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VIEWPOINT

Building effective collaboration between health systems and the life sciences industry

Elize Massard da Fonseca, Mariana Ramos Teixeira and Nilson do Rosario Costa

ABSTRACT
This viewpoint reflects on the challenges of promoting affordable and innovative medicines while fostering a competitive environment for research and development in developing countries. We explore the life sciences industrial policies of Brazil and the United Kingdom in order to identify mechanisms and conditions that could serve as lessons to practitioners in other countries. We suggest three crucial design attributes: a strategic collaboration between a health system and the private sector, coordination and accountability mechanisms, and a network of support (that is, embeddedness).

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Introduction

Aligning access to medicines with industrial policy goals has been one of the major challenges for international development practitioners during the last two decades (World Health Assembly 2008; United Nations Conference on Trade and Development 2011). Particularly troubling for developing countries is how to create an environment that is conducive to innovation in the pharmaceutical sector, while dealing with an increasing demand for providing access to life-saving drugs to treat hepatitis C and HIV/AIDS (Shadlen and Fonseca 2013). Despite the number of international working groups and commitments, we still lack an understanding about which conditions and institutional mechanisms can improve coordination between these two domains. Recently, both the United Kingdom and Brazil have launched health industrial policies to foster the development of the pharmaceutical sector in alliance with their healthcare systems. In the UK this is known as the Life Science Industrial Strategy; in Brazil, it is called the Health Industry Complex Policy. In this viewpoint, we review key aspects of these initiatives in an effort to identify lessons for developing countries about how to integrate the needs of healthcare systems with the goals of promoting pharmaceutical innovation and production.

Some cautionary notes are necessary before we proceed. The extent to which the state should direct industrial activity or maintain a neutral position are issues that have been intensely debated by economists (Rodrik 2008). However, the pharmaceutical sector warrants an analysis about how healthcare policies facilitate (or constrain) industry competitiveness. This is a technology-intense sector and it is extremely regulated, usually, with few direct subsidies. Governments control whether companies can conduct research utilising human genes, define the limits around clinical trials, and determine which products can go into the market and which ones should be considered innovative and how it will pay for these products. These policies may favour certain industries and technologies, which can ultimately affect the supply and access to medicines. Therefore, we support the notion that the discussion should shift away from whether governments are against or in favour of industrial policies, and focus instead on which strategies are chosen and how to promote fruitful cooperation between the health and industrial sectors. Second, we are aware of

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the limitations of institutional transplantation of industrial strategies as these are conditioned to factors including the political-economic environment, the capacity of local industrialists, and the design of healthcare systems; but the cases presented here can serve as an inspiration for finding appropriate coordination mechanisms and policy solutions from other national contexts.

Both Brazil and the UK have been acknowledged as examples of countries that align the interests of their healthcare system with industrial goals (Thomas 1994; Shadlen and Fonseca 2013). While the UK has a long experience of health industry policy, dating back to the 1940s (recently incentives have become more explicit, as a post-Brexit strategy), Brazil initiated mechanisms to coordinate both sectors in 2007. We focused on three mechanisms that resemble Rodrik's (2008) key attributes to develop industrial policies: encourage investments in industrialisation followed by strict discipline about its beneficiaries; accountability; and embeddedness, that is collaboration between the government and the private sector. We applied a framework of "*high-quality lessons learned*" study design (Patton 2001), that is, the analysis is based on multiple sources, grounded in the context of what was implemented. These various forms and sources of knowledge "*cohere, triangulate, and reinforce each other, that very coalescence increases the likelihood of external validity*" (Patton 2001, 334). It is likely that the mechanisms and policies discussed in this article are more easily applied to countries with public pharmaceutical care/schemes and with local production of medicines. We are witnessing a movement towards universal health care coverage and a number of developing countries have established local drug companies (Kaplan 2011; World Bank 2013); therefore, our arguments apply to a wide audience of international development practitioners.

Finally, we consider this viewpoint to be an initial effort to understand key mechanisms put in place by these governments and hope to encourage a new research agenda on this topic.

Strategic collaboration between the private sector and the health system

One of the key elements that supports both the UK and Brazil's health industrial strategies is the existence of a public health care system. This is important for several reasons. In both countries, medicines are covered by public policies. Governments can influence demand for innovative products by adjusting these programmes. These financial resources allow the health system to encourage and reward innovation (original or incremental innovation), while responding to the needs of the population. In the UK, for instance, the Accelerated Access Review expedites the launch of new drugs that are relevant to the health system and the Pharmaceutical Price Regulation Scheme promotes a mechanism of purchasing original products in ways that balance reasonable prices for the industries and the health service. In Brazil, the government has used its purchasing power to stimulate partnerships between multinational and local companies to encourage technology transfer of drugs considered strategically important. This is known as the Partnerships for Product Development (PDP) programme. Successful experiences with this programme include an increased supply of HPV vaccine and the generic version of a novel therapy to treat hepatitis C. This collaboration is designed to respond to vulnerabilities in the healthcare system in supplying life-saving drugs to the population while fostering the technological development of local industries.

An important part of these strategies is achieving an optimal price for medicines; one that is fair to healthcare systems, but also fair to the industry. Therefore, public procurement and uptake are key. For six decades in the UK, instead of regulating the price of medicines directly as many other countries in the world do, the Department of Health regulated the profit that companies could achieve on sales to the NHS. That was a voluntary arrangement between government and research-based pharmaceutical industries and valid for patented drugs only. This has been one of the important pillars of the British model for pharmaceutical industry development, which deliberately used its regulatory responsibilities to create an appropriate environment for innovation (Thomas 1994). In a new arrangement, as part of the 2018 scheme review and aligned with the industrial strategy, the industry agreed to put a cap on the growth of patented medicines sales at a nominal rate of 2% per year, with member companies making payments based on net sales. In

return, the government committed to expediting new health technology assessment and approving earlier engagement to allow doctors and the healthcare infrastructure to quickly uptake new therapies (Department of Health and Social Care 2018). On the other hand, in Brazil, public procurement rules mandate that drugs must be purchased at the lowest price available, except for those produced by public laboratories. This required the Ministry of Health to conduct an institutional engineering to be able to commit to purchasing the PDP supply. By including public laboratories in the PDP arrangement, it would be possible to secure the consortia as a preferred supplier.

These initiatives are not exempt from criticism. Although there have been questions about the costs of such policies to the health care system (Naci and Mossialos 2017; Chaves, Osorio-de-Castro, and Auxiliadora Oliveira 2017); there has been an apparent consensus among healthcare decision-makers and the public health community around these arrangements (Centro Brasileiro de Estudos de Saúde 2014; House of Lords 2018a). It is clear from both countries that to better integrate health and industrial goals requires we acknowledge the inherent tendency of public-private partnerships in the health sector. In the words of Lord Henley, from the UK's Department for Business, Energy and Industrial Strategy: "[the life science industrial strategy] *is not about picking winners or something of that sort, which we might have done in the past. Partnership is the word I want to get over again and again*" (House of Lords 2018b). This means that constant collaboration is necessary.

Countries such as India and China, despite their vibrant generic drug manufacturers, fail to deliver appropriate healthcare and lack a fruitful collaboration between their local industries and health systems (Srinivas 2012). On the other hand, Mexico and South Africa have invested in ameliorating public procurement practices and price regulation, respectively (Moye-Holz et al. 2017). However, none uses innovative strategies to foster local industrial development through procurement strategies, but could benefit from the experiences discussed here.

Coordination and accountability

A crucial aspect of governing the health industrial policy is coordination. The creation of an office with authority to align departments and stakeholders' interests is key. Because industrial policy spans across different governmental bodies, including trade, health, and education, coalescing policies that affect such a range of issues is important. In the UK, Parliament has encouraged the creation of a Life Sciences Governing Body responsible for the delivery of the industrial strategy and with the ability to bring together other government representatives in different departments (House of Lords 2018a). Similarly, in Brazil, the Ministry of Health has created an office, the Secretariat of Health, Science, and Technology, that has responsibilities over the acquisition of medicines and institutional resources to put forward the PDP agenda. This has been crucial to the sustainability of Brazil's experience as it coordinates government purchasing of drugs, with its technology transfer strategy, and also facilitates communication with industrial offices such as the Development Bank and the Ministry of Industry, Trade, and Commerce (Fonseca 2018). Therefore, it is crucial to establish a coordinating body, responsible for bringing together distinct stakeholders in a complex ecosystem of research, highly-skilled labour, intellectual property, and institutions for approval of and procurement of healthcare products. In addition, to monitor the competitiveness of the life science sector, the UK government proposed a set of indicators to assess sectoral evolution using a comparative perspective (see Appendix). These indicators and country comparators were selected by a steering committee, including trade associations, companies, regulators and government departments. This is itself an important advancement, as the effort to provide sound evidence to monitor the evolution of competitiveness in this sector is not a trivial task. Many countries do not even have historical data on these indicators as the UK has. Second, the position of the UK in the ranking of countries is notable. The country occupies the leading position on investment in health research and development, the presence of skilled professionals; while also presenting a reasonable period for appraisal and uptake of new drugs. This means that innovative therapies can be quickly available to patients.

Nevertheless, impact assessment should also be included to better understand the consequences for public health (Naci and Mossialos 2017).

In Brazil, by contrast, key aspects are mainly the monitoring of trade balance data and analysis of cost saving numbers to the Ministry of Health (Gadelha 2006); although there have been recent efforts to develop a systematic plan of evaluation (Silva and Elias 2017). In response to complaints about transparency, in 2014, the Ministry of Health has launched new regulations governing technology transfer agreements as a way to clarify the process (Ministerio da Saude 2014). Procedural monitoring of PDPs is in place, but following a precedent that is different from the UK, Brazil still lacks broader sector monitoring.

Monitoring and evaluation are critical as this sector is plagued with criticism over regulatory and bureaucratic capture; therefore, democratic institutions are essential to oversight these initiatives. In Britain, Parliament has played a crucial role in reviewing the government's strategy (House of Lords 2018a). Specifically, members of Parliament have supported the effort of developing Britain's pharmaceutical sector, but raised concerns about how the policy will be implemented and by whom. This has helped in clarifying the governance and accountability mechanisms of the health industry policy. In Brazil, scrutiny is in the hands of Congress and other internal control institutions but has also a strong oversight from civil society (Secretaria Federal de Controle Interno 2017). Thanks to the demands of such non-state actors, rules about how to govern the technology transfer partnerships for drug development were expanded and clarified.

Network of support

Finally, according to specialists in development policy, embeddedness is crucial to the development of industrial policies (Rodrik 2008). These groups, including industry associations, trade unions, research institutes, and educational institutions, are non-government related and promote communication between the government and private actors. This network is vital to creating cooperation and exchanging ideas to limit bottlenecks and increase the potential for promoting innovation and sectoral improvements.

In that sense, Britain has provided a fertile ground with strong integration of different stakeholders into the policy process. Both the Sir Bell Report, that established the foundations of the post-Brexit life science industrial policy, and the 2018 Parliamentary inquiry have included consultation with different stakeholders such as National Health Service representatives, pharmaceutical companies, academics, and others. Their comments are publicly available and prove their strong support for improved integration of health and industrial policy goals.

In Brazil, the health industrial policy was triggered after several consultations with industry leaders and academics to identify challenges and collect suggestions about how to best foster local production of medicines (Brasil 2003). The Ministry of Health also created a consulting forum where producers, academics, and members of civil society could participate and provide input into policy development. More recently, with the political instability after the impeachment of President Dilma Rousseff, local and transnational industrialists issued a statement of support regarding the continuity of the health industry complex initiative (Valor Economico 2016). This proves the important role of this network in sustaining the industrial policy.

Conclusion

Building responses that better integrate health and industrial goals in developing countries requires first and foremost to acknowledge the potential of healthcare systems as drivers that can foster the pharmaceutical sector capabilities. In other words, the demands of public health systems are powerful incentives to encourage innovators and local producers to behave in certain ways. As international development agencies become more strongly committed to expanding universal healthcare coverage, this potential must be better clarified. Public health policy is not possible without vigorous

integration and collaboration with the life science industrial sector. Identifying mechanisms and best practices, such as policy coordination, accountability, together with a network of support are crucial to put forward an effective agenda to promote a health industry policy.

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Appendix

Life sciences indicators; the UK in comparative perspective.

Category	Indicator	Current value (year)	Current rank among selected comparator countries	Countries
Reinforcing the UK science offer	Government spend on health research and development	$3.1bn (2015)	2nd of 13	USA, UK, Germany, Japan, Canada, Spain, France, Italy, Netherlands, Sweden, Belgium, Ireland, Switzerland,
	Non-industry spend on research and development	£3.6bn (2015/16)	N/A	
	Pharmaceutical industry spend on research and development in the UK	£4.1bn (2016)	N/A	
	Share of patients recruited to global studies (all trial phases)	3.1% (2016)	4 of 10	USA, Germany, Canada, UK, Spain, France, Italy, Australia, Netherlands, Switzerland
	Time from core package received to first patient enrolled in country (all trial phases)	202 days (2016)	7 of 10	USA, Spain, Australia, Italy, Germany, Canada, UK, France, Netherlands, Switzerland
	Share of life sciences academic citations	12% (2014)	2 of 19	USA, UK, China, Germany, Canada, Italy, France, Netherlands, Spain, Japan, Switzerland, Republic of Korea, Brazil, Sweden, India, Belgium, Singapore, Ireland, Russia

(*Continued*)

Continued.

Category	Indicator	Current value (year)	Current rank among selected comparator countries	Countries
	Share of most cited (top 1%) life sciences academic citations	18% (2014)	2 of 19	USA, UK, Germany, China, Canada, France, Italy, Netherlands, Spain, Switzerland, Sweden, Japan, Belgium, Republic of Korea, Brazil, India, Singapore, Ireland, Russia
Growth and infrastructure	Number of people employed in manufacture of basic pharmaceutical products and pharmaceutical preparations	40,500 (2016)	6 of 12	Germany, France, Italy, Switzerland, Spain, UK, Belgium, Ireland, Austria, Sweden, Netherlands, Finland
	Number of people employed in manufacture of medical technology products	40,300 (2016)	4 of 12	Germany, Italy, France, UK, Ireland, Switzerland, Spain, Netherlands, Austria, Sweden, Belgium, Finland
	Gross value added for pharmaceutical manufacturing	€9.2bn (2015)	6 of 11	Switzerland, Germany, France, Ireland, Italy, UK, Spain, Belgium, Netherlands, Austria, Finland
	Exports of pharmaceutical products	$33.3bn (2016)	5 of 18	Germany, Switzerland, USA, Belgium, UK, Ireland, France, Netherlands, Italy, India, China, Canada, Singapore, Japan, Republic of Korea, Mexico, Brazil, Russia
	Exports of medical technology products	$3.8bn (2016)	12 of 18	USA, Germany, Netherlands, China, Mexico, Belgium, Japan, Ireland, France, Singapore, Switzerland, UK, Italy, Republic of Korea, Canada, India, Brazil, Russia
	Imports of pharmaceutical products	$33.4bn (2016)	4 of 18	USA, Germany, Belgium, UK, Switzerland, France, Japan, Italy, China, Netherlands, Canada, Russia, Brazil, Ireland, Republic of Korea, Mexico, India, Singapore
	Imports of medical technology products	$5.1bn (2016)	8 of 18	USA, Germany, China, Netherlands, Japan, France, Belgium, UK, Italy, Canada, Mexico, Singapore, Republic of Korea, Switzerland, India, Russia, Brazil, Ireland
	Life sciences foreign direct investment projects	60 (2017)	2 of 15	USA, UK, China, France, Germany, Ireland, India, Japan, Switzerland, Canada, Russia, Australia, Republic of Korea, Italy, Sweden
	Life sciences foreign direct investment – capital expenditure	£750m (2017)	4 of 15	USA, China, Ireland, UK, India, France, Germany, Japan, Switzerland, Australia, Russia, Italy, Canada, Republic of Korea, Sweden
	Share of global life science Initial Public Offerings (IPOs)	1% (2017)	11 of 20	China, USA, Sweden, Australia, Republic of Korea, India, France, Taiwan, Canada, Japan, UK, Argentina, Bangladesh, Denmark, Luxembourg and Brazil, Norway, Pakistan, Poland, Switzerland, Turkey
	Initial Public Offerings (IPOs) in life sciences – amount raised (where known)	£22m (2017)	16 of 20	USA, China, Switzerland, Sweden, Luxembourg and Brazil, Republic of Korea, India, France, Australia, Denmark, Canada, Norway, Argentina, Japan, Taiwan, UK, Pakistan, Turkey, Bangladesh, Poland
	Private equity investment – total investment	€760m (2016)	3 of 12	France, Italy, UK, Germany, Spain, Sweden, Netherlands, Switzerland, Ireland, Finland, Belgium, Austria

(*Continued*)

Continued.

Category	Indicator	Current value (year)	Current rank among selected comparator countries	Countries
	Number of companies receiving private equity investment	67 (2016)	5 of 12	France, Germany, Spain, Sweden, UK, Netherlands, Finland, Switzerland, Italy, Belgium, Ireland, Austria
NHS collaboration	Speed and volume of NICE Technology Appraisals – time from marketing authorisation to first NICE output	6.0 months (2017/18)	N/A	
	Speed and volume of NICE Technology Appraisals – time from marketing authorisation to final NICE guidance	10.2 months (2017/18)	N/A	
	Uptake of new medicines – NICE approved (relative uptake compared against average comparator uptake three years after launch)	70% (2012–2016)	N/A	
	Uptake of new medicines – non-NICE reviewed (relative uptake compared against average comparator uptake three years after launch)	56% (2012–2016)	N/A	
Skills	Percentage of graduates from tertiary education graduating from natural sciences, mathematics and statistics programmes, both sexes (%)	13% (2015)	1 of 14	UK, India, France, Switzerland, Italy, Ireland, USA, Spain, Sweden, Republic of Korea, Belgium, Brazil, Netherlands, Russia
Regulation	Instances where MHRA is in lead role in EU regulatory procedure (%)	25% (2016)	N/A	

Source: Adapted from Office for Life Sciences (2018).