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Abstract

This article offers a critical contribution to debates around access to medicines and the global politics of pharmaceutical production in Africa. Specifically, we seek to account for a normative shift within these debates whereby the promotion of local pharmaceutical production in Africa has once again come to be viewed as a central modality for achieving access to health across the continent. While the onset of this normative shift has been highlighted by the global Covid-19 pandemic, in this article we argue that its antecedents can be traced to a more incremental process of global and regional normative change that has been in motion since the late 1990s. To illustrate this, we narrow our empirical focus onto the East African Community (EAC) and the regional initiatives its members have pursued to promote local pharmaceutical production capacities since 2012. We draw and build upon the literature on norm localization to emphasize how the emergence and distinctiveness of this policy reflected the complex way in which policy actors within the EAC sought to localize and combine separate (and somewhat competing) changing global norms around access to health and industrial policy. The article also points to the tensions and unintended consequences which emerged from this complex process of norm localization and the challenges of implementing this strategy within the institutional landscape of the EAC.

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Keywords

Regionalism, East African Community, access to health, industrialization, pharmaceuticals, norm localization

Introduction

Africa should not be begging for vaccines. Africa should be *producing* vaccines.

Dr Akinwumi A. Adesina, President of the African Development Bank (AfDB),
speech at AfDB's annual meeting in June 2021

Since the outbreak of the global Covid-19 pandemic in 2020, inequities around Africa's access to medicines have been starkly illustrated by the administration of Covid-19 vaccinations across the world. At the time of writing, only 6.8 vaccination doses per 100 people have been administered across Africa, while in Europe and North America this figure stands at 97 and 92 doses per 100 people, respectively (The New York Times, 2021). As the above quote by the President of the African Development Bank (AfDB) shows, this has reignited calls for the African continent to develop its own regional pharmaceutical production capacities and secure its own access to vaccines and other medicines, rather than relying on foreign imports. This call has been echoed by several western donors who have reaffirmed their commitment to support vaccine production in Africa (The Financial Times, 2021). Pharmaceutical production in Africa, therefore, has come under the spotlight during the Covid-19 pandemic, but was also high on the agenda in previous years (African Union (AU), 2007). Significantly, however, the perceived links between the establishment of local pharmaceutical production capacities and access to medicines in Africa has not always been clear cut. During the 1990s and early 2000s, the prevailing consensus was that access to medicines in Africa would be better served by multinational pharmaceutical firms who were seen to have both the scale and capacity to produce medicines more efficiently and cheaply (see Kaplan and Laing, 2005).

Existing research on the global politics of pharmaceutical production has tended to focus on the origins and impact of major shifts in the global patent regime (see, for example, Muzaka, 2011; Shadlen et al., 2011) as well as the opposition mobilized to this regime by civil society and developing countries (Kapstein and Busby, 2013; 't Hoen et al., 2011) and, more recently, varying policy responses to this regime by developing countries (Chorev, 2020; Chorev and Shadlen, 2015; Löfgren and Williams, 2013; Shadlen, 2009, 2020; Shadlen and Fonseca, 2013). Here, we seek to extend this literature by charting the normative shifts at global and regional levels that saw local production return to the fore as a central modality for achieving access to medicines. More specifically, we ask how local production came to be accepted as a legitimate and viable solution to promoting access to health in Africa.

We do so by narrowing our focus onto the East African Community (EAC) and its agenda since 2012 to promote access to health through local pharmaceutical production. Like many other governments across Africa during the 2000s, EAC members (Burundi, Kenya, Rwanda, Tanzania and Uganda) had sought to procure medicines based on price competitiveness, as opposed to prioritizing local producers. Indeed, as late as 2009, the

EAC members had reduced tariff rates on a selection of imported medicines to reduce their cost (Mackintosh et al., 2018b: 187). In 2012, however, the EAC (2012b) members released a regional strategy that aimed to build on emerging African continental efforts to promote local pharmaceutical production capacities across East Africa. This was then followed in 2017 by a second regional strategy that called for a more assertive push to promote pharmaceutical production, including the use of import-substitution and local procurement (EAC, 2017). Given that access to medicines has been a perennial issue facing the East African region, we consider in this paper how this local pharmaceutical production agenda emerged at the time and in the specific form that it did. Although the origins of this shift can be traced in part to the effects of the HIV/AIDS pandemic, the process through which local production came to be accepted as a feasible answer to the problem of access to medicines and how this agenda came to be combined with a broader drive for industrial development exhibits a number of complexities – and has consequently produced a range of policy tensions.

An emerging strand of the comparative regionalism literature (Briceño-Ruiz and Morales, 2017; Riggirozzi and Tussie, 2012, 2015; Tussie, 2014) points helpfully to recent normative shifts towards heterodox development agendas in the Global South, as well as highlighting the links between global and regional contexts. However, this literature proves less attuned for unpacking how specific regional policy norms emerge and with what consequences. In this article, therefore, we attempt to complement these accounts, by building a more fine-grained analytic framework that draws upon existing accounts of norm localization (see Acharya, 2004; Ban, 2016; Dafe, 2020; Eimer et al., 2016) to stress the agency of actors from the Global South in both shaping global norms and the way they are translated and combined in regional settings. Moving beyond the existing norm localization literature, we also explore the way in which these processes reflect both the complexity of global norms and their interaction with distinct regional institutional and normative settings, which we argue has important implications for the implementation of regional policy agendas. By applying this framework to the politics of pharmaceutical production and access to medicines, we aim to generate insights about both the origins and dynamics of contemporary agendas for local pharmaceutical production in the Global South and to highlight some of the tensions and complexities that continue to characterize the rollout of these policies.

We argue that the emergence of the EAC's pharmaceutical production agenda reflected a 'complex' process of norm localization. The origins of the local production agenda can be traced to challenges to the global patent regime – including by African actors – in the context of the HIV/AIDS crisis in the 1990s. The resulting changes to this regime did not call explicitly for local pharmaceutical production as a platform for promoting access to health in the Global South – indeed they reflected a continued emphasis on the need to procure medicines on the basis of price competitiveness. However, they created space in which policy actors in the EAC and across the continent, as well as external development partners, came to view the promotion of local pharmaceutical production as a politically feasible option. Over time, this agenda for access to medicines through local production was combined with a separate emerging norm promoting regional development through industrialization, which had come to be central to the EAC's broader economic strategy. As a result, the norm of pharmaceutical procurement

on the basis of price competitiveness came to be subsumed to a broader rationale for local production based on both access and industrial upgrading. Following from this, the paper explores the way in which the tensions within the EAC pharmaceutical policy itself – in part, the result of the complex process through which global norms were combined and localized into the EAC’s policy regime and, in part, reflecting a normative and institutional trajectory specific to the East African region – have served to impede aspects of its implementation. More broadly, the paper suggests that the international politics of pharmaceutical production is shaped decisively by complex processes of normative contestation and change at global and regional levels, with actors from the Global South playing a significant role. Moreover, the consequences of these processes of change play out in the idiosyncrasies and tensions within emerging regional regimes for the governance of health and pharmaceutical production.

The rest of this article is organized as follows. In the next section, we develop a theoretical framework around the concept of regional norm localization before turning to outline our methodological approach. In the section ‘Access to medicines: from TRIPS to local production’, we provide background on the global access to health agenda that emerged in the early 2000s and the way this shaped the early stages of the EAC’s local pharmaceutical agenda. In the section ‘The emergence of EAC pharmaceutical policy: from access to health to industrialization’, we then turn to consider the fusion of the EAC’s access to health and industrialization agendas, exploring why the former has taken on a distinctly productivist logic. The penultimate section ‘From conception to implementation: the limits of the EAC’s local pharmaceutical agenda’ then provides an account of the implementation and rollout of the EAC’s pharmaceutical production strategy and the challenges which have emerged from this. The final section summarizes our arguments and key contributions.

Regionalism and access to health: regional norm localization in a complex global order

In recent years, a growing body of comparative regionalism scholarship has considered the changing ideological character of regionalism across the Global South in the context of the decline of US hegemony and broader structural changes in the global order (Briceño-Ruiz and Morales, 2017; Ruggirozzi and Tussie, 2012, 2015; Tussie, 2014). This ‘post-hegemonic regionalism’ literature has principally focused its attention on the Latin American region, noting a shift in the 2000s away from market-driven agendas associated with neoliberalism and towards more heterodox development norms and policies related to welfare, health, education and human rights. One prominent area of focus within this wider literature has centred on the role of regions as policy spaces for promoting access to health and health resilience (see Amaya et al., 2015; Herrero and Tussie, 2015; Ruggirozzi, 2014; Ruggirozzi and Yeates, 2015; Rodríguez and De Lombaerde, 2015). Although the geographic focus of this literature has principally been on Latin America, it is possible to detect similar policy shifts in other regions of the Global South. The African Union, for example, launched its African Health Strategy in 2007 (renewed in 2016) with the aim of highlighting the main challenges faced by African health systems and setting out a framework for achieving health aspects of the Millennium

Development Goals (MDGs). Local pharmaceutical manufacturing emerged as a central concern for the African Union at around the same time, with a focus on improving access to health across the continent (AU, 2007). Such strategies have since found resonance within the various regional economic communities (REC) that exist across Africa. Foremost among them has been the EAC which has gone among the furthest in its attempts to develop mechanisms to promote local pharmaceutical production.¹

The post-hegemonic regionalism literature highlights the importance of regional institutions for advancing normative change as well as making important links between the broader global context and the politics of regions. However, its focus on changing hegemonic structures proves less attuned for unpacking how specific regional policy agendas emerge in the way that they do and with what consequences. For one thing, these existing accounts tend to present a picture of a relatively monolithic global social order underpinned by US hegemony. This both overlooks the complexity of the rules, norms and institutions which define the global order (Murray-Evans, 2018) and the possibility of incremental normative change that is not necessarily linked to dramatic shifts in underlying power structures.

We, therefore, aim to complement these existing accounts by offering a more fine-grained analysis of normative change at the regional level with reference to the literature on norm localization (see Acharya, 2004; Ban, 2016; Dafe, 2020; Eimer et al., 2016). The concepts of norms and normative change have become a key staple of international relations (IR) and international political economy (IPE) scholarship since the so-called Constructivist turn in the 1990s (see Checkel, 1998). Put simply, norms can be understood as 'standards of appropriate behaviour' which govern what courses of action are and are not deemed legitimate in the global order (see Finnemore and Sikkink, 1998: 891). What these early Constructivists argued was that states and other actors oriented their behaviour – whether out of conviction or peer-pressure – to these intersubjectively held standards.

Critics, however, soon began to point out several problematic assumptions with this early norm-based research. Notably, early Constructivists tended to infer a one-way process whereby states and other actors in the global order are socialized under norms formulated at the global level, typically by actors in the Global North (Terhalle, 2011; Xiaoyu, 2012). These critics argued that this tended to overlook the critical role that emerging powers and other states and actors in the Global South played in the formulation of global norms. A further criticism of this early norm research was that it tended to treat norms as fixed social facts that shape behaviour in uniform and predictable ways, which some argued overlooked the ambiguity of norms and the contingency inherent in how actors interpret the standards of behaviour a particular norm is said to invoke (Wiener, 2004; see also Murray-Evans, 2018).

It is this latter point which an emerging literature on norm localization has sought to address (see Acharya, 2004; Ban, 2016; Dafe, 2020; Eimer et al., 2016). The starting point for this literature is the observation that while the global order is built upon shared global norms or standards of behaviour, these are not always universally accepted, nor are they applied uniformly across different policy locales (Acharya, 2004). The literature on norm localization emphasizes this point by drawing attention to the ways global norms are transplanted into local or regional settings by actors in ways that fit with and even legitimize existing policy agendas and the priorities of policy elites. For instance,

Florence Dafe (2020) has examined the localization of financial inclusion norms and highlighted how ambiguities within this agenda opened space for divergence in how central bank officials in Kenya and Nigeria translated this agenda to fit with local political realities in both countries. In effect, Dafe highlights that although a norm of global financial inclusion created an imperative for national policy actors to converge their domestic political priorities towards this agenda, ambiguities within this norm opened a degree of negotiability in terms of how it was localized.

A focus on norm localization, therefore, allows for a more fine-grained approach for unpacking ideational change at the regional level that can complement the existing comparative regionalism literature discussed above. On one hand, whereas the post-hegemonic regionalism literature has focused on the changing ideological character of the global order as a whole, a focus on norm localization enables us to trace ideational changes within specific policy settings at the global level (in our case in global health and industrial policy) and how these manifest within regional policy settings. On the other hand, this approach emphasizes the role of agency and contingency in detailing the ways in which global norms are formed, translated and adopted within regional policy settings.

Taking this literature on norm localization one step further, in this article we also consider the unintended consequences of regional norm localization. Much of the scholarship examining norm localization has tended to focus upon the formal adoption of norms within policy strategies and legal texts and less upon the contradictions and tensions involved in incorporating emerging global norms into regional or local policy agendas. Specifically, we suggest that processes of norm localization both reflect the complexity and ambiguity of the global normative landscape and represent local agents' attempts to make sense of and reconcile it with their own policy preferences and priorities. What is more, in doing so these actors must also navigate the specific institutional trajectories that characterize their own regions, in which distinct sets of regional norms are embedded (see O'Reilly and Heron, 2022). In this paper, we highlight how EAC's pharmaceutical strategy reflected both the emergence of an emphasis on access to health through local production within global health discourses and an attempt to combine this with a broader norm promoting regional development through industrialization. Based on this case, however, we suggest that navigating such normative complexity may not be straightforward and that contradictions between different sets of global norms may manifest themselves in tensions within regional policy agendas. Furthermore, existing regional institutional structures may not be easily amenable to the incorporation of new or shifting global norms, particularly where these are at odds with existing norms embedded in these regional structures.

Methodology

The empirical analysis that follows draws on 12 semi-structured interviews and background briefings with relevant policy officials, private sector representatives, representatives of donor countries and policy experts who are or have been directly involved in the formulation and implementation of EAC's pharmaceutical policy or in research on pharmaceutical production in the wider region. Since this is a relatively small and specialized

field, our approach to sampling was to contact as many informants as possible with detailed knowledge of the policy area. Given the importance placed on African agency in this research, we aimed to ensure that African informants were well represented (8 out of 12) among our interviewees. The remaining informants were representatives of donors or international organizations. All of the participants were wholly or partially based, or had previously been based, in East Africa or the wider African continent. A list of interviewees – by name or agreed anonymized description – is included as Appendix 1. The research took place during the Covid-19 pandemic and was therefore conducted entirely remotely. While every effort was made to select a broad range of interviewees, one limitation of the research is that interviews with policy officials from EAC member states proved difficult to secure, in part because of the ongoing health emergency. While we have made efforts to capture some of the inter-state dynamics of pharmaceutical policy in the analysis that follows, this would be an interesting area for follow-up research. To triangulate information gleaned from the interviews, we draw extensively upon documentary materials, such as official policy strategies and briefing reports, related to this policy agenda.

Following Krebs and Jackson (2007), we acknowledge that it is very difficult to determine empirically the ‘true’ motivations for actors’ behaviour – that is, whether behaviour is shaped principally by ideas or material interests. Instead, our approach to the analysis is based on the broad assumption that political actors behave strategically, but that understandings of acceptable strategic behaviour are infused by social norms (see Murray-Evans, 2018; Seabrooke, 2006). That is to say, norms impose a – broad and open to interpretation – logic of appropriateness that actors both invoke and seek to abide by to legitimate their strategic behaviour and pursue their interests (perceived or otherwise). Our intention, therefore, is not to empirically weigh up the causal importance of social norms versus material interests in the case of EAC pharmaceutical policy, but rather to make sense of the origins and implementation of this policy by tracing the key norms that shaped it and the processes through which these norms were moulded and localized by strategic actors. It is our contention that doing so generates a compelling account of the politics of EAC pharmaceutical policy – as well as broader processes of global and regional change in the politics of pharmaceutical production.

Access to medicines: from TRIPS to local production

Pharmaceuticals have long been viewed as a strategic sector for countries pursuing economic transformation and industrialization. During the 1960s and 1970s, many African countries saw an increase in pharmaceutical production under import-substitution industrialization (Banda et al., 2016: 10). By the 1980s and 1990s, however, the perception that these policies had engendered higher consumer prices had contributed to the widespread view that the promotion of local pharmaceutical production and the achievement of access to medicines in line with public health aims were inherently conflictual (Shadlen and da Fonseca, 2013: 563). Scepticism about local production was exemplified by an influential paper written for the World Bank by Warren Kaplan and Richard Laing (2005), which argued:

[I]n many parts of the world, producing medicines domestically makes little economic sense. If many countries begin local production, the result may be less access to medicines, since economies of scale may be lost if there are production facilities in many countries. (p. iii)

This view aligned with the then dominant neoliberal global development regime (Gore, 2000), which eschewed national or regional efforts to protect or promote strategic industrial sectors in favour of the claim that global markets would deliver efficient production and – in the case of pharmaceuticals – access to medicines at the cheapest prices.

In short, by the 1990s a global norm had come to be set in place where access to medicines for developing countries was viewed to be best served by global price competitiveness, rather than through promoting domestic pharmaceutical production through industrial and trade policy interventions. This norm was reinforced by organizations such as the World Bank and World Health Organization (WHO), which discouraged developing countries from pursuing these policy measures (Shadlen and da Fonseca, 2013: 563). It was given further credence in 1995 with the entry into force of the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. This required developing countries with previously lax or non-existent patent regimes for pharmaceutical products and processes to introduce more stringent rules, albeit with a delay until 2005 for developing countries and 2016 for least developed countries. The consequence of this was that it further restricted the policy space of developing countries to support local pharmaceutical production and increased their reliance on foreign imported medicines ('t Hoen et al., 2011).

Initial pushback against the TRIPS agreement came not in the form of a direct challenge to the price competitiveness norm, but rather from a coalition of developing countries and activists that drew growing attention to the challenges developing countries faced in accessing patented antiretroviral (ARV) treatments in the context of the HIV/AIDS crisis ('t Hoen et al., 2011). This coalition successfully challenged the central justification of TRIPS as a driver of innovation in the pharmaceutical sector and instead developed a narrative that pitted the intellectual property of pharmaceutical firms against access to essential drugs for millions of poor people (Kapstein and Busby, 2013: 65). The logic of TRIPS was also challenged in practical ways, for example, by South Africa's 1997 Medicines Act, which led the charge in aiming to make low-cost medicines more readily available ('t Hoen et al., 2011). Meanwhile, the challenge to the logic of TRIPS also dovetailed with broader changes in the global development landscape. In particular, health became a key focus of the MDGs' people-centred approach to development (Fukudu-Parr, 2004; Natrass, 2014). Access to medicines was directly referenced under goal 8, which included a resolution to 'encourage the pharmaceutical industry to make essential drugs more widely available and affordable' (United Nations General Assembly, 2000: para. 20). Taking all this together, within global public health, there emerged an incremental questioning of the logic of medicines production and distribution associated with TRIPS – if not of the wider norm that procurement of medicines should be based on price competitiveness – sparked by the extreme inequalities of access that had surfaced in the context of the HIV/AIDS crisis.

The other key effect of activism around HIV/AIDS and access to medicines was to help bring about the WTO's (2001) Doha Declaration on TRIPS and Public Health in

2001. This affirmed the right of signatory states to use flexibilities in the TRIPS Agreement 'to protect public health and, in particular, to promote access to medicines for all'. It confirmed the right of governments to issue compulsory licences, under which they could permit the production of a patented product by someone other than the patent holder so long as this was 'predominantly' for domestic use (TRIPS Article 31(f)). Acknowledging the needs of countries that lacked the domestic capability to produce generic versions of patented drugs, WTO members also subsequently agreed a waiver to Article 31(f) and provided a set of guidelines under which compulsory licences could be issued for generic drugs for export to poor countries (Shadlen et al., 2011: 18–19). Despite these changes, concerns of a 'treatment time bomb' (All-Party Parliamentary Group on AIDS, 2009) in poor countries remained as newer ARVs were increasingly widely patented in key generics producing countries such as India and there was little take-up of the use of compulsory licences for export to developing countries (Kaplan and Laing, 2005; Nicol and Owoeye, 2013; 't Hoen et al., 2011). The summative effect of this was to put local production of generic drugs at the centre of a global campaign for better access for the poor, including in countries without well-established pharmaceutical sectors.

In principle, the introduction of TRIPS flexibilities did not fundamentally challenge the access to medicines through price competitiveness norm. It merely added the caveat that in contexts where patents were viewed to be restricting access to essential medicines, governments could issue compulsory licences to domestic or foreign pharmaceutical firms to produce generic versions. Regardless, in the African context, it ended up serving as a springboard for discussions about establishing a more comprehensive agenda to promote local pharmaceutical production across the continent. In the years that followed the 2001 Doha Declaration on Public Health, some African governments began issuing compulsory licences for the domestic production of generic ARV medicines. Initially, generic production was limited to a small number of African countries with the capability to produce ARVs, including South Africa and Zimbabwe whose governments had been at the forefront of the global access to medicines campaign. Yet, as one interviewee remarked, this initial roll out of generic production, despite its small scale, did have the effect of opening African governments up to the realization that domestic pharmaceutical production was feasible on the continent.²

Moreover, while the Doha Declaration on Public Health did not challenge the price competitiveness norm, it did open a degree of negotiability for African governments to begin developing strategies aimed at expanding the generic production of medicines. Among the early signals of this was the Gaborone Declaration on a Roadmap Towards Universal Access to Prevention, Treatment and Care produced by African Ministers of Health in 2005. As part of a drive to meet the MDGs, the Ministers undertook to 'pursue, with the support of our partners, the local production of generic medicines on the continent and to [make] full use of the flexibilities in [TRIPS and the Doha Declaration]' (African Ministers of Health, 2005). The African Union Commission (AUC) followed this up by producing the Draft Pharmaceutical Manufacturing Plan for Africa in 2007, which directly referenced the earlier commitment to use TRIPS flexibilities in the promotion of local production and in turn put in place a technical committee that would produce a detailed report on local production of pharmaceuticals in Africa (Owoeye,

2014: 216). Although progress was initially slow, the AUC ultimately partnered with the United Nations Industrial Development Organization (UNIDO) to produce a much more detailed Business Plan for pharmaceutical manufacturing in Africa, endorsed by the African Union Heads of State in July 2012 (West and Banda, 2016: 278–279).³

Debates about the public health implications of TRIPS and the use of relevant flexibilities were also a key catalyst of donor involvement in initiatives for pharmaceutical production in Africa and in East Africa specifically. Germany's Federal Ministry of Economic Cooperation and Development (BMZ) began investigating the possibilities for fostering local production in developing countries – principally in Africa – in 2005, before launching a programme on this issue the following year (Schmiedchen, 2013). In the EAC specifically, German Development Agency (GIZ) (2018: 30) initiated a programme in 2009 to support the development and implementation of a regional pharmaceutical manufacturing plan and the establishment of a regional pharmaceutical manufacturers association. A former GIZ advisor to the EAC gave the following account of the motivations for GIZ's early involvement in the sector in East Africa:

The whole thing kicked off with the WTO TRIPS flexibilities where a lot of hope emerged for low cost production. [. . .] There are [. . .] two opinions. One is that patents are very bad for least developed countries because they're exploiting them, and the other side says patents are necessary to finance research. GIZ took the position that patent protection actually harms least developed countries and developing countries and therefore TRIPS was seen as a possibility to circumvent patent laws and to fast track generic production even for medicines which are still under patent protection.⁴

In other words, officials in BMZ and GIZ had by the mid-2000s begun to see local production as a tool for developing countries to secure access to essential medicines for vulnerable populations, at least in the narrow context in which this would help to overcome a specific set of inequalities and barriers engendered by TRIPS. Other global development actors – including the WHO – shared this view (WHO, 2011).

The summative point here is that by the early 2000s, and as a result of the HIV/AIDS crisis, the global development agenda had come to shift decisively towards a focus upon health and health outcomes in developing countries, reflected in the MDGs and the WTO's Doha Declaration on Public Health. None of these developments explicitly mandated or pushed for specific strategies aimed at developing local pharmaceutical production in Africa or other developing regions. Indeed, while the ensuing years saw donors and philanthropic organizations devote significant funding for the provision of essential medicines to the world's poor, the purchasing of these continued to be premised on global price competitiveness rather than the location of their production (Mackintosh et al., 2016: 155). However, these developments did open avenues for African governments and certain development partners to begin legitimately promoting local pharmaceutical production agendas. Put another way, these developments enabled these actors to localize the global price competitiveness norm in a way that remained consistent with its core principles while also allowing some room for the promotion of local production in order to take advantage of TRIPS flexibilities. As we outline in the proceeding section,

in the context of East Africa, this provided a starting point for the development of a more expansive pharmaceutical production strategy in the region.

The emergence of EAC pharmaceutical policy: from access to medicines to industrialization

Despite initial hopes, it soon became clear that the opportunities created by TRIPS flexibilities would be difficult to realize in the East African context. The same GIZ advisor cited above reported that the apparent benefits of TRIPS flexibilities and the possibilities for generic production 'never really materialized' in the East African context.⁵ They explained,

[Generic production of drugs under patent] requires a lot of technical know-how. And this technical know-how is simply not there. So, you cannot just easily copy a patented product if you don't have technology transfer from the originator. [. . . Compulsory licensing] was tried in Kenya and Rwanda, but both failed because the multinationals are very powerful and once you have a compulsory license and they start producing for public tender, the multinationals will come in and will offer a price [to which] the government cannot say no.⁶

The EAC's policy agenda to promote access to medicines through local production moved forward despite the relative inapplicability of TRIPS flexibilities in most African contexts. In the EAC, this agenda was initially mindful of the potential tensions between public health priorities and mechanisms for promoting the growth of the pharmaceutical sector and favoured market-based mechanisms for the latter over a more state-led interventionist approach. Officials in the EAC were said to be cautious about prioritizing local pharmaceutical producers through more interventionist policies such as import-substitution and local procurement, over fears that these might negatively distort the supply and price of essential medicines across the region. Over time, however, EAC's approach to the promotion of local pharmaceutical production came to explore and, in part, embrace such policy measures.

Given that this agenda was initially centred around the utilization of TRIPS flexibilities, how then do we explain its endurance even when it became evident that these flexibilities could not be utilized in the EAC context? Moreover, considering the initial hesitations around a more state-interventionist approach, how was it that the EAC's local pharmaceutical agenda later came to embrace policy interventions such as import-substitution and local procurement? In this section, we explain this regional policy trajectory through a process of complex norm localization. The EAC's local pharmaceutical production agenda was initially rooted around TRIPS flexibilities and attendant global price competitiveness norms. However, we argue that its evolution was shaped by the localization of separate and emerging set of global development norms that saw a broader questioning of neoliberal growth models and a return to more state-oriented and productivist understandings of development. In this context, a coalition of industry representatives, regional policymakers, donors and researchers shifted the conversation about local production from one with its origins in TRIPS flexibilities to a more generalized agenda for industrial upgrading in the pharmaceutical sector, while still emphasizing access to

medicines as a key driver of and rationale for the policy. In short, this process facilitated a shift in East Africa from a norm of access to medicines through price competitiveness to one of access through local production.

The starting point here is the shifting attitudes that began to emerge in Africa around industrial policy and state-directed development from the late 2000s onwards. As is now well recounted, from the late 1980s, the global development regime came to be dominated by a set of neoliberal norms which circumscribed state intervention in domestic markets, with the exception of promoting macroeconomic stability and correcting market failures (Gore, 2000). These norms were localized in the African region both by external actors, such as the International Monetary Fund (IMF) and World Bank, and also by local officials working within national ministries of finance and central banks (Harrison, 2004). By the late 2000s and early 2010s, however, the development priorities of many African governments had begun to shift towards promoting industrialization and structural transformation, which included a tentative shift towards previously circumscribed strategies, including industrial policy and import-substitution (Harrison, 2019; Hickey, 2012). This occurred in a global context where the 2008 Global Financial Crisis and the rise of China and other emerging markets had called into question the appropriateness of neoliberal development agendas (Alami et al., 2021; Kurlantzick, 2016; Lin, 2010). In effect, by the turn of the decade, a local production norm – not just in relation to pharmaceuticals but to a range of industries perceived to offer developing countries the opportunity to move up the value chain and specialize in higher value-added activities – had begun to take root across Africa.

From the outset, the EAC's pharmaceutical policy was linked to a broader industrialization agenda emerging in the region. The EAC's Industrialisation Policy (EAC, 2012b) and Regional Industrialisation Strategy (EAC, 2012c) launched in 2012 signalled the region's support for a larger role for national governments in shaping the market for the purpose of structural economic transformation (O'Reilly and Heron, 2022). The Industrialisation Strategy identified the pharmaceutical sector as the third among six strategic sectors in which 'the region has potential comparative advantage' (EAC, 2012c: ii & 23). It was in this context that the EAC member states embraced both the emerging African continental agenda for local production of pharmaceuticals and the specific strategies proposed by BMZ and GIZ in East Africa, seeing these as 'an opportunity to strengthen industrialization processes'.⁷ The EAC's first Regional Pharmaceutical Manufacturing Plan of Action (EAC, 2012b) was developed the same year and was anchored to the Industrialisation Strategy, receiving technical and financial support from GIZ and aligning with the AUC's Pharmaceutical Manufacturing Plan of Action. According to several interview sources, the initial drive towards establishing a bespoke regional strategy for pharmaceutical production came from GIZ.⁸ With that being said, it is important to note that national governments had been key actors in a more general prioritization of pharmaceutical production in the years prior. For instance, the Kenyan government had identified pharmaceutical production as a strategic sector in its 2008 'Vision 2030' agenda (Government of Kenya, 2008).

While the domestication into national law and further utilization of TRIPS flexibilities was part of this Plan of Action, the policy focus had by this point moved on to other issues deemed important for the growth of local production, reflecting a broader

prioritization of industrialization in East Africa at this time (O'Reilly and Heron, 2022). Key pillars of the strategy aimed to strengthen local producers' capacity to compete in the regional market and meet international quality standards for medicines, promote investment in the industry and strengthen and harmonize the regional pharmaceutical regulatory environment (EAC, 2012b: 30–32). These pillars aligned with modalities favoured by donors and international partners such as GIZ and UNIDO, whose work on pharmaceutical sector support in the region focused, *inter alia*, on fostering compliance with Good Manufacturing Practices, strengthening national and regional regulatory regimes and gathering and sharing information on the pharmaceuticals market.⁹ The Plan of Action did not at this stage propose more overt import substitution strategies, such as reversing the decision taken in 2009 to remove duties on imported medicines under the EAC's Common External Tariff (Mackintosh et al., 2018b: 187). It also acknowledged possible tensions between industrial and public health priorities and emphasized the primacy of the latter, stating: 'The idea to improve access through local production is only attractive if the pharmaceuticals produced are cheaper than the imported products' (EAC, 2012b: 18). While the promotion of local production represented a departure from previous orthodoxies on industrial policy and public health – and arguably gave momentum and legitimacy to the EAC's broader industrial strategy – it did not at this stage stray far from market-oriented mechanisms focused on fostering local producers' competitiveness, promoting private sector investment and establishing favourable regulatory environments. In other words, while an emerging regional local production norm reflected broader changes in the global development landscape, in relation to pharmaceuticals specifically the global price competitiveness norm continued to shape considerations about the trade-offs between state intervention and access to medicines.

Over time, a range of actors contributed to the evolution of EAC pharmaceutical policy, and specifically a shift towards more interventionist modalities for the promotion of the sector. In particular, the regional manufacturers' association, the Federation of East African Pharmaceutical Manufacturers (FEAPM) – set up with the support of GIZ – strongly made the case for a package of incentives for local producers that went beyond the market-oriented mechanisms included in the first Regional Pharmaceutical Manufacturing Plan of Action. In particular, industry representatives proposed both a region-wide commitment to preferential procurement policies for locally produced medicines and import restrictions – in the form of a 25 percent tariff – on a list of products that can be reliably produced in the region (Omboki, 2018).¹⁰ Provisions for the former are included in the Pharmaceuticals Bill 2020, currently being considered by the East African Legislative Assembly (EAC, 2020). Discussions on import restrictions have been under way at the regional level for some time, coalescing around a smaller subset of the products originally proposed by the industry.¹¹ Industry representatives make the case for these policy measures by citing the need to create a 'level playing field' in relation to imported goods, in particular from Indian and Chinese producers that benefit from their own governments' intervention.¹² The industry also cites favourably examples of other developing countries – Bangladesh and Ghana in particular – that have used import substitution to successfully increase the share of local production in their domestic pharmaceutical consumption.

Discussions of tariff measures to support the maintenance and expansion of local production were supported by officials within the EAC Secretariat, in particular those working on the region's industrialization agenda.¹³ While the impetus for a more interventionist pharmaceutical strategy came from industry representatives in the region, GIZ also collaborated on aspects of this agenda. For example, GIZ assisted with a FEAPM research and advocacy project highlighting the role of import restrictions in the promotion of the pharmaceutical industry in Bangladesh and suggesting that important lessons can be drawn for the sector in East Africa (Sampath, 2019).¹⁴ Importantly, while the call for greater protection by the sector aligned with the broader industrialization strategy of the region, it seems likely that this was taken seriously by external donors at least in part because of the prior existence of an agenda for local pharmaceutical production and concomitant claims that this was a means for achieving improved access to medicines.

Beyond this, research by academics from the region and beyond has helped to provide a rationale for more interventionist measures to support the sector, principally by examining issues around access to medicines that go beyond price competitiveness. Interviewees for this article cited the particular importance of long-running research led by Samuel Wangwe under the Tanzanian research organization REPOA and by Maureen Mackintosh of the Open University in shaping conversations about and policies for local production in the region.¹⁵ This research showed that while local producers cannot always beat importers on price under conditions of intense competition with large producers in China and India (Banda et al., 2016: 16; Mackintosh et al., 2018a: 604), local production has a range of other benefits in terms of promoting access. These include the ability of local firms to manage distribution networks in underserved rural areas (Mackintosh et al., 2018a: 604) and to support the security and reliability of supply, particularly at times of crisis or emergency (Russo and Banda, 2015: 277). Donors have also worked with some of those involved in the research cited above and have been open to this wider set of justifications for local production. For example, a 2017 report commissioned by BMZ argued that developing local pharmaceutical production can contribute to building 'stronger and more resilient health systems' (Mackintosh et al., 2017: 4). This broader view of the synergies between industrial and health policy signalled a shift away from the global price competitiveness norm within regional discussions and made it possible to justify incentives and protections for local manufacturers even where they were not the cheapest producers.

This shift was reflected in the second iteration of EAC's (2017) Regional Pharmaceutical Manufacturing Plan of Action produced in 2017, again supported by GIZ. Like the first Plan, this document emphasized the importance of regulatory harmonization and capacity-building. Unlike the first, however, the second Plan engaged more explicitly with the idea of trade protection for the pharmaceutical sector and mirrored FEAPM's use of exemplars of import substitution from outside the region. Specifically, the Plan cited the import restrictions used by Ghana, India and Bangladesh as examples of 'best practice' for improved access to medicines through local production (EAC, 2017: 9, 34–35). Under pillar 2 of the strategy – which focuses on fostering increased investment in the pharmaceutical sector – the first Plan of Action had emphasized the '[p]romotion of a conducive investment environment in the region' (EAC, 2012b: 31). By contrast, under the same pillar the second Plan talked much more clearly about the use of 'national incentive packages for local pharmaceutical production' using

mechanisms such as changes to the regional common external tariff, tax regimes, preferential pricing and preferential public procurement (EAC, 2017: 36).

According to one regional pharmaceutical consultant, the more assertive policy prescriptions found within the 2017 strategy reflected a change in policy ownership over the EAC's pharmaceutical production agenda.¹⁶ The consultant noted that the first plan had been developed sectorally under the region's health agenda and primarily in collaboration with the EAC Secretariat's Health Department. By contrast, the 2017 plan had been developed under the purview of the region's industrial development agenda and the EAC Secretariat's Industrial Development Department. They indicated that this reflected a shift in priorities whereby the local pharmaceutical production agenda had come to be less centred around promoting access to medicines and instead oriented towards the region's broader industrialization agenda, which had gathered pace throughout the 2010s (O'Reilly and Heron, 2022). Indeed, the 2012 plan specifically acknowledged the work done by the EAC's (2012b: 5) Technical Expert Committee on TRIPS and Access to Medicines in steering the development of the strategy. By contrast, the same acknowledgements section in the 2017 plan emphasized the importance of this strategy to the region's broader industrialization agenda (EAC, 2017: 8). Although references to access to health did not drop entirely from the second plan, there was a notable shift where pharmaceutical production was being considered as an end in its own right, as opposed to being subordinated entirely to access to health objectives.

What this indicates is how the EAC's pharmaceutical production agenda, initially driven by the introduction of TRIPS flexibilities as an attempt to deliver access to health in the context of the global norm of price competitiveness, over time increasingly diverged from the price competitiveness rationale and came to merge with another set of distinctive norms that prioritized regional development through industrialization. Actors including industry representatives, regional officials, donors and researchers helped to craft a distinctive regional policy for local production that combined market-oriented and import-substitution approaches to promoting the sector, while developing a justification for this strategy that moved beyond price concerns to highlight a broader set of mechanisms through which it could be argued that local production would improve access to medicines. This process can be understood as one in which these actors built upon synergies between the long-standing drive for access to medicines in the global public health arena – albeit under the market-oriented price competitiveness norm – and a shifting global development regime in which industrial policy and import substitution had come to be seen as increasingly legitimate policy options. As we will explore in the next section, while combining these divergent norms helped to justify discussion of a shift towards import substitution in the pharmaceutical sector, this move did not fully paper over the tensions between the industrial policy and public health priorities that lie at the heart of debates about local pharmaceutical production.

From conception to implementation: the limits of the EAC's local pharmaceutical agenda

In this penultimate section, we move beyond a consideration of the origins and motivations underpinning the EAC's pharmaceutical strategy to briefly consider its actual implementation over the last decade. Doing so allows us to stress both the ways in which

tensions may emerge as a consequence of complex processes of norm localization and the ways in which these are embedded within the distinct institutional and normative trajectories of specific regions.

The initial 2012 EAC pharmaceutical plan of action set out a roadmap for the region that included several ambitious policy measures. This included drafting a regional policy and model law on the utilization of TRIPS flexibilities, the establishment and piloting of a regional pooled procurement mechanism for medicines, and the regional harmonization of medicines registration and regulation. As the EAC's (2017: 32) follow-up strategy in 2017 came to note, however, the implementation of these policy objectives largely fell short of their initial ambitions. While a regional policy and model law on TRIPS flexibilities was drafted in 2013 (EAC, 2013), the 2017 pharmaceutical production strategy noted that it had yet to be domesticated into national laws (EAC, 2017: 32). Furthermore, according to interview sources, minimal progress was made towards establishing a regional pooled procurement mechanism for medicines.¹⁷ This appears to be corroborated by a 2014 report by the South Centre, which at the time noted that progress in this area had been slow (Syam, 2014: 11).

Some progress was made in the area of medicines registration and regulatory harmonization. In 2012, the EAC Medicines Regulatory Harmonization (EAC-MRH) programme was established, with support from the World Bank and WHO (Syam, 2014: 13–15). The aim of the EAC-MRH was to establish a common regional mechanism for licensing medicines and to harmonize the EAC's pharmaceutical regulatory environment. Interview sources did suggest that the EAC states had struggled to push forward with the much more complex task of creating a common regulatory environment for the region's pharmaceutical sector.¹⁸ However, some progress was made towards establishing an EAC joint assessment procedure for licensing medicines across the region. Yet, even in this area, where progress has been made, challenges have continued to abound. This includes firms having to still register with national medicines authorities, even when they have received clearance from the regional licensing system, and, in some cases, national regulators not recognizing certificates issued by the EAC's joint assessment procedure (Dansie et al., 2019).

Our interviews with stakeholders in the region emphasized several factors which have inhibited the roll out of the EAC's local pharmaceutical production agenda. First, issues were noted around bureaucratic capacity and the ability of regional institutions to coordinate such an ambitious policy agenda. One interviewee suggested that the EAC Secretariat had very limited resources to coordinate the multitude of actors involved in this process, noting that only two staff members from the secretariat had been allocated to oversee this policy agenda.¹⁹ The limited resources that the EAC Secretariat has at its disposal is a well-documented feature in other African regional organizations. In the EAC's case, however, it also stems from specific institutional and normative path dependencies embedded within its regional policy regime. When the EAC was re-established in 2000 (following its collapse in 1977), it was conceived around and intentionally designed to support a programme of market-led development in the region. Regionalism, as such, unfolded as a process geared towards the removal of intraregional barriers to trade and investment – a process which was to be coordinated by relevant national ministries and overseen by a small regional secretariat (O'Reilly and Heron, 2022). However,

as the EAC's policy agenda has become more ambitious and extended more into coordinated trade and industrial strategies, the capacity of regional institutions has not evolved in order to keep pace with this (O'Reilly and Heron, 2022).

Second, the campaign to promote regional pharmaceutical production has been impeded for the foundational reason that the EAC states lack full commitment to the norm of regional development through industrialization. As the emphasis has turned to issues of industrialization and structural transformation over the last decade, EAC policy discourses have unsurprisingly sought to emphasize the important role that regional integration and cooperation can play in supporting this process (EAC, 2012a, 2012c). In practice, however, this was not the original intention of the member states' reformulation of the EAC and efforts to support industrialization by the EAC states have been pursued with a national rather than regional mindset (O'Reilly and Heron, 2022). Although the EAC's customs union and common market protocols are based around the principle of non-discrimination, governments in the region have been quite willing to go against both the spirit and letter of these agreements. Indeed, several interviewees commented that residual fears continued to pervade across the EAC states about the negative impact that regional competition might have on domestic pharmaceutical firms. In 2017, Uganda even went as far as imposing a 12 percent 'verification fee' on certain pharmaceutical imports, even those coming from within the EAC common market, with the explicit aim 'to discourage importation of locally manufactured drugs' (National Drug Authority, 2017). Others noted the difficulties in acquiring work permits for pharmaceutical workers in other EAC states, despite the regional common market protocol mandating for the free movement of persons.²⁰ The key point here is that region-based industrialization strategies find themselves in tension with those being driven at the national level and the latter are likely to take precedence as long as regional institutions have little power to plan industrial investments or even enforce agreed upon regional harmonization initiatives.

Returning to notions of the complexity and ambiguity of global norms and processes of norm localization introduced earlier, a key factor that appears to have inhibited the implementation of the EAC's pharmaceutical production agenda is the presence of inherent tensions within the policy itself. Although EAC policy documents and pronouncements have sought to downplay the potential tensions that exist between the agendas for access to health and industrialization, interviewees noted that debates on this issue have continued in the background. Indeed, these debates appear to have been reignited more recently as proposals have been put forward to increase import tariffs on several pharmaceutical products. An interviewee noted that those working in trade and health policy at the EAC secretariat were still quite hesitant about such proposals.²¹ While we saw in the previous section that advocates of this policy have advanced alternative arguments that contend that access is about more than cost, our interviewee suggested that these continue to come up against more market-oriented perspectives that animated earlier agendas for access to health. In particular, critics of import substitution strategies 'really feel that such moves will reduce the competition in the market and ultimately make the price [of medicines] go up'.²² For some working in public health in the region, moreover, the chief concern remains 'can East Africans get medicine regardless of where the medicine is coming from'.²³

Furthermore, while the region's industrial body has advocated for the move to greater trade protection, this is also contested within the sector. For example, a pharmaceutical consultant based in the region argued that import tariffs would prevent the regional pharmaceutical sector from acquiring requisite competitiveness and that a more appropriate strategy to support local firms would be to support them through preferential government procurement practices.²⁴ There is also ambiguity about the use of import substitution strategies among donor and international organization communities. For example, a former UNIDO official suggested the potential use of protectionist measures in this regard could be covered from the region's industrialization as opposed to its health budget, and that this would work all the better if embedded in a more comprehensive strategy for the pharmaceutical industry's development overall.²⁵ But, the official stopped short of suggesting that import-substitution would necessarily improve access to medicines in its own right. The key point here is that although the growing global focus on access to medicines that resulted from TRIPS contributed to the impetus and legitimacy of the region's pharmaceutical industrialization agenda, there remain fundamental tensions between the market-based rationale for local production that coexisted with the global norm of pharmaceutical production through price competitiveness and the rationale that emphasizes import substitution in line with the EAC's broader industrialization agenda. In other words, the process of norm localization has not been able to fully realize the reconciliation of at least partly divergent global and regional norms around access to health and local production.

Conclusion

Since the outbreak of the Covid-19 pandemic in 2020 and in the light of the inequities it has exposed around access to vaccines in Africa, long-standing calls (AU, 2007) for the continent to develop its own local pharmaceutical production have been further intensified. Significantly, however, this call for local pharmaceutical production in Africa departed from earlier global health norms, which had emerged in the 1990s and early 2000s, that held that access to medicines in the Global South would be better served by multinational pharmaceutical firms which were able to produce medicines more efficiently and cheaply than local producers. In this article, we sought to account for this normative shift and offer insights into how African political actors as well as international organizations and donors came to view the strategic targeting of local pharmaceutical production as a legitimate policy option. We did so by focusing on the EAC and its agenda since 2012 to promote local pharmaceutical production within East Africa. In particular, the article aimed to provide an account of how it was that an agenda for local production that was originally oriented around circumventing global patent rules in order to generate cost advantages came instead to emphasize a more generalized drive towards industrial upgrading in the pharmaceutical sector via strategies such as local procurement and import substitution. Furthermore, the article sought to go beyond a focus on the formal adoption of new regional policy agendas and legal texts to explore what happens as policy is put into practice – something that proved a significant challenge in the case of EAC pharmaceutical policy.

In order to answer these questions, we argued that it is important to understand the role of regional institutions in advancing normative change and to highlight the interplay between global and regional levels of governance. In order to add to existing literatures in comparative regionalism, we drew on the concept of norm localization to stress the role of agency and contingency in understanding both how global norms are formed and transformed and how they are translated and adopted within regional policy settings. Our contribution to the existing literature on norm localization is to make the case that these processes reflect the complexity of the global normative landscape and represent local agents' attempts to make sense of and reconcile this with their own policy preferences and priorities. This complexity provides regional actors with opportunities to navigate the global social order strategically and to draw on complementarities between different sets of global norms in order to support and legitimate policy agendas built around their own priorities and preferences. On the contrary, we highlight the difficulties and tensions that may emerge as regional actors seek to reconcile competing global norms and to incorporate them into regional institutional structures that have their own more or less independent institutional and normative trajectories.

Applying this to the case of EAC pharmaceutical policy, we argue that the origins of the regions' agenda for the promotion of local production can be located in global access to health campaigns that emerged beginning in the late 1990s. While the emphasis on price competitiveness in the procurement of pharmaceuticals continued to dominate global discourses following these campaigns, the need to circumvent patent rules in order to secure access to drugs at lower prices made the promotion of local pharmaceutical production a policy option that was perceived as legitimate by regional policymakers and donors alike, albeit under specific circumstances linked to the exigencies of the TRIPS patent regime. Subsequently, however, we chart a process by which this agenda for access to medicines came to be shaped by the localization of a separate set of global and regional norms – namely those associated with the questioning of neoliberal development strategies and the promotion of regional development through industrialization – in the EAC. The result was a distinctive regional policy for local production that combined market-oriented and state-led approaches to promoting the sector, while looking beyond immediate concerns about the price of medicines in order to justify the strategy in public health terms. In other words, while EAC's local production agenda was initially compliant with and even driven by the global price competitiveness norm, the latter increasingly came to be rejected in favour of more interventionist strategies for achieving industrial upgrading and access to health. While regional policy documents and discourses have been able to square the circle between public health priorities around access to medicines and industrial policy aims in relation to the promotion of the sector, an examination of the implementation of the strategy reveals some of the ongoing tensions produced by the fusing of these norms. These tensions also intersect with a series of path-dependent institutional and normative trajectories in the EAC, which have tended overall to impede the implementation of the region's pharmaceutical strategy.

Taking all of this together, our central claim is that an appreciation of some of the complexity of processes of global and regional normative change – and the role of actors from the Global South within these – is key to understanding recent shifts within the politics of pharmaceutical production and access to medicines. Furthermore, these

processes of change have concrete consequences for the way that the governance of health operates in regions of the Global South and beyond – in this case in the form of policy tensions and difficulties of implementation.

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Notes

1. Interview 1: Expert in Pharmaceutical Sector Development, via Zoom, 17 April 2020.
2. Interview 10, Julius Mugwagwa, academic researcher, via Zoom, 20 July 2021.
3. Interview 6, former UNIDO official, via Zoom, 30 June 2020.
4. Interview 2, former GIZ advisor to the EAC, via Zoom, 15 May 2020.
5. Interview 2, former GIZ advisor to the EAC, via Zoom, 15 May 2020.
6. See Note 6.
7. Interview 2, former GIZ advisor to the EAC, via Zoom, 15 May 2020.
8. Interview 2, former GIZ advisor to the EAC, via Zoom, 15 May 2020; Interview 3, Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020; Interview 11, Regional Pharmaceutical Consultant, via Zoom, 22 July 2021.
9. Interview 2, former GIZ advisor to the EAC, via Zoom, 15 May 2020; Interview 6, former UNIDO official, 30 June 2020; Interview 7, Expert in Pharmaceutical Sector Development, 10 July 2020.
10. Interview 3, Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020; Interview 4, anonymous interviewee, via Zoom, 4 June 2020.
11. Interview 3, Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020.
12. See Note 12.
13. Interview 4, anonymous interviewee, via Zoom, 4 June 2020.
14. Interview 3, Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020.
15. Interview 9, researcher, via Zoom, 17 July 2021; Interview 10, Julius Mugwagwa, academic researcher, via Zoom, 20 July 2021.

16. Interview 11: Regional Pharmaceutical Consultant, via Zoom, 22 July 2021.
17. Interview 1, Expert in Pharmaceutical Sector Development, via Zoom, 17 April 2020.
18. See Note 18.
19. See Note 18.
20. Interview 3, Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020.
21. Interview 4, anonymous interviewee, via Zoom, 4 June 2020.
22. See Note 22.
23. See Note 22.
24. Interview 5, Regional Pharmaceutical Consultant, via Zoom, 15 June 2020.
25. Interview 6, former UNIDO official, via Zoom, 30 June 2020.

References

- Acharya A (2004) How ideas spread? Whose norms matter? Norm localization and institutional change in Asian regionalism. *International Organization* 58(2): 239–275.
- African Ministers of Health (2005) Gaborone declaration on a roadmap towards universal access to prevention, treatment and care. In: *2nd ordinary session of the conference of African ministers of health*, Gaborone, Botswana, 13–14 October.
- African Union (AU) (2007) *Pharmaceutical Manufacturing Plan for Africa: Business Plan*. Addis Ababa, Ethiopia: AU.
- Alami I, Dixon AD and Mawdsley E (2021) State capitalism and the new global development regime. *Antipode* 53(5): 1294–1318.
- All-Party Parliamentary Group on AIDS (2009) *The Treatment Timebomb: Report of the Enquiry of the All Party Parliamentary Group on AIDS into Long-term Access to HIV Medicines in the Developing World*. London: House of Commons.
- Amaya AB, Rollet V and Kingah S (2015) What's in a word? The framing of health at the regional level ASEAN, EU, SADC and UNASUR. *Global Social Policy* 15(3): 229–260.
- Ban C (2016) *Ruling Ideas: How Global Neoliberalism Goes Local*. Oxford: Oxford University Press.
- Banda G, Wangwe S and Mackintosh M (2016) Making medicines in Africa: an historical political economy overview. In: Mackintosh M, Banda G, Tibandebage P, et al. (eds) *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*. Basingstoke: Palgrave Macmillan, pp. 5–7.
- Briceño-Ruiz J and Morales I (2017) *Post-Hegemonic Regionalism in the Americas: Toward a Pacific-Atlantic Divide*. New York: Routledge.
- Checkel J (1998) The constructive turn in international relations theory. *World Politics* 50(2): 324–348.
- Chorev N (2020) *Give and Take: Developmental Foreign Aid and the Pharmaceutical Industry in East Africa*. Princeton, NJ: Princeton University Press.
- Chorev N and Shadlen KC (2015) Intellectual property, access to medicines, and health: new research horizons. *Studies in Comparative International Development* 50(2): 143–156.
- Dafe F (2020) Ambiguity in international finance and the spread of financial norms: the localization financial inclusion in Kenya and Nigeria. *Review of International Political Economy* 27(3): 500–524.
- Dansie LS, Oduch WD and Ardal C (2019) Industrial perceptions of medicines regulatory harmonization in the East African Community. *PLoS ONE* 14(6): e0218617.
- Eimer TR, Lütz S and Schüren V (2016) Varieties of localization: international norms and the commodification of knowledge in India and Brazil. *Review of International Political Economy* 23(3): 450–479.

- Finnemore M and Sikkink K (1998) International norm dynamics and political change. *International Organisation* 52(4): 887–917.
- Fukudu-Parr S (2004) Millennium development goals: why they matter. *Global Governance* 10(4): 395–402.
- German Development Agency (GIZ) (2018) *EAC-GIZ: Cooperation for Success*. Arusha, Tanzania: EAC-GIZ Programme on Regional Integration.
- Gore C (2000) The rise and fall of the Washington consensus as a paradigm for developing countries. *World Development* 28(5): 789–804.
- Government of Kenya (2008) *Vision 2030: the Popular Version*. Nairobi, Kenya: Government of Kenya.
- Harrison G (2004) *The World Bank and Africa: The Construction of Governance States*. London: Routledge.
- Harrison G (2019) Authoritarian neoliberalism and capitalist transformation in Africa: all pain, no gain. *Globalizations* 16(3): 274–288.
- Herrero MB and Tussie D (2015) UNASUR health: a quiet revolution in health diplomacy in South America. *Global Social Policy* 15(3): 261–277.
- Hickey S (2012) Beyond ‘poverty reduction through good governance’: the new political economy of development in Africa. *New Political Economy* 17(5): 683–690.
- Kaplan W and Laing R (2005) Local production of pharmaceuticals: industrial policy and access to medicines: an overview of key concepts, issues and opportunities for future research. Health, nutrition, and population discussion paper, The World Bank, Washington, DC.
- Kapstein EB and Busby JW (2013) *AIDS Drugs for All: Social Movements and Market Transformations*. Cambridge: Cambridge University Press.
- Krebs RR and Jackson PT (2007) Twisting tongues and twisting arms: the power of political rhetoric. *European Journal of International Relations* 13(1): 35–66.
- Kurlantzick J (2016) *State Capitalism: How the Return of Statism Is Transforming the World*. Oxford: Oxford University Press.
- Lin JY (2010) *New structural economics: a framework for rethinking development*. Policy research working paper no. 5197. Washington, DC: The World Bank.
- Löfgren H and Williams O (eds) (2013) *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South*. Basingstoke: Palgrave Macmillan.
- Mackintosh M, Mugwagwa J, Banda G, et al. (2017) Local production of pharmaceuticals and health system strengthening in Africa: an evidence brief. Available at: http://health.bmz.de/ghpc/evidence_briefs/local_production_pharmaceuticals_health_system_strengthening_africa/index.html (accessed 24 June 2020).
- Mackintosh M, Mugwagwa J, Banda G, et al. (2018a) Health-industry linkages for local health: reframing policies for African health system strengthening. *Health Policy and Planning* 33(4): 602–610.
- Mackintosh M, Tibandebage P, Njeru MK, et al. (2018b) Rethinking health sector procurement as developmental linkages in East Africa. *Social Science & Medicine* 200: 182–189.
- Mackintosh M, Tobandebage P, Kungu JK, et al. (2016) Health systems as industrial policy: building collaborative capabilities in the Tanzanian and Kenyan health sectors and their local suppliers. In: Mackintosh M, Banda G, Tibandebage P, et al (eds). *Making medicines in Africa: The political economy of industrializing for local health*. London: Palgrave Macmillan, pp. 147–165.
- Murray-Evans P (2018) *Power in North-South Trade Negotiations: Making the European Union’s Economic Partnership Agreements*. London: Routledge.
- Muzaka V (2011) *The Politics of Intellectual Property Rights and Access to Medicines*. Basingstoke: Palgrave Macmillan.

- National Drug Authority (2017) Press statement: Government to support local pharmaceutical manufacturers through implementation of 12% verification fee on selected imported medicines. Available at: <https://www.nda.or.ug/nda/ug/dnews/74/Press-statement-on-> (accessed 15 July 2020).
- Nattrass N (2014) Millennium development goal 6: AIDS and the international health agenda. *Journal of Human Development and Capabilities* 15(2–3): 232–246.
- Nicol D and Owoye O (2013) Using TRIPS flexibilities to facilitate access to medicines. *Bulletin of the World Health Organization* 91: 533–539.
- Omboki A (2018) New tax scheme could push up cost of medicine. *Daily Nation*, 31 May. Available at: <https://nation.africa/kenya/news/new-tax-scheme-could-push-up-cost-of-medicine-49676?view=htmlamp>
- O'Reilly P and Heron T (2022) Institutions, ideas and regional policy (un)coordination: the East African Community and the politics of second-hand clothing. *Review of International Political Economy*. Epub ahead of print 18 April. DOI: 10.1080/09692290.2022.2062614.
- Owoye O (2014) Compulsory patent licensing and local drug manufacturing capacity in Africa. *Bulletin of the World Health Organization* 92: 214–219.
- Riggirozzi P (2014) Regionalism through social policy: collective action and health diplomacy in South America. *Economy and Society* 43(3): 432–454.
- Riggirozzi P and Tussie D (eds) (2012) *The Rise of Post-Hegemonic Regionalism: The Case of Latin America*. Dordrecht: Springer.
- Riggirozzi P and Tussie D (2015) A global conversation: rethinking IPE in post-hegemonic scenarios. *Contexto Internacional* 37(3): 1041–1068.
- Riggirozzi P and Yeates N (2015) Locating regional health policy: institutions, politics and practices. *Global Social Policy* 15(3): 212–228.
- Rodríguez LL and De Lombaerde P (2015) Regional and inter-regional economic rules and the enforcement of the right to health: the case of Columbia. *Global Social Policy* 15(3): 296–312.
- Russo G and Banda G (2015) Re-thinking pharmaceutical production in Africa; insights from the analysis of the local manufacturing dynamics in Mozambique and Zimbabwe. *Studies in Comparative International Development* 50: 258–281.
- Sampath PG (2019) *Pharmaceutical manufacturing in Bangladesh – a success story: what can we learn?* Advocacy series no. 1. Pretoria, South Africa: Federation of East African Pharmaceutical Manufacturers.
- Schmiedchen F (2013) Fostering local pharmaceutical industries as an instrument for economic development. In: *International conference on local production and access to medicines*, Bonn, 21 February.
- Seabrooke L (2006) *The Social Forces of Financial Power: Domestic Legitimacy and International Financial Orders*. Ithaca, NY: Cornell University Press.
- Shadlen KC (2009) The politics of patents and drugs in Brazil and Mexico: the industrial bases of health policies. *Comparative Politics* 42(1): 41–58.
- Shadlen KC (2020) Pharmaceutical patents in Latin America: global change, national responses. In: Thompson WR (ed.) *Oxford Research Encyclopedia of Politics*. Oxford: Oxford University Press.
- Shadlen KC and da Fonseca EM (2013) Health policy as industrial policy: Brazil in comparative perspective. *Politics & Society* 41(1): 561–587.
- Shadlen KC, Guennif S, Guzmán A, et al. (2011) Globalization, intellectual property rights, and pharmaceuticals: meeting the challenges to addressing health gaps in the new international environment. In: Shadlen KC, Guennif S, Guzmán A, et al. (eds) *Intellectual Property, Pharmaceuticals and Public Health*. Cheltenham: Edward Elgar, pp. 1–28.

- Syam N (2014) *Regional pooled procurement of medicines in the East African Community*. Research paper 53, September. Geneva: South Centre.
- 't Hoen E, Berger J, Calmy A, et al. (2011) Driving a decade of change: HIV/AIDS, patents and access to medicines for all. *Journal of the International AIDS Society* 14: 15.
- Terhalle M (2011) Reciprocal socialization: rising powers and the West. *International Studies Perspectives* 12(4): 341–361.
- The East African Community (EAC) (2012a) *East African Community Industrialization Strategy: Structural Transformation of the Manufacturing Sector through High Value Addition and Product Diversification Based on Comparative and Competitive Advantages of the Region*. Arusha, Tanzania: East African Community Secretariat.
- The East African Community (EAC) (2012b) *East African Community Regional Pharmaceutical Plan of Action (2012-2016)*. Arusha, Tanzania: East African Community Secretariat.
- The East African Community (EAC) (2012c) *The East African Community Industrialisation Policy 2012-2032: Structural Transformation of the Manufacturing Sector through High Value Addition and Product Diversification Based on Comparative and Competitive Advantages of the Region*. Arusha, Tanzania: East African Community Secretariat.
- The East African Community (EAC) (2013) *Regional Intellectual Property Policy on the Utilization of Public Health-related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation*. Arusha, Tanzania: East African Community Secretariat.
- The East African Community (EAC) (2017) *2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017-2027*. Arusha, Tanzania: East African Community Secretariat.
- The East African Community (EAC) (2020) *Pharmaceutical Bill, 2020*. *East African Community Gazette* 5, 7 February 2020. Arusha, Tanzania: East African Community Secretariat.
- The Financial Times (2021) EU to back expansion of vaccine production capacity in Africa. *The Financial Times*, 17 May. Available at: <https://www.ft.com/content/d2a47c7e-0b00-4e31-92ab-cd3ff0b9070b> (accessed 25 August 2021).
- The New York Times (2021) Tracking coronavirus vaccinations around the world. *The New York Times*. Available at: <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (accessed 25 August 2021).
- Tussie D (2014) Reshaping regionalism and regional cooperation in South America. *Pensamiento Propio* 39: 109–138.
- United Nations General Assembly (2000) United Nations Millennium Declaration. Available at: <https://www.ohchr.org/en/instruments-mechanisms/instruments/united-nations-millennium-declaration> (accessed 30 August 2022).
- West A and Banda G (2016) Finance and incentives to support the development of national pharmaceutical industries. In: Mackintosh M, Banda G, Tibandebage P, et al. (eds) *Making Medicines in Africa: The Political Economy of Industrializing for Local Health*. Basingstoke: Palgrave Macmillan, pp. 278–297.
- Wiener A (2004) Contested compliance: Interventions on the normative structure of world politics. *European Journal of International Relations* 10(2): 189–234.
- World Health Organization (WHO) (2011) *Pharmaceutical production and related technology transfer*. Geneva: World Health Organization.
- World Trade Organization (WTO) (2001) *Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)*. Geneva: WTO.
- Xiaoyu P (2012) Socialization as a two-way process: emerging powers and the diffusion of international norms. *The Chinese Journal of International Politics* 5(4): 341–367.

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Peter O'Reilly is a Lecturer based in the School of Humanities and Social Science at Liverpool John Moores University. Broadly, his research focuses on the politics regionalism and trade governance in East Africa. He is currently working on a research project which is exploring the role and influence of civil society and other non-state actors in the East African Community. His work has recently been published, with Tony Heron, in the *Review of International Political Economy*.

Appendix I

List of Interviews

1. Expert in Pharmaceutical Sector Development, via Zoom, 17 April 2020.
2. Former GIZ advisor to the EAC, via Zoom, 15 May 2020.
3. Nazeem Mohamed, Past Chairperson, Federation of East African Pharmaceutical Manufacturers (FEAPM), via Zoom, 4 June 2020. Follow-up interview conducted on 22 July 2021.
4. Anonymous interviewee, via Zoom, 4 June 2020.
5. Regional Pharmaceutical Consultant, via Zoom, 15 June 2020.
6. Former UNIDO official, via Zoom, 30 June 2020.
7. Expert in Pharmaceutical Sector Development, via Zoom, 10 July 2020.
8. Perviz Dhanani, Managing Director, Universal Corporation Limited, via email, 20 July 2020.
9. Researcher, via Zoom, 17 July 2021.
10. Julius Mugwagwa, academic researcher, via Zoom, 20 July 2021.
11. Regional Pharmaceutical Consultant, via Zoom, 22 July 2021.
12. Anonymous interviewee, via Zoom, 13 August 2021.