

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 organised 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.

Anne Roemer-Mahler is a Lecturer in International Relations and a Fellow at the Centre for Global Health Policy at the University of Sussex. Her research focuses on the role of pharmaceutical companies in global health governance, and she has published widely in leading academic journals including *Review of Political Economy*, *Business and Politics*, *Security Dialogue*, and *Social Science and Medicine*. She took her PhD from the Department of International Development at Oxford University, and worked as a postdoctoral researcher at the London School of Hygiene and Tropical Medicine.

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),¹ discussed whether the rise of the BRICS is leading to a paradigm shift in global health,² and assessed the potential of coalitions among these countries to

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¹ Lara Gautier, Andrew Harmer, Fabrizio Tediosi, and Eduardo Missoni, 'Reforming the World Health Organization: What influence do the BRICS wield?', *Contemporary Politics*, 20:2 (2014), pp. 163–81.

² David Gold, *Shifting Paradigm: How the BRICS are Reshaping Global Health* (Washington, DC: GHSi, 2012); Andrew Harmer and Kent Buse, 'The BRICS – a paradigm shift in global health?', *Contemporary Politics*, 20:2 (2014), pp. 127–45.

shape the global politics of access to medicines.³ In this literature – as in the wider International Relations scholarship on the rise of the BRICS⁴ – the focus has almost exclusively been on how BRICS *states* shape world politics. Little attention has been paid to the question of 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,⁵ 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.

This article analyses the involvement of pharmaceutical companies from emerging markets in global health governance. It shows that they play a key role as low-cost suppliers of medicines and vaccines and, increasingly, also of new technologies. The article shows that, in so doing, pharmaceutical companies from emerging markets not only have become central to the political economy underlying global health governance, but that they have also enabled governments to implement a key goal of global health policy: widening access to medicines and vaccines. The article therefore presents an argument that sits between those highlighting an increasing role of non-state actors in global health governance⁶ and those emphasising the continuing importance of the state in formulating and implementing global health policies.⁷ As Garrett W. Brown shows in his contribution to this Special Issue, national governments and political leadership shape whether and how global health policies are implemented at the local level. Yet, as the present article highlights, the interests and capabilities of companies can significant influence which policy goals can feasibly be pursued and implemented.

³ Peter Yu, 'Access to medicines, BRICS alliances, and collective action', *American Journal of Law and Medicine*, 34:345 (2008), pp. 345–94.

⁴ See, for example, Gerald Segal, 'Does China matter?', *Foreign Affairs*, 78:5 (1999), pp. 24–36; Joshua Cooper Ramo, *The Beijing Consensus* (London: The Foreign Policy Centre, 2004); Aaron Friedberg, 'The future of US-China relations: Is conflict inevitable?', *International Security*, 30:2 (2005), pp. 7–45; Maria Regine Soares de Lima and Monica Hirst, 'Brazil as an intermediate state and regional power: Action, choice and responsibilities', *International Affairs*, 82:1 (2006), pp. 21–40; S. Neil Macfarlane, 'The "R" in BRICs: Is Russia an emerging power?', *International Affairs*, 82:1 (2006), pp. 41–57; and Amrita Narlikar, 'New powers in the club: The challenges of global trade governance', *International Affairs*, 86:3 (2010), pp. 717–28. More recently, scholars are also paying increased attention to growing power of other middle-income countries, such as Indonesia, Mexico, South Africa and Turkey, for example. See Matthias vom Hau, James Scott, and David Hulme, 'Beyond the BRICs: Alternative strategies of influence in the global politics of development', *European Journal of Development Research*, 24 (2012), pp. 187–204; Karen Brooks, 'Is Indonesia bound for the BRICS? How stalling reform could hold Jakarta back', *Foreign Affairs*, 90 (2011), pp 109–18.

⁵ See, for example, Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, (Cambridge: Cambridge University Press, 2003); David Levy and Peter Newell (eds), *The Business of Global Environmental Governance* (Cambridge MA: MIT Press, 2005); and Tim Bueth and Walter Mattli, *The New Global Rulers: The Privatization of Regulation in the World Economy* (Princeton NJ: Princeton University Press, 2011).

⁶ Kent Buse and Gill Walt, 'Global public-private partnerships: Part I – a new development in health?', *Bulletin of the World Health Organization*, 78:4 (2000), pp. 549–61; Simon Rushton and Owain D. Williams (eds), *Partnerships and Foundations in Global Health Governance* (Basingstoke: Palgrave Macmillan, 2011).

⁷ Daniel W. Drezner, *All Politics is Global: Explaining International Regulatory Regimes* (Princeton: Princeton University Press, 2008); Garrett Wallace Brown, 'Norm diffusion and health system strengthening: The persistent relevance of national leadership in global health governance', *Review of International Studies*, this Special Issue.

Existing studies on the global response to the HIV/AIDS pandemic have illustrated the important role played by pharmaceutical companies from emerging markets.⁸ In the 1980s and 1990s, the international community tried to address the spiralling HIV/AIDS pandemic in low- and middle-income countries through improved technical coordination and prevention. Antiretroviral 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.⁹ 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’.¹⁰ 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 \$150,¹¹ which made large-scale subsidies and, hence, the policy goal to provide universal access possible.¹²

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,

⁸ Kenneth C. Shadlen, ‘The political economy of AIDS treatment: Intellectual property and the transformation of generic supply’, *International Studies Quarterly*, 51:3 (2007), pp. 559–81; Anne Roemer-Mahler, ‘Business strategy and access to medicines in developing countries’, *Global Health Governance*, 4:1 (2010); Anne Roemer-Mahler, ‘Business conflict and global politics: The pharmaceutical industry and the global protection of intellectual property rights’, *Review of International Political Economy*, 20:1 (2013), pp. 121–52.

⁹ Lindsay Knight, *UNAIDS: The First 10 Years, 1996–2006* (Geneva: UNAIDS, 2008).

¹⁰ G8 Summit, ‘Gleneagles 2005: Chairman’s Summary’, Gleneagles, 6–8 July 2005, available at: {<http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,contentMDK:20576902~menuPK:34463~pagePK:34370~piPK:34424~theSitePK:4607,00.html>} accessed 14 May 2014.

¹¹ R. Zimmerman and J. Pesta, ‘Drug industry, A.I.D.S. community is jolted by Cipla A.I.D.S.-drug offer’, *Wall Street Journal* (8 February 2001). In 2003, four generics companies from India and South Africa agreed to supply the commonly used combination regimen to the Clinton Access Partnership for about US \$140 pre-treatment year. Mark Schoofs, ‘Clinton program would help poor nations get AIDS drugs’, *Wall Street Journal* (23 October 2003). In 2009, the median price of the six most widely used first-line regimens was US \$137. WHO, UNAIDS, and UNICEF, ‘Towards universal access: Scaling up priority H.I.V./A.I.D.S. interventions in the health sector. Progress Report 2010’ (Geneva: WHO, 2010).

¹² 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. Bernhard 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.’ Bernhard Schwartländer, Ian Grubb, and Jos Perriens, ‘The 10-year struggle to provide antiretroviral treatment to people with HIV in the developing world’, *The 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 Schwartlaender 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’.

including the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the GAVI Alliance, and the Drugs for Neglected Diseases Initiative (DNDi), for instance.¹³ Access policies have also yielded some impressive results. Today, approximately ten million people living with HIV/AIDS in low- and middle-income countries receive ARVs,¹⁴ more than 11.2 million people have been treated for tuberculosis,¹⁵ 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.¹⁶

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.¹⁷ 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 ‘pharmaceuticalisation’ to capture this phenomenon. Importantly, it argues that the pharmaceuticalisation 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

¹³ Simon Rushton and Owain David Williams (eds), *Partnerships and Foundations in Global Health Governance* (Basingstoke: Palgrave Macmillan, 2011).

¹⁴ UNAIDS, ‘Global Report: UNAIDS Report on the Global AIDS Epidemic 2013’, Geneva, 2013, p. 46, available at: {http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf} accessed 16 October 2013.

¹⁵ The Global Fund to Fight AIDS, Tuberculosis and Malaria, available at: {<http://www.theglobalfund.org>}.

¹⁶ GAVI Alliance, ‘Types of Support’, available at: {<http://www.gavialliance.org/support/>} accessed 14 May 2014.

¹⁷ Shadlen, ‘The political economy of AIDS treatment’; Roemer-Mahler, ‘Business strategy and access to medicines in developing countries’; Brenda Waning, Ellen Diedrichsen, and Suerie Moon, ‘A lifeline to treatment: The role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries’, *Journal of the International AIDS Society*, 13:35 (2010); Kapstein and Busby, ‘AIDS drugs for all’.

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 pharmaceuticalisation 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 immunisation.

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.¹⁸ More broadly, the article hopes to fuel a nascent interest¹⁹ 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),²⁰ 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

¹⁸ 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'; and Kapstein and Busby, 'AIDS drugs for all'.

¹⁹ Steven McGuire, 'Multinationals and NGOs amid a changing balance of power', *International Affairs*, 89:3 (2013), pp. 695–710.

²⁰ PATH and OWH merged in 2011.

Abbreviation	Name
Aeras	Aeras
DNDi	Drugs for Neglected Disease Partnership
IAVI	International AIDS Vaccine Initiative
IDRI	Infectious Disease Research Institute
GAVI	GAVI Alliance
GDF	Stop TB Partnership Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
MMV	Medicines for Malaria Venture
PATH/OWH	Programme for Appropriate Technology in Health/ One World Health
Sabin	Sabin Vaccine Institute
TB Alliance	Global Alliance for TB Drug Development
WHO GAP	WHO Global Action Plan for Influenza Vaccines

Table 1. *Global health partnerships included in this study*

based on two considerations: (1) their size, which is considered an indicator of their impact on global health;²¹ and (2) the availability of data about the corporate partners they work with.

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,²² 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, research and development (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. 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

²¹ 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.

²² The Global Fund Price and Quality Reporting (PQR) Tool, available at: <http://www.theglobalfund.org/en/procurement/pqr/?lang=en>.

publicly available because of confidentiality clauses covering several agreements.²³ This limits the conclusions that can be drawn about the relative importance of individual companies as R&D partners. Finally, data was collected for the time period of January 2010 to September 2013. Yet, data on suppliers, R&D partners, board members and funders had to be taken from different sources, such as websites and annual reports, for example, which cover different time periods. The information on individual global health partnerships published in this article therefore cover slightly different periods within the last three years.

Emerging market companies as suppliers of medicines and vaccines

Companies from emerging markets make up between approximately 30–50 per cent of suppliers of medicines and vaccines to global health partnerships.²⁴ An analysis of the orders that GFATM placed for ARVs for HIV/AIDS in the period of January 2010 until September 2013 shows that 14 out of 26 (54 per cent) suppliers were from emerging markets, with nine companies from India and three from South Africa. A different study found that between 2003 and 2008, the number of suppliers from India alone had doubled.²⁵ Similarly, 12 out of 22 (55 per cent) companies supplying antimalaria drugs to the GFATM between January 2010 and September 2013 were from emerging markets, nine of which were from India and two from China.

The percentage was slightly lower with regard to suppliers of antituberculosis medicines to GFATM. Eleven out of 33 (33 per cent) companies were from emerging markets with seven being from India. Similarly, the number of emerging markets suppliers of antituberculosis medicines to the GDF was about one third or 8 out of 22 (36.4 per cent). Six of them were Indian companies. GAVI worked with 12 suppliers of vaccines, 50 per cent of which are based in Africa, Asia, and Latin America. This is a significant increase from 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.²⁶

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 varied between approximately 10–30 per cent. IAVI and the TB Alliance did not 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 2007.²⁷

²³ PDP Funders Group, 'Product Development Partnerships (PDPs): Working Together: Collaborations between PDPs and Pharmaceutical Biotechnology Companies Based in Emerging and Developing Economies' (August 2012), p. 4, available at: {http://www.pdpfundersgroup.org/PFG_Website/PFG_Briefing_Papers_files/PFG%20Briefing%20Paper%203%20-%20August%202012.pdf} accessed 16 October 2013.

²⁴ Data generated from: The Global Fund Price and Quality Reporting (PQR) Tool, available at: {<http://www.theglobalfund.org/en/procurement/pqr/?lang=en>} accessed 24 October 2012; GAVI Alliance, 'Progress Report 2012' (Geneva: GAVI Alliance, 2013), available at: {<http://www.gavialliance.org/results/gavi-progress-reports/>} accessed 24 October 2012; and Stop TB Partnership/Global Drug Facility website {http://www.stoptb.org/gdf/drugsupply/gdf_suppliers.asp} accessed 24 October 2013.

²⁵ Waning et al., 'A lifeline to treatment', pp. 1–9.

²⁶ GAVI Alliance, 'Progress Report 2013' (Geneva: GAVI Alliance, 2014), available at: {<http://www.gavialliance.org/results/gavi-progress-reports/>} accessed 13 July 2014.

²⁷ PDP Funders Group, 'Product Development Partnerships', p. 3.

Country	Firm	Funding/Procurement Partnerships			Product Development Partnerships								Capacity Building Partnership			
		GFATM	GDF	GAVI	IDRI	MMV	Aeras	DNDi	Sabin	PATH/ OWH	TB Alliance	IAVI	IAVI Innovation Fund	WHO GAP		
Brazil	Bio-Manguinhos			X					X							X
	Instituto Butantan								X							
	Orange Life				X											
	Beijing Tiantan									X						
China	Cansino						X									
	Chengdu Institute									X						
	China Gateway									X						
	Chongqing Holley					X										
	CNIBG						X									
	Ease Medtrend				X											
	Frontier Biosciences										X					
	Guilin Pharma	X							X							
	Holley Cotec	X														
	Kunming Pharma					X										
	Shanghai ChemPartner												X			
	Shijiazhuang	X														
	Wuhan Institute												X			
Colombia	Humanx										X					
	Laboratorios Legrand S.A.	X														
Egypt	Vacsera															
	Ajanta	X														
India	Advinus															
	Aurobindo	X														

		Funding/Procurement Partnerships			Product Development Partnerships								Capacity Building Partnership				
		GFATM	GDF	GAVI	IDRI	MMV	Aeras	DNDi	Sabin	PATH/OWH	TB Alliance	IAVI	IAVI Innovation Fund	WHO GAP			
	Bharat	X															
	Biological E.	X		X													
	Cadila	X	X		X												
	Cipla	X	X			X											
	Emcure	X															
	Gennova				X												
	Gland	X															
	Hetero	X															
	Intas	X															
	IPCA Labs.	X				X											
	Lupin	X	X														
	MacLeods	X	X														
	Manesh	X															
	Matrix	X															
	Medopharm	X															
	Micro Labs	X	X														
	Naxpar	X															
	Ranbaxy	X					X										
	Serum Institute of India	X		X			X										X
	Span Diagnostics				X												
	Strand Life																X
	Strides	X	X														
	Syngene																
	Ubio				X												

		Funding/Procurement Partnerships			Product Development Partnerships								Capacity Building Partnership	
		GFATM	GDF	GAVI	IDRI	MMV	Aeras	DNDi	Sabin	PATH/ OWH	TB Alliance	IAVI	IAVI Innovation Fund	WHO GAP
Indonesia	Bio Farma			X										X
Iran	Razi Institute													X
Kenya	Abacus	X												
Korea	Dong-A	X												
	Green Cross					X								X
	LG Life Science			X										
Latvia	Olainfarm	X	X											
Mexico	Birmex										X			X
Romania	Cantacuzino													X
	SC Antibiotice	X												
Russia	Nauka					X								
Senegal	Pasteur Institute			X										X
Serbia	Torlak													X
South Africa	Adcock	X												
	Aspen	X	X											
	Elevation Biotech												X	
	iThemba											X		
	Sonke	X												
Tanzania	Zenufa										X			
Thailand	Government Pharm. Org.													X
Vietnam	Inst. of Vacc. and Med. Biol.													X
Zimbabwe	Varichem	X												

Table 2. Developing countries biopharmaceutical companies' involvement in global health partnerships

IDRI lists six companies from emerging markets as R&D partners out of 18 corporate collaborators (33 per cent) overall. Four of the six are from India.²⁸ MMV works with 62 pharmaceutical companies on R&D, seven of which are from emerging markets (11 per cent), with three from China, three from India, and one from Russia.²⁹ According to Aeras annual report 2010, three out of a total of 15 industry partners were from emerging markets (20 per cent), with one from China, one from India, and one from Korea.³⁰ In 2012, Aeras announced it had started to work with another Chinese biotechnology company.³¹ DNDi lists five companies from emerging markets as collaborators out of 24 corporate partners overall (21 per cent); two of them are from India and the others from Brazil, Colombia, and Tanzania.³² The Sabin Institute lists five corporate R&D partners on their website, three of which are from emerging markets (60 per cent), with two from Brazil and one from Mexico.³³ In addition, the PDP Funders Group reports collaboration between Sabin and the Chinese company Frontier Biosciences.³⁴

PATH and OWH are affiliated institutions but they provide separate data on their corporate R&D partners. OWH lists ten collaborators from the biopharmaceutical industry on their website, two of which (20 per cent) are based in India.³⁵ According to the PDP Funders Group, OWH had research and development agreements with three companies from China and India,³⁶ two 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 organisation has expanded collaboration with emerging market companies in recent years.³⁷ In the Meningitis Vaccine Project, an Indian company was chosen as the manufacturer of the new vaccine.³⁸ In the area of pneumococcal vaccine development, PATH mentions six collaborators from the biopharmaceutical industry, two of which are from emerging markets, China and India.³⁹ For its work on a life rotavirus vaccine, PATH mentions collaboration with

²⁸ IDRI, 'Collaborators', available at: {<http://www.idri.org/collaborators.php>} accessed 25 October 2013.

²⁹ MMV, 'Partnering', available at: {<http://www.mmv.org/partnering/who-we-work/private-sector>} accessed 25 October 2013.

³⁰ Aeras, 'Annual Report 2010: Answering the Call for a TB-Free World', available at: {<http://www.preventtb.org/annualreport2010/partners.html>} accessed 24 October 2013.

³¹ Aeras, 'Aeras and CanSino Partner on Pre-Clinical Study of TB Vaccine Candidate', Press Release (6 May 2012), available at: {http://www.aeras.org/pressreleases/aeras-and-cansino-partner-on-pre-clinical-study-of-tb-vaccine-candidat#.UmmGgr_vw0p} accessed 24 October 2013.

³² DNDi, 'Partners', available at: {<http://www.dndi.org/partnership/partners.html>} accessed 25 October 2013.

³³ Sabin Vaccine Institute, 'Partners', available at: {<http://www.sabin.org/programs/what-we-do/partners>} accessed 25 October 2013.

³⁴ PDP Funders Group, 'Briefing Paper 3 – Annex' (August 2012), available at: {http://www.pdpfunders-group.org/PFG_Website/PFG_Briefing_Papers_files/PFG%20Briefing%20Paper%203%20Annex%20-%20August%202012.pdf} accessed 16 October 2013.

³⁵ OWH, 'Our Supporters', available at: {<http://www.oneworldhealth.org/donors-partners>} accessed 25 October 2013.

³⁶ PDP Funders Group, 'Briefing Paper 3 – Annex'.

³⁷ John W. Boslego, 'PATH's Vaccine Development Program', presentation given at the Phacilitate Vaccine Forum 2014, Washington DC, 27 January 2014.

³⁸ PATH, 'Meningitis Vaccine Project', available at: {<http://www.path.org/menafrivac/>} accessed 25 October 2013.

³⁹ PATH, 'Pneumococcal Vaccine Project', available at: {http://www.path.org/projects/pneumococcal_protein_vaccine_project_partners.php} accessed 25 October 2013.

three biopharmaceutical companies, all of which are from China and India.⁴⁰ PATH is also providing technical assistance to a Chinese biotechnology company for production of oral polio vaccine.⁴¹ For its Malaria Vaccine Partnership, PATH lists six collaborators from the biopharmaceutical industry, two of which are based in India.⁴²

As mentioned above, the TB Alliance did not collaborate with biopharmaceutical companies from emerging markets. In 2007, however, it worked with the Indian company Lupin on two drug candidates for tuberculosis.⁴³ 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.⁴⁴ Like the TB Alliance, IAVI did not have any R&D collaborations with pharmaceutical companies from emerging markets.⁴⁵ Yet, IAVI's Innovation Fund has provided grants to two emerging markets companies out of a total of 15 grantees, one from India and one from South Africa.⁴⁶ 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 per cent of their vaccine production to United Nations agencies for distribution in low- and middle-income countries.⁴⁷ 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.⁴⁸ The funding has been channelled primarily through GAP. In 2009, BARDA established a US

⁴⁰ PATH, 'Live Rotavirus Vaccine Development', available at: {<http://sites.path.org/vaccinedevelopment/diarrhea-rotavirus-shigella-etec/live-rotavirus-vaccine-development>} accessed 25 October 2013.

⁴¹ PATH, 'PATH in China' (November 2012), available at: {<http://www.path.org/publications/detail.php?i=1794>} accessed 24 October 2013.

⁴² MVI/PATH, 'Our Portfolio', available at: {<http://www.malariavaccine.org/rd-portfolio.php>} accessed 24 October 2013.

⁴³ Ann M. Ginsberg and Melvin Spiegelman, 'Challenges in tuberculosis drug research and development', *Nature Medicine*, 13:3 (2007), pp. 290–94.

⁴⁴ TB Alliance, 'China Pioneers International R&D Center for Global Health', available at: {<http://www.tballiance.org/newscenter/view-brief.php?id=974>} accessed 24 October 2013.

⁴⁵ IAVI, 'Scientific Network', available at: {<http://www.iavi.org/Where-We-Work/Pages/default.aspx#map-tabs=0&&ItemType=ScientificNetwork&FilterId=6>} accessed 24 October 2013.

⁴⁶ IAVI, 'Innovation Fund', available at: {<http://www.iavi.org/Where-We-Work/Pages/default.aspx#&&ItemType=ScientificNetwork&FilterId=5>} accessed 24 October 2013.

⁴⁷ Martin Friede, Laszlo Palkonyay, Claudia Alfonso, Yuri Pervikov, Guido Torelli, David Wood, and Marie Paule Kiény, 'WHO initiative to increase global and equitable access to influenza vaccine in the event of a pandemic: Supporting developing country production capacity through technology transfer', *Vaccine*, 29S (2011), pp. A2–A7.

⁴⁸ Michael L. Perdue and Rick A. Bright, 'United States of America Department of Health and Human Services Support for Advancing Influenza Vaccine Manufacturing in the Developing World', *Vaccine*, 29S (2011), pp. A48–A50.

\$7.9 million cooperative agreement with PATH to support the final developmental processes for an influenza vaccine at a Vietnamese manufacturer.⁴⁹ 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.

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.⁵⁰ 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 categorisation 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 two 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 three 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 per cent of board members (seven out of nine) have a business background. Other global health partnerships with comparatively high proportions of board members with a business background are Aeras with 58 per cent and the TB Alliance with 54 per cent. 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 per cent. The remaining global health partnerships have corporate representations of between 5–15 per cent.

⁴⁹ Perdue and Bright, 'United States of America Department of Health and Human Services Support for Advancing Influenza Vaccine Manufacturing in the Developing World'.

⁵⁰ Data gathered from the websites of the global health partnerships.

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.⁵¹ 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.⁵² 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.⁵³

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?

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 2001⁵⁴ made access to medication for HIV/AIDS and the development of a HIV vaccine a key goal of global health governance. The Declaration recognises ‘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’.⁵⁵ In addition, the Declaration commits to ‘increase investment in and accelerate research on the development of HIV vaccines’.⁵⁶

⁵¹ Data gathered from the websites of the global health partnerships.

⁵² Kent Buse and Andrew Harmer, ‘Power to the partners? The politics of public-private health partnerships’, *Development*, 47:2 (2004), pp. 49–56.

⁵³ PATH, ‘2012 Annual Report: Innovation in Motion’ (Seattle: PATH, 2012), available at: {http://www.path.org/publications/files/ER_annual_report_2012.pdf} accessed 15 October 2012.

⁵⁴ UN General Assembly, ‘Declaration of Commitment on HIV/AIDS’ (2 August 2001), available at: {http://www.unaids.org/en/media/unaids/contentassets/dataimport/publications/irc-pub03/aidsdeclaration_en.pdf} accessed 13 May 2014.

⁵⁵ See fn. 54 above, para. 24, p. 9.

⁵⁶ See fn. 54 above, para. 70, p. 33.

In the following years, a consensus emerged that global access to ARV treatment was possible.⁵⁷

In the area of neglected tropical diseases, a roadmap by WHO in 2012 identifies preventative chemotherapy, that is, the delivery of medicines, as the key global governance strategy to tackle these diseases.⁵⁸ 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'.⁵⁹

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.'⁶⁰ 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.'⁶¹

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.⁶² Perhaps the most important precedent for a global mobilisation of

⁵⁷ WHO/UNAIDS, 'Progress on Global Access to HIV Antiretroviral Therapy: A Report on 3 by 5 and Beyond' (Geneva: World Health Organization, 2006).

⁵⁸ WHO, 'Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation' (Geneva: World Health Organization, 2012), available at: {http://www.who.int/neglected_diseases/NTD_RoadMap_2012_Fullversion.pdf} accessed 13 May 2014.

⁵⁹ London Declaration on Neglected Tropical Diseases (2012), available at: {https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/67443/NTD_20Event_20-20London_20Declaration_20on_20NTDs.pdf} accessed 13 May 2014.

⁶⁰ European Commission, Press Release Database: Daily News of 6 November 2013, available at: {http://europa.eu/rapid/press-release_MEX-13-1106_en.htm?locale=FR} accessed 13 May 2014.

⁶¹ WHO, 'Global Pandemic Influenza Action Plan to Increase Vaccine Supply' (Geneva: WHO, 2006), p. v, available at: {http://whqlibdoc.who.int/hq/2006/WHO_IVB_06.13_eng.pdf?ua=1} accessed 13 May 2014.

⁶² Jeremy Youde, *Global Health Governance* (Cambridge: Polity, 2012).

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 Long⁶³ draw on the concept of ‘pharmaceuticalisation’. This concept had originally been developed by sociologists and anthropologists to highlight the proliferation of pharmaceuticals in various areas of social life.⁶⁴ While much of this literature focuses on how the pharmaceutical industry drives pharmaceuticalisation, 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 pharmaceuticalisation in the field of security because they incentivise 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.

Pharmaceuticalisation 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 pharmaceuticalisation 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,

⁶³ Stefan Elbe, Anne Roemer-Mahler, and Christopher Long, ‘Medical countermeasures for national security: A new government role in the pharmaceuticalization of society’, *Social Science & Medicine* (2014), available at: {<http://dx.doi.org/10.1016/j.socscimed.2014.04.035>}.

⁶⁴ Adele Clarke, Laura Mamo, Jennifer Fosket, Jennifer Fishman, and Janet Shim (eds), *Biomedicalization: Technoscience, Health and Illness in the U.S.* (Durham NC: Duke University Press, 2010); Simon Williams, Jonathan Gabe, and Peter Davis, *Pharmaceuticals and Society: Critical Discourses and Debates* (Oxford: Wiley-Blackwell, 2009); Adriana Petryna, Andrew Lakoff, and Arthur Kleinman, *Global Pharmaceuticals: Ethics, Markets, Practices* (Durham NC: Duke University Press, 2007); Susan Reynolds Whyte, Sjaak van der Geest, and Anita Hardon, *Social Lives of Medicines* (Cambridge: Cambridge University Press, 2003).

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 – large European and US companies – as potential suppliers and development partners.⁶⁵ 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.⁶⁶ Opportunity costs are high, profit margins comparatively low, and demand is often difficult to forecast.⁶⁷ 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 repurposing of existing products and/or the opening of markets of commercial interest to these companies.⁶⁸

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.⁶⁹ Finally, Indian manufacturers were able to supply at prices far below those of big pharma companies.⁷⁰

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.⁷¹ While innovation currently tends to be incremental rather than for entirely new molecules,⁷² a study on the health biotechnology sectors in Brazil, China, and India identified 165 innovative products

⁶⁵ Interviews with representatives from three Product Development Partnerships.

⁶⁶ BioVentures for Global Health, 'Developing New Drugs and Vaccines for Neglected Diseases of the Poor. The Product Developer Landscape' (San Francisco: BioVentures for Global Health, 2012), available at: {<http://www.bvgh.org/LinkClick.aspx?fileticket=h6a0cJK9drq%3D&tabid=91>} accessed 12 January 2014; James R Hargreaves, Brian Greenwood, Charles Clift, Akshay Goel, Anne Roemer-Mahler, Richard Smith, and David L. Heymann, 'Making new vaccines affordable: A comparison of financing processes used to develop and deploy new meningococcal and pneumococcal conjugate vaccines', *The Lancet*, 378:9806 (2011), pp. 1885–93.

⁶⁷ Stefan Elbe and Anne Roemer-Mahler, 'Pharmaceuticals and Security: Strengthening Industry Engagement', Summary Report of a Roundtable Discussion hosted by the Centre for Global Health Policy, University of Sussex, 7 February 2014, available at: {<https://www.sussex.ac.uk/webteam/gateway/file.php?name=erc-report.pdf&site=346>} accessed 13 May 2014.

⁶⁸ Stefan Elbe and Anne Roemer-Mahler, 'Pharmaceuticals and security'; Sebastian Buckup, 'Global public-private partnerships against neglected diseases: Building governance structures for effective outcomes', *Health Economics, Policy and Law*, 3:1 (2008), pp. 31–50.

⁶⁹ Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry?: Patent Protection, TRIPS, and Developing Countries* (New Delhi: Oxford University Press, 2005).

⁷⁰ Waning et al., 'A lifeline to treatment', p. 1.

⁷¹ Rahim Rezaie, Anita M McGahan, Abdallah S. Daar, and Peter A. Singer, 'Innovative drugs and vaccines in China, India and Brazil', *Nature Biotechnology*, 30:2 (2012), pp. 923–6.

⁷² Sarah E. Frew, Stephen M. Sammut, Alysha F. Shore, Joshua K. Ramjst, Sara Al-Bader, Rahim Rezaie, Abdallah S. Daar, and Peter A. Singer, 'Chinese health biotech and the billion-dollar market', *Nature Biotechnology*, 26:1 (2008), pp. 37–53; Sarah E. Frew, Rahim Rezaie, Stephen M. Sammut, Monali Ray, Abdallah S. Daar, and Peter A. Singer, 'India's health biotech sector at a crossroads', *Nature Biotechnology*, 25:4 (2007), pp. 403–17.

within 41 domestic firms in these countries.⁷³ Indian companies had the largest share of innovative products with 55 per cent, followed by Chinese firms with 29 per cent, and Brazilian firms with 16 per cent of the total number of products identified.⁷⁴ As a result, governments and global health partnerships have recently intensified collaboration for pharmaceutical development with emerging market producers.

The pharmaceuticalisation 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.⁷⁵ 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 colleagues⁷⁶ 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’.⁷⁷ 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’⁷⁸ as key aims of the Network. Indeed, when DCVMN was founded in 2001, ‘[i]t was hoped . . . that GAVI would support the Network by

⁷³ Frew et al., ‘Chinese health biotech and the billion-dollar market; Frew et al., ‘India’s health biotech sector at a crossroads’; Rahim Rezaie, Sarah E. Frew, Stephen M. Sammut, Maya R. Maliakkal, Abdallah S. Daar, and Peter A. Singer, ‘Brazilian health biotech – fostering crosstalk between public and private Sectors’, *Nature Biotechnology*, 26:6 (2008), pp. 627–44.

⁷⁴ Frew et al., ‘Chinese health biotech and the billion-dollar market’; Frew et al., ‘India’s health biotech sector at a crossroads’; Rezaie et al., ‘Brazilian health biotech’.

⁷⁵ Klaus E. Meyer and Ornjira Thajongrak, ‘The dynamics of emerging economy MNEs: How the internationalization process model can guide future research’, *Asian Pacific Journal of Management* (2012), 10.1007/s10490-012-9313-9; Peter Ping Li, ‘Toward a learning-based view of internationalization: The accelerated trajectories of cross-border learning for latecomers’, *Journal of International Management*, 16:1 (2010), pp. 43–59; John Mathews, ‘Dragon multinationals: New players in 21st century globalization’, *Asia Pacific Journal of Management*, 23:1 (2006), pp. 5–27.

⁷⁶ Rezaie et al., ‘Brazilian health biotech’.

⁷⁷ Frew et al., ‘India’s health biotech sector at a crossroads’.

⁷⁸ Suresh S. Jadhav, Manish Gautam, and Sunil Gairola, ‘Emerging markets and emerging needs: Developing countries vaccine manufacturers’ perspective and its current status’, *Biologicals*, 37:3 (2009), pp. 165–8.

“push” mechanisms such as facilitating access to technology’.⁷⁹ 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 an important consideration for SII’s decision to manufacture the vaccine at the low price of US \$0.5 per dose.⁸⁰

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’.⁸¹ 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 organisations, 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.⁸²

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 favour 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 ‘[s]everal 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 [companies]’.⁸³

The increasing involvement of emerging market companies as suppliers and R&D partners of global health partnerships may therefore be explained by a combination of a policy shift in global health governance towards greater pharmaceuticalisation 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

⁷⁹ Suresh S. Jadhav, Mahima Datla, Hans Kreeftenberg, and Jan Hendriks, ‘The Developing Countries Vaccine Manufacturers’ Network (DCVMN) is a critical constituency to ensure access to vaccines in developing countries’, *Vaccine*, 26:13 (2008), pp. 1611–15.

⁸⁰ Hargreaves et al., ‘Making new vaccines affordable’; Sanjukta Sen Gupta, G. Balakrish Nair, Narendra Kumar Arora, and Nirmal Kumar Ganguly, ‘Vaccine development and deployment: Opportunities and challenges in India’, *Vaccine*, 31S (2013), pp. B43–B53; interviews with representatives of Serum Institute of India and PATH.

⁸¹ Julie B. Milstien and Miloud Kaddar, ‘The role of emerging manufacturers in access to innovative vaccines of public health importance’, *Vaccine*, 28 (2010), p. 2118.

⁸² Roemer-Mahler, ‘Business conflict and global politics’; Kapstein and Busby, ‘AIDS drugs for all’.

⁸³ Wilson and Rao, ‘India’s role in global health R&D’, p. 32.

governance are based on neoliberalist notions of the role of the state as facilitator, rather than provider, of social policies,⁸⁴ and changing conceptions of the relations between public and private,⁸⁵ both of which have their roots in Anglo-Saxon schools of thought.⁸⁶ 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 per cent and 18 per cent.

Kent Buse and Andrew 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’.⁸⁷ 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.⁸⁸ 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,⁸⁹ 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

⁸⁴ Tim G. Evans and Lincoln C. Chen, ‘Public-Private Partnerships in Global Health’, Discussion Paper (Washington DC: The Rockefeller Foundation, 2005); Karin Holm (ed.), ‘Public-Private Partnerships for Health and Guaranteeing Drug Delivery through Health Systems: Issues Needing Further Analysis’, Report of a Meeting Hosted by the London School of Hygiene and Tropical Medicine, London, 27–8 September 2001, available at: {http://announcementsfiles.cohred.org/gfhr_pub/assoc/s14832e/s14832e.pdf} accessed 24 October 2013.

⁸⁵ Jane Lethbridge, ‘Privatisation in Health Care – Implications for Health for All’ (London: PSIRU, 2002), available at: {<http://www.psiu.org/publications?type=report>}, accessed 23 September 2013.

⁸⁶ Anuj Kapilashrami, ‘Understanding Public Private Partnerships: The Discourse, the Practice, and the System Wide Effects of the Global Fund to Fight AIDS, Tuberculosis, and Malaria’ (PhD thesis, London: Queen Margaret University, 2010).

⁸⁷ Buse and Harmer, ‘Power to the partners?’, p. 54.

⁸⁸ Rita Abrahamsen, ‘The power of partnerships in global governance’, *Third World Quarterly*, 25:8 (2004), pp. 1453–67.

⁸⁹ Robert Michael Doble, ‘NGO Influence in Global Health Governance: An Evaluation of the HIV/AIDS Medicines Patent Pool and the Advance Market Commitment for Pneumococcal Vaccines’, unpublished PhD thesis, London School of Hygiene and Tropical Medicines (2013).

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. On 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 ten million⁹⁰ today has been built largely on ARVs produced by pharmaceutical companies from emerging markets.⁹¹ 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.⁹²

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'.⁹³ 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.⁹⁴ 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.⁹⁵

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

⁹⁰ UNAIDS, 'Global Report: UNAIDS Report on the Global AIDS Epidemic 2013' (Geneva: 2013), p. 46, available at: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf accessed 16 October 2013.

⁹¹ WHO, UNAIDS, and UNICEF, 'Towards Universal Access'.

⁹² WHO, 'Meningococcal disease: 2013 epidemic season in the African Meningitis Belt' (2013), available at: http://www.who.int/csr/don/2013_06_06_menin/en/ accessed 13 May 2014.

⁹³ Ravi Ramamurti, 'What have we learned about emerging-market MNEs', in Ravi Ramamurti and Jitendra Singh (eds), *Emerging Multinationals from Emerging Markets* (Cambridge UK: Cambridge University Press, 2008), pp. 399–426.

⁹⁴ Peter Williamson and Ming Zeng, 'Value-for-money strategies for recessionary times', *Harvard Business Review*, 87:3 (2009), pp. 66–74.

⁹⁵ Alfonso Fleury and Maria T. Leme Fleury, 'Brazilian multinationals: Surfing the waves of internationalization', in Ravi Ramamurti and Jitendra Singh (eds), *Emerging Multinationals from Emerging Markets* (Cambridge UK: Cambridge University Press, 2008), pp. 200–43; Louis T. Wells, *Third World Multinationals: The Rise of Foreign Investment from Developing Countries* (Cambridge, MA: MIT Press, 1983).

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.⁹⁶ 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 pharmaceuticalisation 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.⁹⁷

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 it further to the fore.

The tension between political demand and market demand for pharmaceuticals affects not only the global politics of HIV/AIDS⁹⁸ 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 medicines and vaccines globally and sustain the successes already achieved, greater investment from the public in the development, production, and procurement of medicines and vaccines is required.

⁹⁶ Rezaie et al., 'Brazilian health biotech'.

⁹⁷ Elbe and Roemer-Mahler, 'Pharmaceuticals and security'; Interviews with representatives of six Indian biopharmaceutical companies.

⁹⁸ Shadlen, 'The political economy of AIDS treatment'; Roemer-Mahler, 'Business strategy and access to medicines in developing countries'.