The rise of companies from emerging markets in global health governance: opportunities and challenges


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The Rise of Companies from Emerging Markets in Global Health Governance: Opportunities and Challenges

Anne Roemer-Mahler

Abstract:

The article analyses the involvement of pharmaceutical companies from emerging markets in global health governance. It finds that they play a central role as low-cost suppliers of medicines and vaccines and, increasingly, new technologies. In so doing, pharmaceutical companies from emerging markets have facilitated the implementation of a key goal of global health policy: widening access to pharmaceutical treatment and prevention. Yet, looking closer at the political economy underlying their involvement, the article exposes a tension between this policy goal and the political economy of pharmaceutical development and production. By declaring access to pharmaceuticals a goal of global health policy, governments and global health partnerships have made themselves dependent on pharmaceutical companies to supply them. Moreover, to provide pharmaceutical treatment and prevention at the global level, they depend on companies to supply medicines and vaccines at extremely low prices. Yet, the development and production of pharmaceuticals is organized around commercial incentives that are at odds with the prices required. The increasing involvement of low-cost suppliers from emerging markets mitigates this tension in the short run. In the long run, this tension endangers the sustainability of global access policies and may even undermine some of the successes already achieved.

Acknowledgement:

The research leading to this article has received funding from the European Union's Seventh Framework Programme (FP/2007-2013) ERC Grant Agreement n. 312567
Introduction

The role of emerging market countries in global health governance has attracted increasing scholarly attention. Studies have investigated the influence of Brazil, Russia, India, China and South Africa (BRICS) on reforms in the World Health Organization (WHO), discussed whether the rise of the BRICS is leading to a paradigm shift in global health, and assessed the potential of coalitions among these countries to shape the global politics of access to medicines. In this literature – as in the wider International Relations scholarship on the rise of the BRICS – the focus has almost exclusively been on how BRICS states shape world politics. Little attention has been paid to the question how the rise of companies from these and other emerging markets has affected global political dynamics. This is surprising not only because the importance of business in global politics is now widely recognised, but also because the rise of the BRICS is driven largely by the spectacular growth of their economies and share in world trade, both of which is carried by companies from these countries.

The impact that companies from emerging markets can have on global health politics has been illustrated with regard to the global response to the HIV/AIDS pandemic. For many years, the international community tried to address the spiralling HIV/AIDS pandemic in low- and middle-income countries through improved technical coordination and prevention. Anti-retroviral medicines (ARVs) were available to patients in high-income countries, but donors rejected the idea of subsidising treatment in low- and middle-income countries because of the high costs of medicines. In the early 2000s, however, a policy change occurred, and in 2005, G8 leaders endorsed the goal of providing “as close as possible to universal access to treatment for AIDS by 2010”. An important factor for the change of heart among donors was the emergence of pharmaceutical companies from middle-income countries on the scene. They helped bring the price of ARVs down from approximately US$ 10,000 to less than US$ 150, which made large scale subsidies and, hence, the policy goal to provide universal access possible.
Since then, widening access to pharmaceuticals has become a key policy goal of global health governance not only with regard to HIV/AIDS but also with regard to many other diseases, including malaria, tuberculosis, and neglected tropical diseases, and, most recently, antibiotics. This has had a significant effect on the institutional structure of global health governance leading to a range of public-private partnerships to facilitate the procurement and development of medicines and vaccines. Global health partnerships are now a key feature of global health governance, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the GAVI Alliance, and the Drugs for Neglected Diseases Initiative (DNDi), for instance. Access policies have also yielded some impressive results. Today, approximately 10 million people living with HIV/AIDS in low- and middle-income countries receive ARVs, more than 11.2 million people have been treated for tuberculosis, and more than 440 million children in low- and middle-income countries have been vaccinated against diseases such as diphtheria, tetanus, pertussis, hepatitis B, haemophilus influenzae type b, meningitis, polio, Japanese encephalitis, diarrheal diseases, pneumococcal diseases, and, most recently, cervical cancer.

There are indications that companies from emerging markets play an important role in the political economy underlying access policies, not only with regard to medicines for HIV/AIDS. Systematic evidence is, however, scarce. This article analyses the involvement of pharmaceutical companies from emerging markets in global health governance by examining their contribution to some of the largest public-private partnerships for financing, procurement and drug development. It shows that these companies are key suppliers and increasingly important partners in the development of new medicines and vaccines. This places them in a crucial position for the implementation of what has become a central goal of global health governance, widening access to pharmaceuticals.
The article offers an explanation for this phenomenon by looking at both policy dynamics and company interests. It shows that the focus on access to pharmaceuticals is part of a wider policy shift in global health governance from technical coordination and prevention to fighting specific diseases. This shift has moved access to pharmaceutical treatment and prevention into the centre of global health policy. Drawing on literature from medical sociology and health security, the article uses the concept of ‘pharmaceuticalization’ to capture this phenomenon. Importantly, it argues that the pharmaceuticalization of global health governance has created a dependency of governments and global health partnerships on pharmaceutical companies. In particular, it has created a dependency on pharmaceutical companies that can supply at extremely low prices because the ability to scale up access policies and achieve ‘universal’ access depends on the price that governments and global health partnerships have to pay for medicines and vaccines. It is this price pressure that has led many global health partnerships to turn to pharmaceutical companies from emerging markets as partners in global health governance.

Drawing on insights from the International Business literature, the article shows that emerging market companies are willing to supply at low prices not only because of lower production costs but also to get access to new technologies. Yet, the analysis points out, pharmaceutical companies from emerging markets are - like their counterparts from Western Europe and the US - for-profit organisations. There is evidence to suggest that the continuous drive for lower prices is reducing the interests also of emerging market producers to supply medicines and vaccines at the prices required by global health partnerships.

By studying the role of emerging market companies in global health governance, the article exposes a tension between the policy goal to widen access to pharmaceuticals and the incentives for companies to supply them. In other words, the article exposes a tension between the pharmaceuticalization of global health governance and the political economy of pharmaceutical
production. It argues that this tension can endanger the sustainability of global access policies and even undermine some of the recent successes in expanding treatment and immunization.

By providing the first analysis of the role that pharmaceutical companies from emerging markets play in global health governance the article contributes to the burgeoning research on the political economy of global health\textsuperscript{xx}. More broadly, the article hopes to fuel a nascent interest\textsuperscript{xvii} in International Relations scholarship about the role of emerging markets firms in world politics. It underlines that the rise of the BRICS and other emerging market countries brings with it a rise of companies that affect not only the structure and workings of the global economy but also that of global politics.
The role of pharmaceutical companies from emerging markets in global health governance

Before turning to the empirical analysis of the role that emerging market companies currently play in global health partnerships, I will briefly explain the data underlying the analysis. Global health partnerships take on a variety of functions, including financing, procurement, product development and capacity building for companies in low- and middle-income countries. The article looks at the three largest partnerships focusing on the financing of medicines and vaccines, GFATM, Stop TB Partnership Global Drug Facility (GDF), and GAVI, and eight partnerships working on the development of new medicines and vaccines, so called Product Development Partnerships, including Aeras, DNDi, International AIDS Vaccine Initiative (IAVI), Infectious Disease Research Institute (IDRI), Medicines for Malaria Venture (MMV), Programme for Appropriate Technology in Health (PATH)/One World Health (OWH)¹, Sabin Vaccine Institute (Sabin), and the Global Alliance for TB Drug Development (TB Alliance). In addition, the article looks at a global health partnership aimed at increasing the capacity of pharmaceutical companies from low- and middle-income countries to manufacture vaccines for pandemic influenza, the WHO Global Action Plan for Influenza Vaccines (GAP). The selection of global health partnerships is based on two considerations: 1) their size, which is considered an indicator of their impact on global health² and 2) the availability of data about the corporate partners they work with.

Table 1: Global health partnerships included in this study

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Name</th>
</tr>
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<tbody>
<tr>
<td>Aeras</td>
<td>Aeras</td>
</tr>
<tr>
<td>DNDi</td>
<td>Drugs for Neglected Disease Partnership</td>
</tr>
<tr>
<td>IAVI</td>
<td>International AIDS Vaccine Initiative</td>
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</tbody>
</table>

¹ PATH and OWH merged in 2011.
² PEPFAR is a similarly large financing mechanism as GFATM, GAVI and the GDF; it was not included here, however, because it is a bilateral mechanism run by the US government.
<table>
<thead>
<tr>
<th>IDRI</th>
<th>Infectious Disease Research Institute</th>
</tr>
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<tbody>
<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
</tr>
<tr>
<td>GDF</td>
<td>Stop TB Partnership Global Drug Facility</td>
</tr>
<tr>
<td>GAVI</td>
<td>GAVI Alliance</td>
</tr>
<tr>
<td>MMV</td>
<td>Medicines for Malaria Venture</td>
</tr>
<tr>
<td>PATH/OWH</td>
<td>Programme for Appropriate Technology in Health/ One World Health</td>
</tr>
<tr>
<td>Sabin</td>
<td>Sabin Vaccine Institute</td>
</tr>
<tr>
<td>TB Alliance</td>
<td>Global Alliance for TB Drug Development</td>
</tr>
<tr>
<td>WHO GAP</td>
<td>WHO Global Action Plan for Influenza Vaccines</td>
</tr>
</tbody>
</table>

Data has been generated from a variety of sources, including annual reports and other publications made available by the global health partnerships and by individual companies; the Global Fund Price and Quality Reporting Tool\textsuperscript{xviii}, which is a database recording all orders that GFATM has placed with pharmaceutical companies; reports about global health partnerships published by other organisations, such as Policy Cures, the PDP Funders Group, and BioVentures; websites of global health partnerships, partner companies and international organisations; and articles from the mainstream press and pharmaceutical trade publications.

Data was collected about the number of companies from emerging markets that individual global health partnerships work with as suppliers, R&D partners, board members, and funders. Subsidiaries of companies where the parent company is headquartered in a high-income country were not included. In addition, the proportion of companies from emerging markets in the total number of suppliers and R&D partners of global health partnerships was calculated. With regard to data on board membership, the proportion of companies from emerging markets in the total number of board members was calculated. Publicly available data on the funders of global health partnerships
was insufficient to conduct the same calculation for the proportion of companies from emerging markets in the total number of funders.

There are some limitations to the data, which have implications for the conclusions that can be drawn from the analysis. Firstly, data on the volumes procured from individual companies has not been collected because of time constraints. This limits the conclusions that can be drawn about the relative importance of individual companies as suppliers of medicines and vaccines. Secondly, comprehensive data on the number of relationships that each global health partnership has with individual companies is not publicly available because of confidentiality clauses covering several agreements\textsuperscript{xix}. This limits the conclusions that can be drawn about the relative importance of individual companies as R&D partners.

\textit{Emerging market companies as suppliers of medicines and vaccines}

Companies from emerging markets make up between approximately 30-50\% of suppliers of medicines and vaccines to global health partnerships\textsuperscript{xx}.

[insert Table 2]

An analysis of the orders that GFATM placed for ARVs for HIV/AIDS in the period January 2010 until September 2013 shows that 14 out of 26 (54\%) suppliers were from emerging markets, with 9 companies from India and 3 from South Africa. A different study found that between 2003 and 2008, the number of suppliers from India alone had doubled\textsuperscript{xxi}. Similarly, 12 out of 22 (55\%) companies supplying anti-malaria drugs to the GFATM between January 2010 and September 2013 were from emerging markets, 9 of which were from India and 2 from China.

The percentage is slightly lower with regard to suppliers of anti-tuberculosis medicines to GFATM. 11
out of 33 (33%) companies are from emerging markets with 7 being from India. Similarly, the number of emerging markets suppliers of anti-tuberculosis medicines to the GDF was about one third or 8 out of 22 (36.4%). 6 of them were Indian companies. GAVI works with 12 suppliers of vaccines, 50% of which are based in Africa, Asia and Latin America. This is a significant increase from to 2001 when only 1 supplier was from a low-income country (Senegal). In 2014, GAVI announced that it was extending its supply base to China\textsuperscript{xii}.

\textit{Emerging market companies as partners for innovation}

The proportion of emerging market companies among corporate R&D partners of global health partnerships is not as high as among their suppliers. In most global health partnerships studied here it varies between approximately 10-30%. IAVI and the TB Alliance do not currently have R&D collaborations with emerging markets companies. A study by the PDP Funders Group suggests that the role of emerging markets companies as R&D partners has increased significantly since 2007\textsuperscript{xxiii}.

IDRI lists 6 companies from emerging markets as R&D partners out of 18 corporate collaborators (33%) overall. 4 of the 6 are from India\textsuperscript{xxiv}. MMV works with 62 pharmaceutical companies on R&D, 7 of which are from emerging markets (11%), with 3 from China, 3 from India and one from Russia\textsuperscript{xxv}. According to Aeras annual report 2010, 3 out of a total of 15 industry partners were from emerging markets (20%), with 1 from China, 1 from India and 1 from Korea\textsuperscript{xxvi}. In 2012, Aeras announced it had started to work with another Chinese biotechnology company\textsuperscript{xxvii}. DNDi lists 5 companies from emerging markets as collaborators out of 24 corporate partners overall (21%); 2 of them are from India and the others from Brazil, Colombia and Tanzania\textsuperscript{xxviii}. The Sabin Institute lists 5 corporate R&D partners on their website, 3 of which are from emerging markets (60%), with 2 from Brazil and 1 from Mexico\textsuperscript{xxix}. In addition, the PDP Funders Group reports collaboration between Sabin and the Chinese company Frontier Biosciences\textsuperscript{xxx}. 
PATH and OWH are affiliated institutions but they provide separate data on their corporate R&D partners. OWH lists 10 collaborators from the biopharmaceutical industry on their website, 2 of which (20%) are based in India\textsuperscript{xxxi}. According to the PDP Funders Group, OWH has research and development agreements with 3 companies from China and India\textsuperscript{xxxii}, 2 of which are not listed on the OWH website. PATH does not provide an overview of corporate R&D partners but a look at PATH’s various product development programmes suggests that emerging markets companies play an important role. According to John Boslego, director of PATH’s vaccine development program, the organization has expanded collaboration with emerging market companies in recent years\textsuperscript{xxxiii}. In the Meningitis Vaccine Project, an Indian company was chosen as the manufacturer of the new vaccine\textsuperscript{xxxiv}. In the area of pneumococcal vaccine development, PATH mentions 6 collaborators from the biopharmaceutical industry, two of which are from emerging markets, China and India\textsuperscript{xxxv}. For its work on a life rotavirus vaccine, PATH mentions collaboration with 3 biopharmaceutical companies, all of which are from China and India\textsuperscript{xxxvi}. PATH is also providing technical assistance to a Chinese biotechnology company for production of oral polio vaccine\textsuperscript{xxxvii}. For its Malaria Vaccine Partnership, PATH lists 6 collaborators from the biopharmaceutical industry, 2 of which are based in India\textsuperscript{xxxviii}.

As mentioned above, the TB Alliance does not currently collaborate with biopharmaceutical companies from emerging markets. In 2007, however, it worked with the Indian company Lupin on 2 drug candidates for tuberculosis\textsuperscript{xxxix}. There also seems to be some interest in the growing R&D potential of China. In 2011, the TB Alliance signed a Memorandum of Understanding with the International Scientific Exchange Foundation of China to establish a Global Health R&D Center\textsuperscript{xl}. Like the TB Alliance, IAVI does not have any current R&D collaborations with pharmaceutical companies from emerging markets\textsuperscript{xli}. Yet, IAVI’s Innovation Fund has provided grants to 2 emerging markets companies out of a total of 15 grantees, 1 from India and 1 from South Africa\textsuperscript{xlii}. IAVI’s Innovation Fund was established to harness early stage technology in AIDS vaccine development, and to support companies in proof of concept work, which is important to attract commercial investors.
Capacity building is the focus of the WHO GAP, which WHO has been implementing in collaboration with governments and pharmaceutical companies since 2006. GAP supports vaccine companies in emerging markets in order to increase the global supply of influenza vaccines. Companies in 11 countries, notably Brazil, Egypt, India, Indonesia, Iran, Korea, Mexico, Romania, Serbia, Thailand, and Vietnam, have received grants so far. The grants are awarded under the condition that, in the case of a pandemic, the companies sell 10% of their vaccine production to United Nations agencies for distribution in low- and middle-income countries\textsuperscript{exii}. An important contributor to the GAP has been the US Biomedical Advanced Research and Development Authority (BARDA). BARDA manages the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents, and for emerging infectious diseases on behalf of the US government. Since 2005, the US has provided more than US$ 50 million to advance influenza vaccine development in low- and middle-income countries\textsuperscript{exiv}. The funding has been channelled primarily through GAP. In 2009, BARDA established a US$ 7.9 million cooperative agreement with PATH to support the final developmental processes for an influenza vaccine at a Vietnamese manufacturer\textsuperscript{exiv}. The considerable engagement of the US in these global partnerships suggests that the government believes it can best protect its population from future influenza pandemics by intercepting them in the countries that they likely to spread in first, namely low- and middle-income countries.

\textit{Emerging market companies as board members of global health partnerships}

Compared to their role as suppliers and R&D partners, the involvement of emerging market companies as board members of global health partnerships is negligible\textsuperscript{xlvi}. For this study, board members were categorised according to whether they are likely to represent the perspectives of companies from emerging markets. Sometimes, board members are selected as representatives of a specific organisation or government. In these cases, the categorization did not present any difficulty. Sometimes, board members are selected because of the expertise and contacts they have
accumulated in the course of their careers. In these cases, it was examined whether they had significant work experience in companies from low- and middle-income countries.

GAVI is the only global health partnership analysed in this study that has an almost equal balance of corporate board members from low- and middle-income countries and high-income countries. The organisation reserves one seat for vaccine producers from low- and middle-income countries and one for producers from high-income countries. In addition, there are 2 independent members on GAVI’s governing board with a background in businesses from low- and middle-income countries and 3 with a background in business from high-income countries. The only other global health partnership that has a board member with a business background from an emerging market country is MMV (out of 3 board members overall with a business background). WHO GAP is an exception as it is part of WHO, where only states can be members. Also GAP’s advisory board has only members from the public sector.

Overall corporate representation on the governing boards of the global health partnerships analysed in this study varies greatly. GDF does not have any representatives from the business sector on its governing board, while at IDRI almost 80% of board members (7 out of 9) have a business background. Other global health partnerships with comparatively high proportions of board members with a business background are Aeras with 58% and the TB Alliance with 54%. On IAVI’s governing board, approximately one third of the members have a background in business, and at the governing boards of GAVI and MMV the proportion is approximately 25%. The remaining global health partnerships have corporate representations of between 5-15%.

*Emerging market companies as funders of global health partnerships*

The picture that emerges with regard to the role that emerging market companies play as funders of global health partnerships is similar to that of their role as board members **xlvi**. From publicly
available data on the funding base of global health partnerships two key insights emerge. First, most funding seems to originate from the public sector, notably from governments in North America and Western Europe. The second major funder is the Bill and Melinda Gates Foundation. Funding from the commercial sector is significantly smaller. The insight that “the private sector has not generally met the initial .... expectations that it would become the principal patron of these partnerships” is not new.\textsuperscript{xviii} Perhaps less well known is that emerging market companies hardly feature at all as funders of global health partnerships. Among the global health partnerships analysed for this research, only PATH names companies from emerging markets among its funders. Out of the 27 corporate funders listed by PATH, 1 is a biopharmaceutical company from China and 1 is from India.\textsuperscript{xix}

In sum, pharmaceutical companies from emerging markets contribute significantly to the work of global health partnerships as suppliers and R&D partners, but their representation at the decision-making level is weak. In other words, pharmaceutical companies from emerging markets have become important partners in the implementation of global policies to widen access to pharmaceuticals, but not in the design of these policies. How can we explain this?

\textbf{Emerging market companies: Partners in policy implementation – but not policy design}

Let us turn first to the rise of emerging market companies as partners in the implementation of access policies. In the last 15 years, the fight against specific diseases, notably HIV/AIDS, malaria, tuberculosis, neglected tropical diseases, and pandemic influenza, has emerged as a key feature of global health governance. With it has come a focus on access to medicines and vaccines as a key policy goal. This focus is manifest at both the discursive and the institutional levels of global health governance.
With regard to HIV/AIDS, the Declaration of Commitment on HIV/AIDS passed by United Nations General Assembly in 2001\(^1\) made access to medication for HIV/AIDS and the development of a HIV vaccine a key goal of global health governance. The Declaration recognizes “that access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”\(^{II}\). In addition, the Declaration commits to “increase investment in and accelerate research on the development of HIV vaccines”\(^{III}\). In the following years, a consensus emerged that global access to ARV treatment was possible\(^{I\!I\!I}\).

In the area of neglected tropical diseases, a roadmap by WHO in 2012 identifies preventative chemotherapy, i.e. the delivery of medicines, as the key global governance strategy to tackle these diseases\(^{IV}\). The roadmap was endorsed by a stakeholder group comprising representatives of governments, the pharmaceutical industry and global health partnerships in the London Declaration on Neglected Tropical Diseases. The first three of the Declaration’s seven commitments are about access to medicines. The Declaration’s ‘endorsers’ commit to contribute to: (1) “Sustain, expand and extend programmes that ensure the necessary supply of drugs and other interventions to help eradicate Guinea worm disease, and help eliminate by 2020 lymphatic filariasis, leprosy, sleeping sickness ... and blinding trachoma”, (2) “Sustain, expand and extend drug access programmes to ensure the necessary supply of drugs and other interventions to help control by 2020 schistosomiasis, soil-transmitted helminthes, Chagas disease, visceral leishmaniasis and river blindness (onchocerciasis)”, and (3) “Advance R&D through partnerships and provision of funding to find next generation treatments and interventions for neglected diseases”\(^{V\!I\!V}\).

In the area of pandemic preparedness, the EU adopted a Decision on Serious Cross-border Threats to Health in 2013, and the EU Health Commissioner highlighted, “[t]he next milestone for health
security under this legislation is the Joint Procurement Framework Agreement... Under this agreement, Member States can ... purchase, together, vaccines and other medical countermeasures needed to fight a cross border health threat. This is to ensure that all Member States, big and small, are able to secure vaccines and other medicines for their people and under better conditions than in the past\textsuperscript{vi}. Similarly, the Global Action Plan for Influenza Vaccines of the World Health Organization (WHO) emphasises that “[i]nfluenza vaccine development and deployment are critical elements of pandemic influenza preparedness”\textsuperscript{vii}.

The focus on widening access to pharmaceuticals as a key policy goal in global health governance has become manifest also at the institutional level. Many organisations that make up the organisational landscape of global health governance today are mandated with the financing, procurement and development of pharmaceuticals, and most of them have been created in the period since the late 1990s.

Concerted global efforts to make pharmaceuticals more widely available, especially in low- and middle-income countries, are a relatively new phenomenon. Prior to the late 1990s, international health policies focused largely on coordinating national activities for the events of infectious disease outbreaks and technical guidance through WHO\textsuperscript{viii}. Perhaps the most important precedent for a global mobilisation of resources to make pharmaceuticals widely available in low- and middle-income countries is the smallpox eradication programme. Between 1967 and 1979, vaccines were procured and supplied to endemic countries with the help of funding from WHO and especially its largest donor the US.

In order to conceptually grasp the recent focus on widening access to pharmaceuticals in the field of health security policy, Elbe, Roemer-Mahler and Long\textsuperscript{lix} draw on the concept of ‘pharmaceuticalization’. This concept had originally been developed by sociologists and
anthropologists to highlight the proliferation of pharmaceuticals in various areas of social life. While much of this literature focuses on how the pharmaceutical industry drives pharmaceuticalization, Elbe et al. apply this concept to investigate government responses to the emergence of bioterrorism and pandemic preparedness as security issues. The authors find that a key element of governments’ responses to these new security threats has been the development of medicines and vaccines as ‘medical countermeasures’ and the stockpiling of existing pharmaceuticals. Governments, they argue, are important drivers of pharmaceuticalization in the field of security because they incentivize the commercial development of medicines and vaccines by providing funds, granting legal protections for pharmaceutical companies, introducing emergency use procedures, and developing systems for mass drug administration. Such incentives are necessary because profit-oriented companies are reluctant to invest in products that may never be needed and for which the number of potential buyers are limited to a few governments.

Pharmaceuticalization is a useful concept for the present study because it helps understand the role that pharmaceutical companies, in general, and emerging market firms, in particular, have obtained in global health governance in the last 15 years. The concept highlights that during this period global health has become strongly associated with the pharmaceutical treatment and prevention of specific diseases. It points out that, like in the field of security policy, the recent policy shift has been accompanied by efforts to widen access to pharmaceuticals and led to a set of institutional and policy responses aimed at incentivising their development and production, such as grants, technology transfer, advance market commitments, and pooled procurement, for example. Such incentives are required for similar reasons as in the field of security and medical countermeasures: commercial market demand and, hence, profit margins are low.

The concept of pharmaceuticalization highlights a set of social and policy dynamics that promote a dependency of societies and governments on pharmaceutical products and, hence, companies.
Pharmaceuticals are developed and produced largely in the private, for-profit sector. Hence, by making access to drugs and vaccines a key focus of policy, governments and global health partnerships have made themselves dependent on commercially operating pharmaceutical companies to enable the implementation of this policy. Moreover, in order to be able to provide ‘universal’ access, they depend on commercially operating companies to supply drugs and vaccines at extremely low prices.

Initially, governments, global health partnerships and advocacy groups had approached the world’s ‘big pharma’ companies, i.e. large European and US companies, as potential suppliers and development partners. These companies were already producing many of the required medicines and vaccines and had the financial and technological capabilities to develop new products. Yet, big pharma companies have shown limited interest in engaging in global health partnerships and supplying medicines and vaccines at such low price levels. Opportunity costs are high, profit margins comparatively low, and demand is often difficult to forecast. There is some evidence to suggest that big pharma companies have substantially invested in partnerships for pharmaceutical development particularly when these investments could be linked to the re-purposing of existing products and/or the opening of markets of commercial interest to these companies.

As a result, governments and global health partnerships have increasingly turned to pharmaceutical companies from emerging markets, particularly from India. The Indian pharmaceutical industry has long been the fastest growing pharmaceutical industry in emerging markets, and Indian companies had early on developed the technological capabilities to produce many of the medicines and vaccines required by global health partnerships. Furthermore, until 2005, Indian companies operated under a national intellectual property regime that prevented the patenting of pharmaceutical products. Finally, Indian manufacturers were able to supply at prices far below those of big pharma companies.
Until recently, however, they did not have the technological and financial capabilities to develop new products. This, however, is changing. In the past decade, the innovative capabilities of companies from emerging markets, particularly Brazil, China and India, has increased substantially. While innovation currently tends to be incremental rather than for entirely new molecules, a study on the health biotechnology sectors in Brazil, China and India identified 165 innovative products within 41 domestic firms in these countries. Indian companies had the largest share of innovative products with 55%, followed by Chinese firms with 29%, and Brazilian firms with 16% of the total number of products identified. As a result, governments and global health partnerships have recently intensified collaboration for pharmaceutical development with emerging market producers.

The pharmaceuticalization of global health governance and the price pressure resulting from the goal to achieve ‘universal’ access has been a key driving force for governments and global health partnerships to turn to pharmaceutical companies from emerging markets as partners for the supply of existing and the development of new medicines and vaccines. Yet, why have these companies invested in these products given extremely low prices and profit margins? While companies from emerging markets are as heterogeneous as companies from high-income countries, and generalisations are therefore difficult, research in International Business has found that companies from emerging markets tend to differ from companies from high-income countries in a variety of ways that may be relevant for this question. Scholars researching the internationalisation strategies of emerging markets companies have argued that their investment decisions can often be explained better by how investments contribute to the capability-building process of the firm than by calculations of short-term returns. For pharmaceutical companies from emerging markets, access to technology and expertise appears to be of particular importance to build capabilities in areas such as manufacture, scale-up, regulation and international market penetration.
A Brazilian biotech entrepreneur, who is cited by Rezaie and colleagues argued that “the increasing attention to neglected diseases by prominent nonprofits... presents Brazilian SMEs [small and medium-sized companies] with an ideal opportunity to build up their international linkages”.

A study on Indian biotech companies found that “firms are interested in working with [global health partnerships] for access to their expertise and resources in tackling global health issues”. The Developing Countries Vaccines Manufacturers Network (DCVMN), an alliance of 27 vaccine producers from 14 low- and middle-income countries, names “strengthening and enhancement of technology ..., encourage[ing] continuation of research and development efforts ..., and facilitate[ing] innovative models of ownership of health related intellectual property” (Jadhav et al 2009: 166) as key aims of the Network. Indeed, when DCVMN was founded in 2001, “[i]t was hoped ... that GAVI would support the Network by “push” mechanisms such as facilitating access to technology” (Jadhav et al 2008: 1612). With regard to the involvement of the Indian vaccine company Serum Institute of India (SII) in a public-private partnership for the development of a new meningitis vaccine, scholars have found that access to a new technology for vaccine manufacture, namely conjugation technology, was key for SII’s decision to manufacture the vaccine at the low price of US$ 0.5 per dose.

Collaboration with global health partnerships as a means to access new technologies is a strategy that has been observed also in a study on Chengdu Biological Products, a large public-sector vaccine manufacturer in China. The authors find that collaboration with PATH “provided Chengdu with much vaccine production hardware and software that they would not ordinarily have, and thus gives them an advantage on the international market, even if they cannot control the sales price”. Scholars researching the growing market for generic ARVs for HIV/AIDS in the early 2000s found that the creation of new markets by humanitarian groups, such as Médecins Sans Frontières, and international financing organizations, such as GFATM, was an important factor in the decisions of
Indian companies to supply the drugs at low prices because it increased volumes and improved the predictability of the market\textsuperscript{lxvii}.

Finally, research suggests that differences in ownership structure between companies from high-income countries and companies from emerging markets may influence investment decisions. It has been argued that the prevalence of state- and family-ownership among emerging markets companies may make decisions in favor of long-term and less secure investments more likely than the shareholder model of corporate governance and financing that is prevalent among most big pharmaceutical companies from high-income countries. In their study of the Indian biopharmaceutical sector, Wilson and Rao report that “\textquoteleft\textquoteleft several firms told us that they could consider products that had only modest markets as long as they thought they would be able to at least cover costs; this attitude may reflect the freedom conferred by being privately held (as opposed to publically traded) or ... state-owned \textquoteleft\textquoteleft [companies]\textsuperscript{lxvii}.

The increasing involvement of emerging market companies as suppliers and R&D partners of global health partnerships can therefore be explained by a combination of a policy shift in global health governance towards greater pharmaceuticalization and a set of internal and external factors that can create a more compelling business case for emerging market companies to produce at low-profit margins than for big pharma firms from Western Europe and the US. In light of the significant role that pharmaceutical companies from emerging markets play as suppliers and R&D partners, their weak representation on the governing boards and among the funders of global health partnerships is puzzling, however.

An explanation may be found in the history of global health partnerships. The ideas and values underlying the rise of public-private partnerships as instruments of governance are based on neo-liberalist notions of the role of the state as facilitator, rather than provider, of social policies\textsuperscript{lxviii}, and
changing conceptions of the relations between public and private, both of which have their roots in Anglo-Saxon schools of thought. Representatives of high-income countries tend to be significantly more numerous on the governing boards and among the funders of global health partnerships than representatives from low- and middle-income countries, not only with regard to representatives from the business sector. Among the global health partnerships analysed here, only the governing board of GAVI shows an equal balance of representatives from high-income countries and low- and middle-income countries. At GFATM and DNDi, approximately one third of board members are from low- and middle-income countries. On the governing boards of the remaining global health partnerships, representatives from low- and middle-income countries make up between 0% and 18%.

Buse and Harmer trace the under-representation of low- and middle-income countries in global health partnerships back to the early days of their creation. They find that the partnership model was promoted by a small group of individuals and organisations “from wealthy, middle-class socio-economic groupings; none were African, indeed all but one were ‘white’, and only four were female. The politics and power dynamics inherent in global health partnerships are evident also in the tension between the terminology of ‘global’ health partnerships and the actual direction of most of their efforts towards low- and middle-income countries. Similarly, there is a mismatch between the absence of emerging market companies on the governing boards of global health partnerships and the language used by many of these organisations, which describes these companies as ‘partners’.

Despite the emergence of pharmaceutical companies from low- and middle-income countries as key suppliers and R&D partners, global health partnerships seem to still be embedded in the power relations of an aid-based model of global health governance. The question why these dynamics persist goes beyond the scope of this article, but it is an important one. While board representation
and provision of financial resources do not automatically guarantee influence\textsuperscript{lxxxiii}, they certainly can open doors and generate access to information that is important to influence policy.

**Conclusion: Implications for global health governance**

What are the implications of this analysis for global health governance? The concluding section argues that the increasing involvement of pharmaceutical companies from emerging markets in global health governance can be interpreted as a double-edged sword. On the one hand, their increasing involvement as suppliers of low-cost pharmaceuticals and technologies has enabled governments and global health partnerships to implement a key goal of global health policy: widening access to pharmaceutical treatment and prevention. One the other hand, the analysis points to a fundamental tension between this policy goal and the political economy of how medicines and vaccines are developed and produced.

Many of the achievements of universal access policies would not have been possible without emerging market companies supplying low-cost, high-quality medicines and vaccines. For example, the rapid scale up of HIV/ AIDS treatment in low- and middle-income countries from a few hundred thousand people in the early 2000s to almost 10 million\textsuperscript{lxxxiv} today has been build largely on ARVs produced by pharmaceutical companies from emerging markets\textsuperscript{lxxxv}. Also, the significant reduction of meningitis cases in Africa, which in 2013 was the lowest in ten years, has been attributed to the introduction of a vaccine produced by an Indian company in collaboration with a public-private partnership\textsuperscript{lxxxvi}.

Moreover, the rapid growth of biopharmaceutical innovation in emerging markets provides potentially great opportunities for global health governance because the types of innovation produced by emerging market companies may be well aligned with the needs of patients in low- and
middle-income countries. The International Business literature has found that the low average income in the domestic markets of emerging market companies has “spurred innovations to serve people at the middle or bottom of the economic pyramid”. Many emerging market companies seem to have developed particular strengths in developing or adapting products so as to lower production costs without necessarily affecting quality. In addition, many companies from these countries were found to have the skills and customer knowledge required to make products easier to use in the more difficult conditions of low- and middle-income countries.

Several examples of such innovations by pharmaceutical companies from emerging markets exist that have played a significant role in global health governance. In 2001, the Indian company Cipla introduced the first internationally recommended 3-in-1 fixed dose combination of three key ARVs (Stavudine + Lamivudine + Nevirapine) to treat HIV/AIDS. The combination of the three ingredients in one fixed-dose treatment made it much easier for patients in low- and middle-income countries to adhere to the complex drug regimen required for successful treatment. More recently, the Brazilian Butantan Institute developed an innovative process to produce a cellular pertussis vaccine at a cost of only US$ 0.12–0.15 per dose compared with its counterpart costing US$ 8 per dose. The involvement of emerging market companies as R&D partners, therefore, may provide an opportunity to access the specific skills required for the development of products that are more affordable and adapted to the needs of users in low- and middle-income countries.

The growing involvement of emerging market companies in global health governance therefore provides great opportunities for the implementation of global access policies. Yet, the analysis in the previous section of why emerging market companies have become involved in global health governance points to the fragility of this contribution. It shows that the pharmaceuticalization of global health governance has created great pressure on governments and global health partnerships to find ever-cheaper sources of medicines and vaccines. It is this price pressure that has made them
turn to suppliers from emerging markets. Yet, while emerging market companies may be able to produce at lower profit margins than their counterparts in Western Europe and the US, they too are profit-oriented organisations. The partnership language used to describe many of the new organisations in global health can obscure the fact that companies – including emerging market firms – engage in global health partnerships for commercial reasons. They are not predominantly partners in global health but first and foremost *business* partners in the legitimate pursuit of profit for their owners. It is therefore not surprising that a growing number of pharmaceutical companies from emerging markets are responding to the continuous price pressure from global health partnerships with concern.

The tension between global health policy goals that require access to pharmaceuticals with extremely small profit margins and the organisation of pharmaceutical supply by for-profit organisations is familiar to most scholars and practitioners in global health governance. In fact, the creation of public-private-partnerships to widen pharmaceutical access and the use of partnership language are manifestations of this tension. While the increasing involvement of emerging market companies in global health partnerships seems to have mitigated this tension at first glance, a closer look reveals that it has also brought further it to the fore.

The tension between political demand and market demand for pharmaceuticals affects not only the global politics of HIV/AIDS but also the global response to a wide - and growing - range of other diseases, including malaria and tuberculosis, neglected tropical diseases, pandemic influenza, bioterrorism and, most recently, antibiotics. In light of the threat that some of these diseases pose to public health it seems risky to base policy responses on the quest for ever cheaper sources of commercial supply. Pharmaceutical companies can play a role in the development and production of medicines and vaccines for which there is effective market demand, and some companies are willing to produce at lower profit margins than others. Yet, for-profit operating companies will not take on
the costs and risks of producing goods for which the market is very small or unpredictable. If global health governance is to pursue the goal of providing access to essential medicines and vaccines globally and to sustain the successes already achieved, greater investment from the public in the development, production and procurement of medicines and vaccines and, not least, greater public investment in prevention is required.


10 As Stephen Lewis, former UN Special Envoy for AIDS in Africa, stated: “[W]e wouldn’t have this extraordinary run of treatment in Africa now if it weren’t for the generic drugs”. New Internationalist, ‘A.I.D.S. Without the Aid’ (17 June 2008), available at (http://www.newint.org/blog/radio/2008/06/17/aids-without-the-aid/), accessed 13 May 2014. Berhard Schwartländer, former Chief of the UNAIDS epidemiology unit, commented that: “A unique combination of generic competition and strong political, activist and media pressure were crucial factors leading to the rapid reduction in prices”. Berhard Schwartländer, Ian Grubb, Jos Perriëns, ‘The
10-Year Struggle to Provide Antiretroviral Treatment to People with HIV in the Developing World, *Lancet*, 368 (2006), p. 542. Certainly, the emergence of generics producers from emerging markets was not the only factor enabling universal access policies for HIV/AIDS ARVs. As Schwartzlender points out, political leadership, and civil society activism played a key role. Not only did they bring the issue on the political agenda, but they also helped create an institutional environment that provided commercially interesting opportunities for emerging market firms, such as large financing and procurement mechanisms and the WHO Prequalification of Medicines Programme. See Ethan B. Kapstein and Joshua W. Busby, *AIDS Drugs for All: Social Movements and Market Transformations* (Cambridge: Cambridge University Press, 2013); Roemer-Mahler, ‘Business Strategy and Access to Medicines in Developing Countries’.


xviii Data generated from: *The Global Fund Price and Quality Reporting (PQR) Tool*:


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xvi Existing studies are largely limited to ARVs for HIV/AIDS. See, for example, Shadlen, ‘The Political Economy of AIDS Treatment’; Roemer-Mahler, ‘Business Strategy and Access to Medicines in Developing Countries’; Roemer-Mahler, ‘Business Conflict and Global Politics’; Kapstein and Busby, ‘AIDS Drugs for All’.


xviii The Global Fund Price and Quality Reporting (PQR) Tool:


xxviii PDP Funders Group, Product Development Partnerships, p. 3.


xxx PDP Funders Group, Briefing Paper 3 – Annex
xxv Perdue and Bright, United States of America Department of Health and Human Services Support for Advancing Influenza Vaccine Manufacturing in the Developing World.
xxv Data gathered from the websites of the global health partnerships.
xxv Data gathered from the websites of the global health partnerships.
xxv Buse and Harmer, *Power to the Partners?,* p. 267

See n. xiv above, paragraph 24, p.9.

See n. xiv above, paragraph 70, p.33.


77
Vaccine, 31S (2013), pp. B43–B53; interviews with representatives of Serum Institute of India and PATH.


\[ \text{Roemer-Mahler, ‘Business Conflict and Global Politics’; Kapstein and Busby, ‘AIDS Drugs for All’.} \]

\[ \text{Wilson and Rao, India’s Role in Global Health R&D, p. 32.} \]


\[ \text{Kapilashrami, Understanding Public Private Partnerships.} \]

\[ \text{Buse and Harmer, Power to the Partners?, p. 54.} \]


\[ \text{WHO, UNAIDS, and UNICEF, ‘Towards Universal Access’.} \]


\[ \text{Ramamurti, What Have We Learned about emerging-market MNEs, p. 403.} \]


\[ \text{Alfonso Fleury and Maria T. Leme Fleury, ‘Brazilian Multinationals: Surfing the Waves of Internationalisation’, in Ravi Ramamurti and Jitendra Singh (eds), Emerging Multinationals from Emerging Markets (Cambridge UK: Cambridge University Press, 2008), pp. 200-243; Wells, Third World Multinationals.} \]

\[ \text{Rezaie et al., Brazilian Health Biotech.} \]

\[ \text{Elbe and Roemer-Mahler, Pharmaceuticals and Security; Interviews with representatives of six Indian biopharmaceutical companies.} \]

\[ \text{Shadlen, The Political Economy of AIDS Treatment; Roemer-Mahler, Business Strategy and Access to Medicines in Developing Countries.} \]