholesale value.
[28] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[29] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.

The Executive Group, the central executive body of the Alliance, is supported by volunteering staff from GAELF partners, including the Liverpool and Emory universities. Regional and national meetings for PELF implementation rely on contributions from GSK and Merck. The UK government also provides support for the organizational costs of the GAELF.

2.6 Motivation and interests of corporate partners

The GAELF Chair reckons that corporate citizenship is the most important reason for corporate support to the partnership. The most important business benefit for companies like Merck and GSK would be the positive identity they derive from their contributions. Merck and GSK have written to other companies, including from other business sectors, attempting to convince them to provide support for LF elimination. In their letters of support, Merck and GSK explained that this was a right thing to do for a company.[30]

Merck

Merck firmly believes that the best way to address complex health issues is through partnerships, because no corporation, government, international agency or other entity can do it alone. Merck therefore stresses that it is important that organizations join together, drawing on the complementary expertise of all stakeholders, to work toward mutually beneficial program goals.[31] Furthermore, the company explains it is not in a position to have full knowledge of public health needs and therefore relies on information from others.[32]

Merck believes that corporations have a role to play in expanding access to medicines in the developing world and should provide its resources, including cash, products, manpower and management expertise, in order to address societal needs. [33] Merck sees its contributions as essential to being a socially responsible corporation, and part of its corporate mission to improve the health and well-being of people globally.

While the company stresses that the primary objective of its participation in GPPIs is to address important societal needs, Merck also recognizes business benefits. Probably the most important benefit is that it helps to retain employees. Other perceived benefits are an enhanced corporate image and a higher public profile, better employee morale, and more possibilities to build relationships with key constituents. These key constituents include the governments involved in the GPPIs, public health experts and policy leaders.

[30] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[31] Communication with S. Khalil, June 17, 2004.
[32] Communication with B. Colatrella, 15 September 2004.
[33] Communication with B. Colatrella on 24 May 2004.

The production of Mectizan takes place in separate manufacturing facilities. Therefore the Mectizan donations for the MDP do not provide advantages for the production of other ivermectin drugs, such as Stromectol, a drug against strongyloidiasis. Metizan itself does not have formal regulatory approval for other uses than the treatment of onchocerciasis and the prevention of LF.

In the case of Mectizan donations for LF, the majority do not qualify for tax exemptions, because Merck donates the product directly to the African governments. This is a consequence of the structure of the LF programme and the prominent role of Ministries of Health and local governments in PELF implementation. Donations would qualify for tax breaks only if they were provided to a US-based non-profit organization, like the majority of Mectizan donations for onchocerciasis.

GSK

GSK is proud of its leading role in community partnerships that support healthcare. The support for such partnerships is one of the three areas where GSK considers it can make a valuable contribution to improve health in developing countries, next to R&D and preferential pricing.

Although the global community partnerships (GCPs) of GSK have a philanthropic nature, they also serve to build pride with employees. Most employees are enthusiastic about the contributions made by GSK. GSK explains that its commercial success allows it to sustain a broad range of philanthropic partnerships. In many cases GSK's support consists of funding for healthcare programmes only and in principle these grants could be provided by other companies or other donors as well.[34]

GSK points out that the Albendazole donations to the GAELF do not provide the company with a competitive advantage by lowering the marginal production costs of Zentel, a commercial drug for de-worming with the same active ingredient, because the production of Albendazole and Zentel are separated. Albendazole is manufactured in France and Zentel is manufactured in other countries. The two drugs have a different colour and shape as well.[35]

2.7 Conditions of cooperation and use of the donated drugs

GSK has signed a Memorandum of Understanding with the WHO that specifies its commitments to GAELF. However, this agreement is not publicly disclosed. [36] Zentel, is also widely used in developing countries for intestinal health programmes. For this purpose, the drug is administrated at least 2 times a year. Sometimes there is partial

[34] Interview with J. Frain, 1 June 2004.
[35] Communication with J. Frain, 21 September 2004.
[36] Interview with J. Frain, 1 June 2004.

integration with the GAELF, which means that once a year the drug is given against LF, and it is provided a second time each year outside the GAELF to be also effective for de-worming in general. GSK explains that it is working to increase integration of LF and intestinal health programmes and that there is still some way to go. However, the Albendazole donations of GSK are for use against LF only. GSK does not want to donate the drug for use against intestinal helminths.

The donations of Merck have not been formally specified in an agreement with another organization. Mectizan is only approved for onchocerciasis and LF and not sold commercially.

2.8 Added value of the partnership

According to the GAELF Secretariat, the coordination by the Global Alliance is very important and generates the added value of the partnership.[37] Recall that the GAELF is an umbrella organization only and LF programmes are implemented by GAELF partners, not by the GAELF as a whole. However, it seems that the combined advocacy efforts of the Alliance have helped to raise additional resources for LF programmes, even though funds are still far from sufficient.

2.9 Transparency

The GAELF is transparency about the perceived roles of different partners. However, transparency about financial contributions is relatively low. A specification of the sources of currently available funding and detailed information about programme costs could not be found in reports of the GAELF. Only total funding and programme costs are mentioned. The GAELF is not transparent about conditions of cooperation either, as the MoU between GSK and the WHO is not publicly disclosed.

[37] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.

3 Governance of the GAELF

3.1 Introduction

It is important to distinguish between the governance structure of the Global Alliance (GAELF) and implementation structure for the Global Programme (PELF). The Global Programme is ultimately owned by endemic countries. The Global PELF and National PELFs are designed with technical support of the WHO and academic institutions. The GAELF is not a separate legal entity, and supports the implementation of the Global Programme. All members of the GAELF are also involved in PELF implementation.

3.2 PELF Implementation structure

The WHO acts as the Secretariat of the GAELF. At country level, the drugs are administrated through national programmes. Countries have to submit proposals for National PELF to the partnership. The WHO supports the National PELFs, and communicates with the following bodies.[38]

- The **Regional Programme Review Groups (RPRGs).** A Global Programme Review Group was set up under the Memorandum of Understanding between the WHO and GSK for the donation of Albendazole, before the GAELF was launched. The task of this group was reviewing applications from national ministries of health for LF programmes. The global group was later replaced by six Regional Programme Review Groups (RPRGs) for each WHO region, which were better geared to handle the rapid increase in programme activities.[39] Although they are separately represented in the new governance structure of the GAELF, their tasks are mainly related to the implementation of the programme. The members are appointed by the Regional Directors of the WHO. The six RPRGs are the following:

    - African Programme Review Group
    - Eastern Mediterranean Programme Review Group
    - American Programme Review Group
    - Indian Subcontinent Programme Review Group
    - Mekong-plus Programme Review Group
    - Pac-CARE (Pacific) Programme Review Group

- The **Technical Advisory Group (TAG)**. The TAG meets annually to give non-binding recommendations to the WHO on all aspects of the elimination of LF. It provides technical guidance to the Global PELF and is made up of a group of specialists, selected for their personal expertise in LF science and programme management.

[38] GAELF website, http://www.filariasis.org/index.pl?iid=2766, accessed in August 2004; Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[39] GAELF website, http://www.filariasis.org/index.pl?iid=2660. Accessed in September 2004.

The members are of the group are appointed by the Director General of the WHO, based on a balanced technical and geographical representation.

- The **GSK/WHO Collaborating Coordination Committee (CCC)**. This Committee was set up to support the Albendazole donations. It has mainly a managerial and logistical role and forecasts drug needs.

- The **Expanded Mectizan Expert Committee (EMEC).** The EMEC, unlike the CCC, has an important technical function. The African PRG forwards programme requests from countries where onchocerciasis is co-endemic to the EMEC for final authorization. Its role is similar to that of a TAG for the concurrence of LF and onchocerciasis. The members of the EMEC are experts appointed by the MDP.

- The **Mectizan Donation Program (MDP)** acts as the secretariat of the EMEC. It is not a separate legal entity, but part of Merck. The MDP provides managerial and logistical support for the Mectizan donations and is based within the Task Force for Child Survival & Development, a US-based NGO. Specific Merck staff interacts on a regular basis with the secretariat regarding decisions about the operation of the programme and to facilitate the delivery of Mectizan for both onchocerciasis and lymphatic filariasis.[40]

According to the GAELF Chair, the approval structure for drug donations is functioning very well. After a positive decision, the drugs are made available without any problems. [41]

3.3 GAELF governance structure[42]

The main function of the Global Alliance is to mobilize support for PELF implementation; it seems that technical decisions are taken by the WHO, and some of the committees mentioned above (RPRGs and EMEC). Because of its supportive role, the GAELF has a 'light' governance structure that is considered inexpensive. At the first GAELF meeting in May 2000, it was decided how to organize issues like fundraising. At the outset the Alliance had a very loose structure. The GAELF was set up differently from previous GPPIs, like the African Programme for Onchocerciasis Control (APOC), which had a much more rigid and top-down governance structure. At first, the looser structure of the partnership caused some confusion, but the governance of the GAELF gradually evolved since its establishment.

At the second global meeting in May 2002, it became clear that the Alliance needed to be better structured. A temporary partnership structure was designed and set up by September 2002. Two Task Forces were created, one for Advocacy and Fundraising and one

[40] Correspondence with B. Colatrella, Merck Office of Contributions, on May 24 & 26, June 4 & June 25, 2004.
[41] Interview with Y. Dadzie, GAELF Chair, on 20 August 2004.
[42] This section is largely based on an interview with Y. Dadzie, GAELF Chair, on 20 August 2004.

for Communication. Each taskforce has a chair and 4 members. A GAELF Secretariat was set up, consisting of the 2 chairs of the Task Forces and a Secretariat Chair of the WHO. This temporary structure was in place for one and a half years, until the third global meeting of the Alliance in Cairo, Egypt, March 2004.

At this meeting a new governance structure for GAELF was proposed and adopted by the various partners. According to the Chair, the GAELF is now having a proper structure, with a democratic basis, but without a rigid bureaucracy. The GAELF is still a relatively loose association. There are now three levels of governance.

1. **Global Assembly**

This is the bi-annual global meeting of all GAELF partners.

2. **Representative Contact Group (RCG)**

At the third global meeting, a Representative Contact Group (RCG) was established, composed of 30 representatives from various constituencies:

- The Chairs of the 6 RPRGs
- 3 country representatives from the African region, and 2 from each other region
- WHO
- World Bank
- Non-governmental organizations (NGOs)
- Academic/research institutions
- Pharmaceutical industry
- Donors

The RCG met for the first time after the meeting in March 2004. An endemic country representative was chosen as president of the Group. The most important function of the RCG is to appoint the members of the Executive Group. The RCG also mobilizes funds, including for the TAG, RPRGs and the implementation of the PELFs in endemic countries.

3. **Executive Group**

The RCG selected a smaller Executive Group of 6 members, to carry out the recommendations made at the Global Alliance meeting in May 2004. Main selection criteria were availability and personal merits, like required skills, commitment, and access to resources. The Chair of the Executive Group is Mr. Yankum Dadzie, from Ghana. The Executive Group includes one representative from GSK and one from Merck (MDP). According to the Chair, the company representatives do not wield real power. The role of these representatives is mainly supportive, for example by providing the facilities for teleconferences. An important role of the pharmaceutical companies, apart from drug

donations and cash contributions, is to use their networks to bring in other donors. GSK comments that the Executive Group works as a team and GSK brings in technical skills.[43]

The mission of the Executive Group is to '… *support the Global Programme to Eliminate Lymphatic Filariasis as a public health problem by enhancing the effectiveness of national, regional and global fundraising, advocacy, communication and planning for the Programme*'. [44] It is in charge of mobilizing support and plays an important role in the governance and functioning of the Global Alliance. The Executive Group meets at least 3 times a year and has additional teleconferences. From March to September 2004, there have already been 3 meetings and 4 teleconferences, and a 4th meeting was scheduled for September. A main task of the Executive Group is to review and carry out the recommendations made by the two Task Forces. It is supported by volunteering staff from GAELF partners, including the Liverpool and Emory universities.

3.4 Financial structure

Although GAELF reports do not provide detailed information about this, it is most likely that donor support for LF programmes is provided directly to national Ministries of Health in endemic countries and to other implementing partners. These funds do not pass through the GAELF, and the efforts of partners are coordinated by the RCG, it can be assumed that the GAELF does not have any authority over the allocation of funds by GAELF partners. Such a structure is common for GPPIs like the GAELF. The precise organizational costs of the Alliance itself are unknown, but are probably small when compared to total programme costs.

3.5 Monitoring and evaluation

The TAG has a subgroup for monitoring and evaluation of LF programmes and progress towards disease eradication.[45] Detailed studies about Mass Drug Administration (MDA) coverage are available.[46] The recent changes in the governance structure of the Alliance indicate that shortcomings in the functioning of the GAELF itself are also signalled and addressed.

3.6 Transparency

Transparency about the governance of the GAELF is rather low. The precise composition of the Executive Group, Representative Contact Group and Technical Advisory Group is not communicated. Minutes or reports of the meetings of these bodies are not publicly

[43] Interview with J. Frain, 1 June 2004.
[44] GAELF website, http://www.filariasis.org/index.pl?iid=1875. Accessed in September 2004.
[45] GAELF website, http://www.filariasis.org/index.pl?iid=2388&isa=Category&op=show. Accessed in September 2004.
[46] See e.g. WHO (2003). *Lymphatic Filariasis*. In: Weekly epidemiological record, 78(20), p170-9.

available, except for very short information on the meetings of the TAG. As of October 2004, the report of the third global meeting of the Alliance in March 2004 was not yet publicly available. The GAELF did not produce this information when requested.

4 Controversial issues

The strategy of drug donations, which is a central aspect of the GAELF, is not without controversies. The sustainability of drug donations is not a major source of concern, because GSK and Merck committed to donate the drugs for as long as required. However, donations may have the effect – whether intended or not - of prohibiting the development of local generic drug producers through unfair competition. In India, for example, it seems that local producers of generic Zentel (Albendazole), which is used against intestinal parasites, are forced out of business because of the Albendazole donations for LF programmes.

In addition, responsibilities may be transferred from donor governments to companies. Because pharmaceutical companies decide which drugs they want to donate and for which purposes, they gain a large influence in the prioritizing of disease-specific health programmes. In the case of Mectizan donations for use against LF, it could also be considered controversial that the EMEC, controlled by Merck itself, has to approve the country programmes. Critics might argue that this would give Merck an opportunity to put pressure on governments that apply for donations to offer certain favours (such as changes in regulations) in exchange.

An alternative for drug donations could be the procurement of preferentially priced drugs with donor funds. Yet in the case of the GAELF, this is generally considered impossible because even with drugs provided for free, funds are falling short for PELF implementation.

Merck explains that following the discovery, development and regulatory approval of Mectizan for onchocerciasis in 1987, the company first sought a third-party payer like (e.g. USAID or WHO) to purchase Mectizan at a low price or at cost, and then provide it free to patients in Africa and Latin America who needed the medicine. However, due to limited government budgets and competing health priorities, no external donor funding was available. Because Mectizan was the only safe and effective medicine available for onchocerciasis, the poor people who needed it would not be able to afford it at any price and no donor was prepared to buy the medicine, Merck committed itself to providing Mectizan for free. The financial stability of the company at the time enabled Merck to make this large and long-term commitment. In 1999 the donation of Mectizan was expanded to include the treatment of LF in African countries where LF and onchocerciasis co-exist. [47]

Regarding the present situation, Merck has no intention of going back on its pledge, nor any plans to stop the donation until the goals of elimination are reached or until such time as experts agree that there is a better treatment available for the diseases. The Merck

[47] Communication with B. Colatrella on 24 May, 26 May, 4 June & 25 June 2004.

Office of Contributions points out that even if it were interested in pursuing other donors today (which it is not), this would be even more difficult than when the programme started 17 years ago. The problem of competing health priorities and has increased and there is still a lack of resources to fund programmes like the MDP, because of the large amount of resources absorbed by e.g. HIV/AIDS programmes.[48]

GSK chose to provide Albendazole free of charge because donor funding to buy the medicine was not available and many of the endemic countries could not afford to buy it. This position is similar to that of Merck on the donation of Mectizan to GAELF. Most donor funds are absorbed by other health priorities, notably programmes for HIV/AIDS, malaria and TB. The funding requirements for LF elimination are small when compared to the funds required for these priority diseases. [49]

GSK normally takes the position that medicine prices should cover production costs because medicine donations are unsustainable in the long term. However, A difference is made between different kinds of treatments. The medicine donations to GAELF are considered an exception, because the objective of GAELF is elimination of the disease. Although the medicine donations to this partnership are huge, the company explains that they are not unlimited. The disease will be eliminated in an area if the population has received an annual treatment for five subsequent years, which is the lifetime of an adult worm. This contrasts with e.g. ARV treatment, a lifelong therapy. It therefore becomes feasible to sustain the Albendazole donations. [50]

[48] Communication with B. Colatrella on 24 May, 26 May, 4 June & 25 June 2004.
[49] Interview with J. Frain, 1 June 2004.
[50] Communication with J. Frain, 1 June & 21 September 2004.

5 Analysis and conclusions

Merck & Co. and GlaxoSmithKline (GSK) have a central role in the Global Alliance to Eliminate Lymphatic Filariasis (GAELF). As no budget for drug procurement is available, the Lymphatic Filariasis (LF) programmes would be impossible without drug donations. A main partnership rationale for the GAELF is the coordination of activities of different partners. It is in the first place an 'umbrella organization'. However, resource mobilization and especially company donations are also essential for LF programmes.

Merck and GSK have an important role in the implementation of the Programme to Eliminate LF (PELF) beyond donations and grants, especially in managerial and logistical support for the donations. Both companies have a central position in governing bodies and decision-making of the partnership as well, as they both have a representative in the Executive Group.

A remarkable difference between the involvement of GSK and Merck concerns the approval of national programmes that receive drug donations. For LF programmes that require Albendazole but not Mectizan, this is done by the Regional Programme Review Groups (RPRGs) on the basis of recommendations from the Technical Advisory Group (TAG), which both fall under the authority of the WHO. For programmes that involve Mectizan, in contrast, technical expertise and final approval come from the Expanded Mectizan Expert Committee (EMEC), which is part of the Mectizan Donation Programme (MDP) and controlled by Merck. This second construction, in which the company itself approves the LF programmes to which it donates drugs, provides less safeguards against potential conflicts of interests. On the other hand, GSK has a significant commercial interest in sales of Zentel, the branded version of Albendazole, for other uses than LF programmes. Merck does not have comparable interests, because the approved uses of Ivermectin (for humans) are much more limited. It is difficult to assess how potential conflicts of interests are dealt with because of the low transparency about the governance of the GAELF.

A main controversy is whether it is appropriate for companies to make such large donations to a Global Public-Private Initiative (GPPI). Firstly, they may be crowding out generic drugs producers. Secondly, the companies are in fact taking over donor government responsibilities. Donations and grants from pharmaceutical companies to other GPPIs that are in a similar financial crisis, like the Global Polio Eradication Initiative (GPEI), are sometimes much lower. Thus, this transfer of responsibilities provides companies with a large influence in the prioritizing of public health programmes.

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