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The AU-EU Partnership and the COVID-19 Pandemic: Moving towards health sovereignty in Africa?

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The 6th AU-EU Summit presented a joint vision for a renewed inter-regional partnership with a strong emphasis on public health. With the COVID-19 pandemic as its backdrop, a common health agenda was agreed which pledged support for Africa's fully-fledged health sovereignty. Different packages contemplated technical assistance and funding for improving health governance, infrastructures, human resources, health information and regulation, whilst ensuring vaccine dose sharing. This article looks at EU's inter-regional health diplomacy and its ambition to shape African institutions, and the African Medicines Agency in particular. It addresses strategic considerations, comparing EU and AU models, regulatory policies, and their implementation, while considering the broader implications for African health sovereignty.

Keywords: 6th AU-EU Summit, COVID-19 pandemic, health diplomacy, public health, African Medicines Agency

A parceria UA-EU e a pandemia de COVID-19: Rumo à soberania sanitária em África?

A VI Cimeira UA-UE apresentou uma visão conjunta para uma parceria inter-regional renovada com uma forte pendente de saúde pública. Tendo a pandemia COVID-19 como pano de fundo, acordaram uma agenda comum de saúde para atingir a soberania completa de saúde para África. Diferentes pacotes contemplavam assistência técnica e financiamento para melhorar a governação de saúde, as infraestruturas, os recursos humanos, a informação e regulamentação, ao mesmo tempo que era assegurada a partilha de vacinas. Este artigo analisa a diplomacia inter-regional de saúde da UE e a sua ambição de moldar as instituições africanas, e em particular a Agência Africana de Medicamentos. Para tal, aborda considerações estratégicas, comparando modelos da UE e da UA, políticas regulamentares e a sua implementação, além das suas implicações para a soberania de saúde africana.

Palavras-chave: VI Cimeira UA-UE, COVID-19, diplomacia de saúde, saúde pública, Agência Africana de Medicamentos

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Global health diplomacy and inter-regionalism

Given that studies on global and regional health diplomacy relating to Africa are rare (Almeida, 2020; Havik, 2020; Loewenson et al., 2014; Pearson, 2018), a significant knowledge gap persists. In analytical terms, health diplomacy in and with Low- and Middle-Income Countries (LMICs) has been framed in terms of development and its cornerstone, the donor-recipient relationship. Diplomatic relations and their accomplishments are categorised in different typologies, for example by tools (comprising charity, investment, security and social justice; Loewenson et al., 2014; Steurs et al., 2018), by rationale (as development, commodity/trade, humanitarian action, global public good or human rights; Almeida, 2020; Smith, 2016), by discourse (imperialism, colonialism, neo-colonialism, decolonisation; Bhattacharya & Campani, 2020; Coghe, 2020; Kell & Vines, 2020; King, 2002; Langan, 2022; Müller, 2013); by encounter (formal/informal multilateral/bilateral cooperation, inter-regional relations; Amaya & Lombaerde, 2019; Fazal, 2020; Havik, 2020; Keijzer, 2020; Kickbusch & Liu, 2022; Lee & Smith, 2011; Pearson, 2018; Rollet, 2017 & 2019), by agency (individual, collective, national, supranational, international, global; Brown & Harman, 2013; Loewenson et al., 2014; Patterson & Balogun, 2021), and by power (geopolitics, global and regional power relations; Anderson, 2018; Fargion & Maier, 2013; Killeen et al., 2018; Langan, 2022; Lenz, 2013; Rollet, 2019).

Figure 1
Theoretical perspectives on global health diplomacy

Focus	*Key threads*
Tool	Charity, investment, security, social justice
Rationale	Development, commodity/trade, humanitarian action, global public good, human rights
Encounter	Bilateral/ multilateral cooperation, inter-regional relations
Discourse	Imperialism, colonialism, neo-colonialism, decolonisation
Agency	(Trans-)national, supranational, international, global
Power	Geopolitics, global and regional power relations

Approaches to international relations have increasingly incorporated sociological and anthropological theory which look beyond territorial inter-state encounters. Issues such as national belonging, trans-national networks, personal bonds, and boundaries have guided an epistemology of everyday diplomacy. As such they privilege the negotiated "lived experience" of diplomacy and how it is perceived by those involved and affected by it (Marsden et al., 2016). The inner workings of multilateral institutions, which often remain opaque have also become the subject of scrutiny by the social sciences (Müller, 2013). These dimensions tend to be absent from much of the literature on international/global diplomacy, and EU-Africa diplomacy in particular.

While geostrategic power play between different global actors and governance related issues have tended to dominate the literature on health diplomacy with Africa in a New Cold War setting, the EU's responses to it have been couched in a metanarrative of inter-regional partnerships on an equal footing. Despite the carefully crafted benevolent tropes associated with North-South partnerships (Langan, 2022, p. 3), these relations are steeped in economic donor-recipient dependency, neo-colonial heritage, and normative power tropes. The COVID-19 pandemic forcefully brought to the fore these elements in debates on AU-EU relations, demonstrating tensions between policy goals, programmes and their (non-)implementation in different fields of multilateral cooperation. As the immediate COVID-19 pandemic threat has receded, this paper intends to shed more light on the complex interactions between the AU and EU on the one hand, and the intricate dynamics of regional and sub-regional relations on the other. To that end, it explores initiatives that emanated from the 6th AU-EU Summit with a particular focus upon multilateral programmes promoting institution building in three of sub-Saharan Africa's regional communities.

Several definitions have been proposed for global health diplomacy, terminology which emerged in the 1990s, replacing international health as the new norm (Almeida, 2020). The literature on the subject is highly fragmented and suffers from a dearth of epistemological frameworks (Ruckert et al., 2016), not in the least owing to its inter-disciplinary character (Almeida, 2020, p. 39). Global health diplomacy has been defined as:

> policy-shaping processes through which state, non-state and other institutional actors negotiate responses to health challenges or utilise health concepts or mechanisms in policy-shaping and negotiation strategies, to achieve other political, economic or social objectives. (Lee & Smith, 2011, p. 10)

It has been credited with a key role in facilitating consensus through bargaining at multilateral or bilateral international level (Kickbusch & Liu, 2022), but also extends to health governance, surveillance and biosecurity associated with epi-pandemic threats (Adams et al., 2008; King, 2002).

Attempts to better understand health as an integral component of foreign policy agendas promoted by multilateral organizations put forward the notion of inter-regionalism coined by Rüland (cf. Rollet, 2017). Applied to health it focuses upon "relations developed by regional entities (regional organizations or regional groups of states) in the domain of health." (Rollet, 2019, p. 133). Given its focus on institution building, multilateral health diplomacy tends to overlap with multilateral governance. Health systems governance involves "ensuring strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system-design and accountability" (WHO, 2007, p. vi).

Certain functions have been attributed to health AU-EU inter-regionalism. They include institution building, strengthening regional integration, diffusing regional-international norms, promoting a regional organisation's role as a multilateral actor, building collective identity and legitimacy as a regional health agency (Rollet, 2019). In addition, geopolitical dimensions of inter-regional relations involve the EU and AU in the "soft balancing" between different global and inter-regional actors (Patterson & Balogun, 2021, p. 150). Health inter-regionalism promoted by the 6th AU-EU Summit highlights EU's unique role as global actor "that actively and systematically promotes the norm and practice of regional integration around the world" (Lenz, 2013, p. 212). In the case of AU-EU cooperation, inter-regionalism tends to view either side as monolithic entities, which ideally negotiate the joint coordination and oversight of strategies and policies based upon a broad consensus on criteria, goals, and targets.

In diplomatic terms, the COVID-19 pandemic triggered a "cosmopolitan moment" (Kickbusch, 2013) moving towards a new AU-EU inter-regional partnership. Besides policy tools, in institutional terms the 6th AU-EU Summit renewed EU's commitments towards reinforcing its support for regional regulatory harmonization projects as building blocks for the African Medicines Agency. EU health diplomacy thus promoted a tested institutional model, with normative standards, a functional rationale and external funding, to enhance AU's status as a regional public health actor. AU's implementation of these processes, hinges above all upon its capacity to oversee and facilitate sub-regional consensus on supranational institution building. Evidence from the field reveals multi-level, differential, non-synchronous dynamics within highly diverse regional economic communities.

Three aspects are highlighted below, namely the evolution of multilateral health diplomacy between Europe and Africa, health crises and epi-pandemic responses, and African health sovereignty. A review of approaches to and debates on health diplomacy of past and present and of epi-pandemic emergencies in the African region, is followed by a case study of the African Medicines Agency (AMA) modelled on the European Medicines Agency (EMA). The (meta)narratives surrounding AU's ambitions as a regional player and EU's newfound role as global health actor are discussed, as well as the implementation of regulatory harmonisation programmes with EU support. The paper shows that while the regulatory harmonization initiatives are the subject of growing research, dominant perspectives on inter- and intra-regional developments reveal important knowledge gaps on the diplomatic culture surrounding the building blocks of African health sovereignty.

Research for this paper centred upon primary sources produced by the EU, EU Commission, the European Medicines Agency (EMA), and other institutions with a European purview. Documents produced by the AU and regional African economic communities, as well as reports by multilateral institutions including the World Health Organisation (WHO), and AFRO, its regional bureau, on health diplomacy and governance were also consulted. An extensive literature review was undertaken using keywords on Scopus, JSTOR, PubMed Central, SSRN, ResearchGate, Academia.edu and Google Scholar on health diplomacy, strategies, policies, their evolution, institution building, regulatory frameworks, with a special focus on Africa.

The 6th AU-EU Summit and the COVID-19 pandemic

The 6th AU-EU Summit held in February 2022 reaffirmed the already existing strategy for cooperation in the field of public health, including the strengthening of health systems and their resilience, the local manufacturing of medical products and the reinforcing of national regulatory frameworks. In the face of the COVID-19 pandemic, additional technical assistance and funding was agreed upon for pandemic preparedness, collective health security and equitable access to health services, suffering from underinvestment, lack of human resources and equipment. AU-EU cooperation in the field of health operates through five different programmes, namely the Global Gateway Package (GGP), TEAM Europe, the Strengthening of Health Systems, the African Medicines Agency (AMA) and Vaccine Dose Sharing. The GGP provides funding for infrastructural investment in health and other priority area projects (EC, 2021a), while TEAM Europe sup-

ports initiatives via partnerships with sub-Saharan AU countries in sustainable health security, sexual and reproductive health, digital health, and the local production of a medicines and vaccines production capacity (EC, 2021b).

Additional support for a complex undertaking such as the African Medicines Agency, first proposed by AU in 2014, has been pledged by EU and other institutions, to establish and coordinate a regulatory framework for medicinal products and health technologies to safeguard their quality, safety, and efficacy (Hwenda et al., 2022; Ncube et al., 2021). The initiative to strengthen health systems centres on policy development and implementation to improve, amongst others, health service delivery, the training of the health workforce health information systems, and health system funding (EC, 2021b). Finally, Vaccine Dose Sharing coordinated by TEAM Europe – which has received ample media coverage during the pandemic – has resulted in pledges of donations for hundreds of millions of doses by manufacturers to African and South-East Asian countries. However, these donations have been the subject of investigations on account of an alleged lack of transparency regarding the procurement and negotiations with pharmaceutical companies (Sciacchitano & Bartolazzi, 2021).

Although these programmes are (co-)funded by the EU, technical assistance is also forthcoming from other international partnerships and agencies, which contribute to the African Centres for Disease Control (African CDC), the Vaccine Acquisition Trust (AVAT) and the COVAX facility (Facility for COVID-19 Vaccines Global Access). The African CDC – which forms part of the AU – set up in 2017 are responsible for providing support to member states in the field of disease control and prevention and epidemiological surveillance, emergency preparedness and response and public health information, as well as capacity building of laboratory networks and public health institutions. The Vaccine Acquisition Trust was set up in 2020 by the African COVID-19 Vaccine Acquisition Task Team to implement the AU's COVID-19 Vaccine Development and Access Strategy. The COVAX facility is coordinated by the World Health Organization (WHO), the United Nations International Children's Emergency Fund (UNICEF), the Coalition for Epidemic Preparedness Innovations (CEPI) and the Global Alliance for Vaccines and Immunization (GAVI). It aims to provide stimulate research and development, the production of COVID-19 vaccines and to assist African countries in vaccine price bargaining. The official joint statement of the Summit underlines the importance of securing "fair and equitable access" to COVID-19 vaccines in the African region (AU, 2022a).

The above-mentioned programmes aim to promote sustainable public and private investment in health through a special Health and Education Package in

line with the Rome Declaration which emanated from the Global Health Summit in 2021. It declared support for enhancing the preparedness, prevention, detection, and response to the pandemic, embracing a multi-sectoral One Health approach, securing reliable medical supply chains, effective responses and vaccine delivery systems (GHS, 2021). Raised awareness during the COVID-19 pandemic of the need for a coordinated emergency response brought forward the call for a European Health Union and for EU's coordinated Global Health Policy (EU, 2020). The latter underwrites adherence to achieving the Sustainable Development Goals (SDG), placing good health and well-being in a broader framework with advancing education, biodiversity, climate, and security to combat poverty, hunger, disease and want. However, political differences between EU member states – who conduct their own parallel health diplomacies – reflect fault lines between multilateral priorities geared to social justice and collective security, which have tended to shift towards the latter in recent years (Steurs et al., 2018).

The outcome of the 6th AU-EU Summit and the commitments regarding the revised partnership made at the time, have since been the subject of review and critique. The AU's call for Africa's New Public Health Order in 2022 affirmed the urgent need for strengthening institutions and the health workforce, for increased investment in health and the local manufacture of health products, as well as for promoting effective partnerships. Given that the COVID-19 pandemic has since subsided, immigration and violent conflict elsewhere are now casting their long shadow over international relations, diverting EU's attention towards its eastern and southern border. Together with other topical issues such as climate change and securitarian concerns, public health and disease control remain high on the international agenda, building upon the diplomatic momentum they gained during the pandemic. While health diplomacy with the African continent has lost none of its urgency, not in the least owing to – partly unfulfilled – pledges made by the EU, tensions between economic and health priorities have revealed cracks in the harmonious metanarrative. Following over two decades of AU-EU summits, the COVID-19 pandemic laid bare "the marginal role played by health policies" (Carbone, 2021, p. 15). Critique has centred on the dispersion of collaborative frameworks, inadequate timeframes, and inappropriate institutional models, as well as the lack of priority given to health or poverty – overshadowed by security, migration, economic development, and trade (Carbone, 2021, p. 27).

The EU's declaration "Toward a comprehensive strategy with Africa" published two days before the COVID-19 pandemic was declared, revealed – with hindsight – a serious gap, namely that "health was the most important issue that the EU's strategy failed to cover" (Teevan, 2021, p. 44). Indeed, together with ed-

ucation health took a rearguard place in EU's Africa development strategy in the pre-2020 years, surpassed (in disbursements) by government and civil society, emergency response, agriculture forestry and fishing, budget support, banking and financial services, and transport and storage (Jones et al., 2020, p. 34). The COVID-19 pandemic triggered a greater emphasis on human development in which health figured prominently. Despite a vision of an "equal partnership" enshrined in the Joint Africa Europe Strategy (JAES) initiated in 2007, EU relations with African states have been profoundly marked by donor-recipient relationships (Keijzer, 2020; Kell & Vines, 2020). Questions have been raised to what extent these relations shed their neo-colonial dimensions as they moved from outright dependency under Yaoundé (1963) and Lomé (1975) conventions to "asymmetrical interdependence" in the new millennium with the Cotonou (2000) agreement (Olivier, 2011, p. 56). Diplomatic terminology such as "partnership, equality, co-ownership, co-responsibility and interdependence" aims to dispel lingering concerns over values and perceptions regarding EU's interests and intentions (Olivier, 2011, p. 59).

The COVID-19 pandemic exposed certain shortcomings, such as weak health systems, a lack of equitable access to basic services and vaccines, and a notable reliance on the donor-recipient model that the 6th AU-EU Summit appeared to address. Measures in support of strengthening health systems, vaccine supply and roll-out, and sexual and reproductive rights formed the mainstay of the Summit's Team Europe pandemic induced commitments. The Partnership for African Vaccine Manufacturing (PAVM) launched by the AU and the African Centres for Disease Control and Prevention (African CDC) in 2022 set targets for achieving greater regional manufacturing autonomy (Bilal et al., 2022), while putting in place regulatory frameworks for technology transfers, research and development, quality control, training, and funding (Makenga et al., 2022). This approach spells a significant shift from the GAVI-led importation model which has dominated global vaccine procurement and distribution since 2000 (Makenga et al., 2022).

Multilateral health diplomacy: biosecurity and public health

Besides reiterating "respect for sovereignty, mutual respect and accountability, shared values, equality between partners and reciprocal commitments," the 6th AU-EU Summit held in February 2022 also made a point of acknowledging the importance of history. Multilateral health diplomacy focusing upon Africa has a chequered history embedded in global and regional institutional networks ever

since the League of Nations inputs during the interwar period (Kickbusch, 2013). The historical dimensions of post-1945 international and regional geopolitics conditioned Africa's relations with its former colonial overlords and the continent's long-term external dependency in terms of health governance (Fazal, 2020; Havik, 2020; Hotez, 2014; Loewenson et al., 2014).

Developmental narratives and strategies based upon multilateral technical assistance which emerged during the Cold War have dominated relations with African states and regional organisations ever since (Packard, 2016). Tensions and contradictions between the perceived continuity of neo-colonial relations with independent African nations centring upon the twin goals of economic and human development – already in evidence during late colonialism (Havik, 2020) – have gained greater visibility over the last decades. Bio-securitarian considerations and population management dominated the combat against endemic diseases such as Human African Trypanosomiasis (HAT) which formed one of the main pillars of inter-imperial disease control programmes (Coghe, 2020). Subsequently, HIV-AIDS, Ebola and the COVID-19 pandemic played significant roles in shaping EU's cooperation with Africa in the realm of public health in the post-colonial era (Fazal, 2020; Quaglio et al., 2016).

One of the under-researched aspects of Africa's health history is that of disease control and immunization. Colonial powers undertook mass vaccination campaigns against certain endemic diseases such as smallpox, yellow fever, tuberculosis, typhus, and cholera in the interwar period. To that end vertical programmes were devised and implemented, connecting colonial possessions with a mixture of fixed and mobile facilities covering large areas hitherto ignored or underserviced. Scientific collaborations in tropical medicine between colonial powers underpinned the combat against epi-endemic diseases such as HAT, malaria, yellow fever, bubonic plague, cholera, yaws, tuberculosis, and sexually transmitted diseases. From the late 1920s onwards, bilateral sanitary conventions between these powers regulated border controls, cross-border campaigns, and medical exchange. Multilateral diplomatic efforts remained limited to a few conferences co-sponsored by the League of Nations Health Organisation (LNHO) in the 1930s, which mainly focused on epidemiological issues. However, little progress was made in the field of public health (Havik, 2020, p. 126).

With the establishment of the UN system after 1945, multilateral efforts putting public health on the agenda accelerated in the African region, with the establishment of WHO's regional body, AFRO, in 1951. Amongst others, it promoted sub-regional cooperation between member states to collaborate on cross-border disease surveillance and control, data sharing and the pooling of resourc-

es. Despite attempts by colonial powers (UK, France, Belgium, and Portugal) to control its progress via the Combined Commission for Technical Co-operation in Africa south of the Sahara (CCTA), following decolonization, AFRO consolidated its position as the region's multilateral health authority (Havik, 2020; Pearson, 2018). Operating in a bilateral fashion until the mid-1960s, it was eventually absorbed into the Organisation of African Unity (OAU) in 1965. However, the OAU exhibited a "poor record on following through on intra-continental agreements/treaties" (Babarinde, 2007, p. 3) while also failing to prioritise health as a prime policy driver. Its replacement by the African Union in 2002, appeared to suggest a shift in approach towards an institutional template more akin to the EU (Babarinde, 2007, pp. 3-4).

During the Cold War health and vaccine diplomacy grew into a global phenomenon, involving political and scientific collaborations which benefited the successful implementation of the smallpox and oral polio vaccine and programmes (Hotez, 2014). Vaccines were widely weaponized by First and Second World states to further particular geo-political interests; their usage to that end intensified with the COVID-19 pandemic in a multipolar world (Liu et al., 2022). Preparations for the smallpox vaccine rollout showed that multilateral diplomatic overtures were accompanied by highly selective metanarratives that privileged a positive diffusionist rhetoric. Although "a willingness to negotiate with wide-ranging actors on equal terms," forged "expansive networks of solidarity" under WHO auspices, problems associated with pre-intensive phase actions and actors were omitted from the official narrative (Bhattacharya & Campani, 2020, pp. 91-93).

The "gloss of harmony" embellishing such tropes disseminated by international agencies (Müller, 2013) served to claim legitimacy for the combined global effort to eradicate infectious disease as examples to follow for regions with high morbidity and mortality rates. WHO's successful global eradication campaign against smallpox (1967-1980) almost completely eliminated the disease from highly endemic areas in West and Central Africa by the early 1970s (Schneider, 2009). Taking cues from the smallpox campaign, the Global Polio Eradication Initiative (GPEI) launched in 1988 – which resulted in a polio free African continent in 2020 – facilitated the "harmonisation and standardisation of public health strategies" (Mohammed et al., 2021, p. 823). It also demonstrated the collaboration across ideological lines in the global polio inoculation campaigns in a Cold War setting, including African states (Vargha, 2017; Shin, 2023).

Benefiting from the focus on neglected tropical diseases (NTDs) of the WHO's TDR programme (Special Programme for Research and Training in Tropical

Diseases, 1974) and the shift towards primary health care following the Alma Ata meeting, disease surveillance and mass immunisation drove the cooperation between WHO-AFRO, AU, and its member states. Thus, securitarian dimensions of health risk management and epi-pandemic readiness became watchwords for disease control and immunization interventions. The historical dimensions of post-1945 international and regional geopolitics conditioned Africa's relations with its former (European) colonial overlords, underlining the continent's long-term external dependency in terms of health governance (Fazal, 2020; Havik, 2020; Hotez, 2014; Larson et al., 2022; Loewenson et al., 2014). Strategies based upon technical assistance and development aid which emerged during the Cold War have largely guided relations with African states and regional organisations ever since. Tensions and contradictions regarding the place of public health in inter-regional relations with the donor-dependent AU and multilateral projects gained greater projection during the COVID-19 pandemic (Langan, 2022).

Epi-pandemic responses and health sovereignty

HIV-AIDS, Ebola and SARS-CoV-19 all played significant roles in boosting EU's cooperation with Africa in the realm of public health and disease control (Fazal, 2020; Quaglio et al., 2016). The Abuja declaration of 2001 pledged that AU and African countries were to strive towards the progressive exercise of health sovereignty – "ownership" – over the combat against HIV-AIDS, TB, and malaria. As African states' expenditure on public health rose and the multilateral scale-up intensified, HIV and TB incidence rates have steadily declined on the continent.

Programmes such as Action on AIDS, Tuberculosis and Malaria involved a partnership between the EU and the Global Fund started in 2002. Comprising of the distribution of TB vaccines, antiretroviral therapy (ARV) and anti-malarial drugs, it was discontinued during the 2008 economic crisis (Smith, 2016, pp. 152-153). In the process, the EU shifted away from its universal human rights approach to adopting a risk management strategy based upon specific epidemiological priorities (Smith, 2016). Under strong international pressure, the EU and the USA did change their restrictive policy towards pharmaceutical patents and compulsory licensing of HIV drugs in 2000, thereby facilitating the subsequent ART scale-up in Africa (IIPI, 2000).

The Ebola outbreak in West Africa in 2013 exposed flaws in EU's health diplomacy and the need to develop an adequate response to public health emergencies. EU's delayed reaction to the epidemic and the quest for a vaccine

focused attention on a coordinated response. After all, WHO's slowness in activating its Global Outbreak Alert and Response Network (GOARN, 2000) had prompted the UN to lead and coordinate interventions via its Mission for Ebola Emergency Response (UNMEER) (Fazal, 2020, p. 86). Epidemic preparedness thus figured on EU's policy agenda when the COVID-19 pandemic struck. The European External Action Service - EEAS (Jørgensen & Schvartzman, 2016) and the Emergency Response Coordination Centre (ERCC) had been established over the preceding decade (Quaglio et al., 2016). These institutional tools aimed to facilitate the coordination of medical emergency and humanitarian relief efforts, and the mobilisation of key resources together with international organizations and NGOs. Despite these European initiatives, however, the political question of drug development and vaccines was still unresolved when the COVID-19 pandemic struck early 2020.

Slow to respond to AU and African states' requests for assistance in the wake of the emergence of the COVID-19 pandemic, the EU eventually moved in the course of 2020 to support the African CDC's testing and surveillance programmes as well as developing a Joint Continental Strategy for COVID-19 (Patterson & Balogun, 2021, p. 147). African responses to the pandemic suggest that it was largely contained in a prompt and coordinated fashion, benefiting from the WHO response plan, African CDC's taskforce and lessons learned from the 2013 Ebola outbreak, despite underfunded and understaffed health systems (Talisuna et al., 2022). While these outcomes appear to have enhanced AU-CDC's reputation as a regional health actor, they also resulted from interventions at regional community level (Medinilla et al., 2022). However, narratives of Africa's success were tempered by "intersecting precarities" affecting vulnerable populations (MacGregor et al., 2022) and largely overshadowed by vaccine related issues (Sciacchitano & Bartolazzi, 2021).

Constituting its main topic and justification, the 6th AU-EU Summit acknowledged that the COVID-19 pandemic set "the immediate challenge [...] to ensure a fair and equitable access to vaccines". The joint AU-EU declaration underscored the existence of:

> a common agenda for manufacturing vaccines, medicines, diagnostics therapeutics and health products in Africa, including investment in production capacities, voluntary technology transfers as well as strengthening of the regulatory framework to enable equitable access to vaccines, diagnostics and therapeutics. (AU, 2022a)

A recent example of multilateral cooperation in this field is the African Vaccine Regulatory Forum (AVAREF), created by WHO and supported by the European

Developing Countries Clinical Trials Partnership (EDCTP). Strengthening African national regulatory authorities and ethics committees to harmonize standards across the region, it played a role in developing the Ebola vaccine following the 2013 outbreak in West Africa.

Nevertheless, the EU has showed great reluctance to relinquish control over the product patents of European based vaccine manufacturers. Given that Africa imports 99% of the vaccines administered on the continent, as well as importing 95% of biomedicines (WHA, 2021), the AU aims to establish partnerships with producers and suppliers. Dose sharing or donations of "excess" vaccines or medicines from the EU and other entities are seen as mere stop-gap measures. The impact of global resource scarcity on low-income countries' access to vaccines, medicines and equipment was strongly felt during the COVID-19 pandemic (McMahon et al., 2020). Hence, the World Health Assembly (WHA) passed a resolution in support of the local production of COVID-19 medicines to ensure their "equitable distribution" and "of other health technologies" (WHA, 2021). To that end, it envisages "technology transfer on voluntary and mutually agreed terms, cooperation with, support to and development of voluntary patent pools and other voluntary initiatives." Among the available means to do so, the resolution recommended the WHO COVID-19 Technology Access Pool (C-TAP) and the UN supported Medicines Patent Pool (MPP). Whilst the former offers a collaborative global platform to speed up the development of COVID-19 therapeutics, diagnostics, and vaccines "by sharing intellectual property and data" (WHO, 2020), the latter focuses on pooling "intellectual property to encourage generic manufacture and the development of new formulations" by negotiating licenses with manufacturers (MPP, 2021).

So far however, the EU has declined to commit to supporting vaccine waivers. It also succeeded in watering down the approval in 2022 by the World Trade Organization (WTO) of a waiver with respect to Trade Related aspects of Intellectual Property Rights (TRIPS) for patents on COVID-19 vaccines, initially proposed by African and Asian countries. Despite the joint AU-EU statement for the 6th AU-EU Summit reiterating its support for "fully fledged African health sovereignty" (AU, 2022a, p. 2), AU officials and civil society groups accused the EU of "hypocrisy" given its refusal to grant waivers for vaccine licensing (Langan, 2022, p. 11). Extending the notion to pharmaceutical and public health sovereignty, the AU reaffirmed the need for autonomy in the field of end-to-end medicine and vaccine production in the wake of the COVID-19 pandemic, and health technology and equipment, including cold chains, clinical trials, and raw materials (Mugabe et al., 2020).

The practice of "viral sovereignty," with countries exerting control over pathogenic samples, resulted in a sharing regime contained in the Pandemic Influenza Preparedness Framework in 2011 under WHO auspices following the H1N1 pandemic (Fidler, 2020). Whereas the sharing of SARS-CoV-2 genomic sequences early in the current pandemic enabled and accelerated the rapid development of potential vaccines, it failed to significantly promote health sovereignty for LMICs. Local initiatives to manufacture unique second-generation versions of existing vaccines using mRNA technology, as in the case of South Africa, envisage circumventing legal patent restrictions (Bryce & Ong, 2022). Whilst some pharmaceutical companies have declared their willingness not to enforce COVID-19 vaccine patents and facilitate "voluntary licensing," overall, these initiatives are still far from enacting effective technology transfers (Furlong, 2022).

The African Medicines Agency (AMA)

The notion of health sovereignty has been associated with a variety of rather loose definitions. They range from an emphasis on human rights dimensions such as "the realization of specific national constitutional and policy objectives on citizens' access to and enjoyment of good health" (Mugabe et al., 2020, p. 3) to bio-securitarian approaches aiming for "early warning systems, supply chain resilience, medical research and development, and cyber security and technology" (Hackenbroich et al., 2020, p. 12). One of the consensual aspects of enhancing health sovereignty is the strengthening of health systems, the management of human and material resources and of oversight mechanisms such as regulatory frameworks based upon a set of common standards of performance, accountability, and transparency. Thus, the adoption of institutional reforms raises the issue of how to square the transfer of concepts, policies, and models to Africa with health sovereignty in donor-recipient relationship (Odoch et al., 2022).

The African Medicines Agency (AMA) founded in 2019 forms the centrepiece of the EU's inter-regional strategy towards the AU achieving long-term regional health sovereignty as announced at the 6th AU-EU Summit. Whereas Africa harbours 17% of the global population and shoulders 25% of the global disease burden, the continent is responsible for less than 3% of clinical trials (Hwenda et al., 2022). Whilst Africa has witnessed a decline in morbidity and mortality levels resulting from diseases such as malaria, HIV-AIDS, diarrhoea, and respiratory infections – with regional variations – non-communicable, and (re-)emerging diseases such as Ebola and Marburg haemorrhagic fever, Zika, chikungunya, measles and monkeypox (m-pox), have added to the disease burden over the

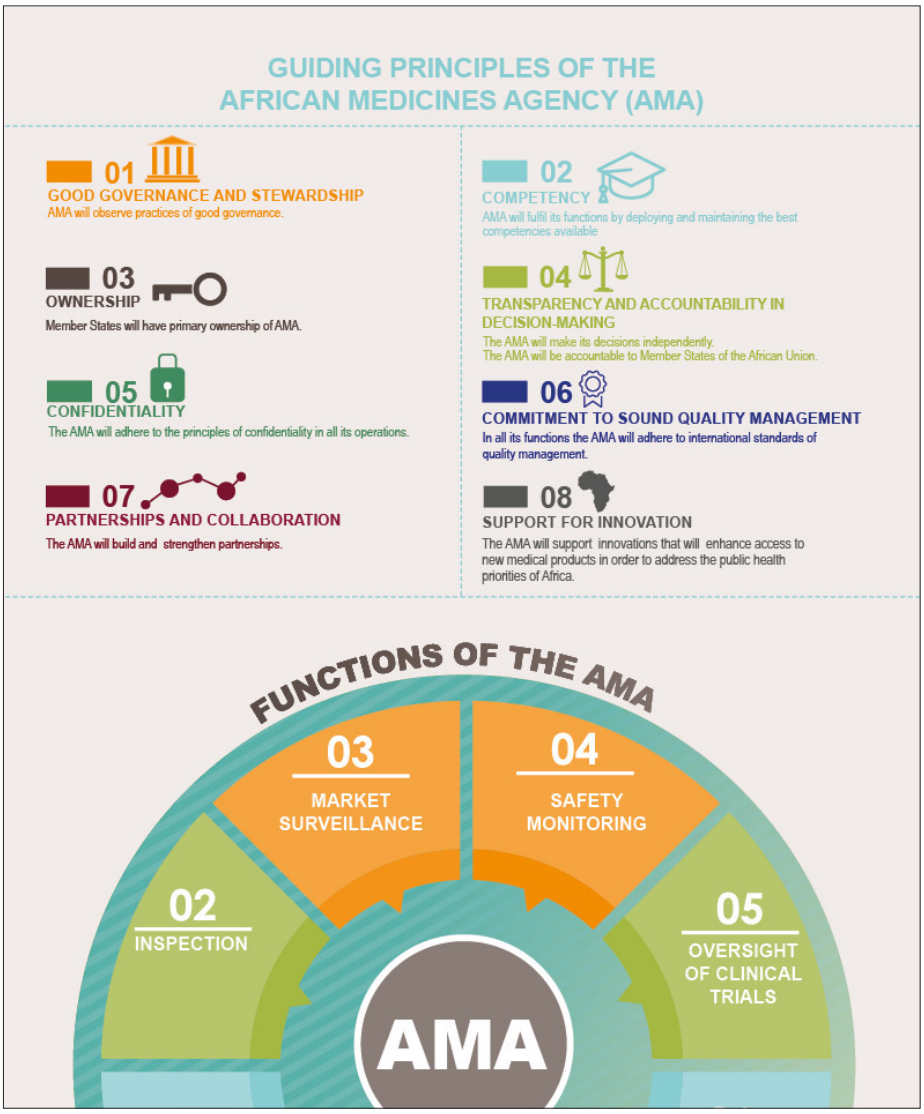
last decades. Whereas the impact of COVID-19 is low compared to malaria, HIV-AIDS, and tuberculosis, it absorbed significant resources from Africa's fragile health systems and had strong socio-economic repercussions (Bell & Hansen, 2021). The continents' "double burden of disease" associated with infectious and non-communicable diseases (Hwenda et al., 2022) highlights the acute need for regional regulatory platforms and partnerships to pool expertise, evaluate medicinal products, stimulate their local production, and monitor their marketing (Ncube et al., 2021).

The existence of informal health providers – healers and herbalists – which have been the subject of multilateral inputs towards the registration, regulation and monitoring of traditional medicines under WHO-AFRO guidance for over two decades (WHO-AFRO, 2010), constitute a formidable challenge for regional health agencies such as AMA. While the literature on multilateral inter-regional cooperation in health does mention the African CDC, it has largely ignored already existing forms of multilateral collaborations, such as WHO-AFRO's strategy for traditional and complementary medicine. Legislative frameworks, quality control, clinical testing, monitoring, commercial licensing, and intellectual property related issues – key to the AMA project – have been addressed by many African countries over the last two decades (WHO, 2019). Institutional reforms included centres for botanical and pharmacological testing, the setting and monitoring of standards and commercial licensing, thereby creating a basis for the regulation of phyto-therapeutic medicines and for integrating associated practices in biomedical health services (WHO-AFRO, 2010).

The COVID-19 pandemic triggered a renewed interest in research into traditional herbal medicines in the region. Despite strategies to promote access to medicines in LMICs, the EU-EMA's impact has been negligible in this respect. In 2019, the AU decided to adopt a treaty for the establishment of AMA presenting it as a pivotal "unified continental regulatory framework" to ensure the quality, safety and efficacy of medicines and medical products in Africa. Its main functions are to harmonise the regulation of medicines, conduct regulatory oversight and pooling expertise (AU-AMA, 2019). AMA is expected to set the standards for good public health practice, coordinate and oversee regulatory harmonisation in member states and regions, promote a common framework for regulatory procedures on medical products, monitor the medicines market, share information, provide technical assistance, and promote the adoption of AU Model Law on medical products regulation (AU-AMA, 2019, pp. 10-12). After its ratification by 15 member states in 2021, the AMA treaty entered into force, Rwanda being appointed as the host country of the future AMA headquarters.

Figure 2

AMA Infograph



Source: AUDA-NEPAD. https://www.nepad.org/microsite/african-medicines-agency-ama

The African Medicines Regulatory Harmonisation Initiative (AMRH) casts access to affordable essential medicines as a fundamental human right. The AMRH which received financial support from the World Bank aimed to implement regional mechanisms to facilitate and accelerate procedures for the approval of medicines and medical products. AMA is expected to reduce the significant delays that Marketing Authorisations (MA) and Clinical Trials Authorisations

(CTA) for vaccines and medicines in LMICS (Ndomondo-Sigonda et al., 2018). Partnerships of government, the private sector and civil society were negotiated as sub-regional level in preparation for the AMA launch. The African Medicines Agency Treaty Alliance (AMATA) launched in 2021 urged AMA to engage with non-state actors, including civil society and patients as partners in the agencies' regulatory development (Wale et al., 2023).

The AU's prime objective for AMA is to promote the local production of pharmaceutical products, in accordance with the Pharmaceutical Manufacturing Plan for Africa (PMPA) within the NEPAD framework. AMA's assessments are to be directed towards medical products that prioritise endemic diseases and conditions on the African continent under AU's guidance (AUDA-NEPAD, 2019). To that end, NEPAD designated Regional Centres of Regulatory Excellence (RCOREs) to promote academic and technical training to spearhead the development of regulatory mechanisms in five Regional Economic Communities (RECs) that joined the initiative (Luthuli & Robles, 2017, p. 7).

Before the 6th AU-EU Summit, the European Commission (EC) pledged 100 million Euros support for strengthening AMA's regulatory framework (see above), co-funded by EMA, EU member states Belgium, France and Germany and the Bill & Melinda Gates Foundation. These funds will be directed at the "sharing of technical expertise between the EMA and the AMA and support several African National Medicines Regulatory Authorities (NMRAs) to achieve the minimum WHO requirements for effective regulatory oversight for quality local vaccine production" (EC, 2022). EU funds will be administered by Team Europe on local Manufacturing and Access to Vaccines, medicines, and health technologies in Africa (MAV+) to buttress AMA's initial phase. International WHO regulations oblige countries to install NMRAs, monitored by its regional offices, such as AFRO. First created in Europe in the late 1800s, NMRAs were intended to safeguard the protection of patents, product safety and regulate the medicines trade. Promoted by WHO, its guidelines have become a key public health policy tool across the globe. The African NMRAs are held to perform five tasks: concede authorisations for product marketing, conduct pharmaco-vigilance, post-market surveillance and product quality control, as well as overseeing clinical trials (Ncube, 2021, p. 3). Implementing different funding models, some NMRAs are gradually achieving greater financial autonomy as their fee-based revenue increases (Ndomondo-Sigonda et al., 2020).

The impact of NMRAs in Africa has so far been welcomed as positive (AU, 2022b), and most particularly in the case of the East African Community Medicines Regulatory Harmonization Initiative. Operating since 2012 with World Bank sup-

port, joint assessments are increasingly common among member states (Burundi, Democratic Republic of Congo - DRC, Kenya, Rwanda, South-Sudan, Tanzania, and Uganda) as are inspections, whilst the time needed for the registration of medicines has been halved (Mashingia et al., 2020). In the case of its West African, Central and Southern African sister communities, some progress has also been made in terms of approval times. In all regions, the progressive harmonisation of procedures has been accompanied by the phased introduction of standardised information and quality management systems (Ndomondo-Sigonda et al., 2018).

So far, the imagined AMA network only exists – albeit partially – at regional level, through regulatory harmonisation initiatives. The number of countries involved (55) and the integration of NMRAs at regional community level, differs from its European example (Fig. 3).

Figure 3
Comparative overview of EMA and AMA

Agencies	*EMA*	*AMA*
First harmonization measures	1965	2009 (AMRH)
Treaty negotiation	1988-1995	2007-2014
Constitution	1995	2021
Member states	27	55
Ratification	Complete	15 countries
Building blocks	Member States	Regional Economic Communities
Centralised procedure	1995	no
Expert pool	> 4500	n.a.
Expert committees	7 + working parties	n.a.
Regulatory harmonization	Complete	AMRH ongoing
Budget	417.5 million € (2022)	100 million € (2022-2027)
Funding	86% fees; 13% EU	Donor-dependent

Source: AU, 2016; AUDA-NEPAD, 2019; EMA, 2019; Ncube et al., 2021

The diversity of health systems, the fact that more than 70% of medical products consumed on the African continent are imported, the extensive recourse to locally produced traditional therapies, and the key role of the informal economy form a daunting challenge for regulation, as does the combat against substandard or falsified medical products in the region. Hence, the importance of cooperation

between NMRAs and the pooling of expert knowledge, the approval and oversight of clinical trials, inspections of manufacturers, and compliance with good clinical-, manufacturing-, distribution- and pharmacovigilance practice (EMA, 2016; Ncube et al., 2021). These regulatory bodies respond to the AU Model Law on Medical Products' Regulation drawn up by the AMRH programme and proposed by AUDA-NEPAD which was introduced in 2016 (Ncube et al., 2021). However, adopting AU Model Law has proved to be time-consuming process (Ncube et al., 2023).

These regional collaborations are part of global regulatory networks, which include a variety of standardised mechanisms for medicines' evaluation, authorisation and distribution that potentially benefit LMICs. The International Conference on Harmonisation (ICH) launched by regulatory authorities from high income countries including the EU, has set global standards and procedures since the 1990s. ICH procedures are however considered to be more stringent and costlier (Calder, 2016, p. 11) and disadvantageous to LIMCs. As a result, many developing countries have opted for EMA's article 58 procedure, or the WHO Prequalification of Medicines Programme established in 2001. EMA's article 58 covers all medicinal products, with an emphasis on innovative products rather than generics, which respond to unmet needs or represent a major public health interest outside the EU, which are submitted to scientific review by EMA, WHO and regulatory bodies and experts in target countries. The latter have a final say in the matter based upon the available benefit-risk assessments which consider local conditions, whilst conducting health technology assessments of their own. EMA has thus extended its global status with LMICs' efforts to obtain market authorisations for local products from a "stringent" agency (Perehudoff et al., 2021).

Currently labelled "EU Medicines for All," article 58 expresses EU's "global mission" in public health; most of the limited number of approvals were issued to AU member countries, with an emphasis on HIV/AIDS, malaria, and vaccines (Bellaubi et al., 2020). Under WHO auspices, the quality, safety and efficacy of medicines and medical products are assessed, giving priority to certain diseases and medical conditions; this has resulted in a list of hundreds of approved medicines. Manufacturers are invited to submit an expression of interest for the evaluation of a particular product, which is thereupon evaluated, and once approved added to the list of prequalified products, thus facilitating bulk buying for distribution in LIMCs. Given that certain medicines such as anticancer and antihypertensive products are not eligible for the WHO Programme, regional NMRAs have invited manufacturers to submit evidence for evaluations. However, NMRA's lack of awareness of the pathway, prohibitive costs of article

58 assessments for manufacturers, the non-validity of authorizations for the EU, and the lack of effective coordination between EU and WHO have limited its use and impact (EMA, 2015).

The AMA model and regional regulatory networks

Regulatory harmonisation initiatives are a global phenomenon. Besides the African project, there are ongoing initiatives in South-East Asia, the Middle East, the Asia-Pacific, and Latin American regions (Calder, 2016, pp. 11-14). The implementation of AMA was overseen by a task team created by WHO, AUDA-NEPAD and the AU Commission. It soon became clear that the project was underfunded, undercutting the AMA business plan, as resources were diverted to regulatory activities in the different community member countries (WHO-AFRO, 2015). The sustainability of the AMA model based upon the European Medicines Agency (EMA) (Fig. 3) depends on its financial – and political – autonomy and of the regional networks that support it, and on its capacity to transform a set of national and regional mechanisms into a well-coordinated, effective and harmonised whole, adaptive to changing needs.

EMA's constitution by individual member states – which took seven years of inter-member state negotiations – was a hard-fought political compromise, which safeguarded the partial retention of states' national sovereignty. The latter had already been diluted from 1965 onwards when the first supranational harmonisation directive for pharmaceutical products was issued. Founded in 1995, EMA has been portrayed as a success story (Banzi & Garratini, 2015; EMA, 2016). EMA's revenue derives exclusively from fees charged by manufacturers, and contributions from the EU and EEA (European Economic Area) budgets. The EMA model is centred on providing incentives for the pharmaceutical industry by reducing the costs of and delays in regulatory procedures and evaluations, accelerating the marketing of medicines and vaccines for populations in need. During its initial phase, fees were not directly cost-based as "a system of graduated fees" was put in place, charging lower rates for product development related activities (Smith et al., 2018, p. 21).

Jointly funded by the pharmaceutical industry and the EU, unitary (procedural) and annual fees for the evaluation, authorisation, and supervision of medicinal products cover the lion's share of costs of EMA's activities, accounting for about 86% of the total budget. Part of the revenue from the current fee system, in place since 2005**,** goes to national regulatory authorities to pay for assessments and to their respective expert pools. Its regulatory framework and oversight – in the

case of pharmacovigilance and inspections – have grown and become increasingly complex over time, with the system losing some of its flexibility (Smith et al., 2018). The long-standing practice of reductions and fee waivers and exemptions depends on intricate, negotiated outcomes which increase the systems' flexibility but lessen its transparency. Whilst they provide incentives for small and medium sized enterprises since 2005, fee breakdowns for manufacturers and the criteria applied for exemptions and reductions have been the subject of critique, notably so regarding vaccine assessments and their timeline during the COVID-19 pandemic.

At the top of the system, EMA's coordinating activities managing the centralised registration procedure have become more demanding as the system expands and becomes ever more complex. At the base of the system, the national regulatory bodies which manage the decentralised procedures are particularly diverse. Given that medicinal products can be registered in a member country, a system of mutually recognised evaluations and authorisations operates, based upon the first country's decision (Calder, 2016, p. 10). NMRA based revenue does not necessarily cover costs made for performing services at EMA's behest and for keeping pace with biomedical and pharmaceutical development and innovation (Smith et al., 2018). The tendency to out-contract rapporteurs to favour the offices of better organised member states with greater economic clout, suggests that there are internal hierarchies and competing interests underlying procedural decisions. Hence, there are "differences in the uptake of medicines between EU Member States" which "reflect their economic situation and resource possibilities […]. Despite harmonization of marketing authorizations in Europe, innovative medicines are not equally available to all citizens in the EU in a timely and equitable manner" (Banzi & Garratini, 2015).

AMA's future role depends primarily on its capacity to act as a neutral coordinator of NMRAs, to promote their efficacy, implement and monitor standards and guidelines, and support national and regional regulatory networks. Its future coordinating role is to be facilitated by expanding collaborative regional frameworks and the African Vaccine Regulatory Forum (AVAREF), created by WHO in 2006. The latter has succeeded in engaging a growing number of MRNAs in the process of improving regulatory actions and monitoring mechanisms for clinical trial requests, joint reviews thereof and on-site inspections. AVAREF and NMRAs are seen as key building blocks paving the way for AMA (Ndomonda-Sigonda et al., 2018).

These positive narratives notwithstanding, studies of AMRH initiatives (Fig. 4) show that several barriers stand in the way of their effective operation. "Weak

and inefficient regulatory systems" and "differing regulatory processes" bar access, cause delays and allow falsified medicines to circulate (AU, 2022b). So far, a small number of NMRAs exercise legal jurisdiction to perform the tasks allotted to them (Ncube et al., 2021, p. 3). While the accelerated processing of applications for market authorisations has benefited community projects, "uneven levels of progress" have been recorded. East African Community (EAC) and ZaZiBoNa/SADC have emerged as the "frontrunners" of regulatory harmonization, while the "latecomer" ECOWAS has demonstrated slower progress, with Nigeria and Ghana attaining a more advanced status. While shorter dossier approval times were achieved with shared expert pools and higher quality levels with stringent assessment criteria, the lack of a centralised submission, a tracking mechanism and of joint jurisdiction has hampered West Africa's MRNA development (Owusu-Asante et al., 2022).

Figure 4
Regulatory harmonization initiatives in sub-Saharan Africa

Region	*MRNA*	*Member states*
East African Community (EAS)	2012	Burundi, the Democratic Republic of the Congo, Kenya, Rwanda, South-Sudan, Tanzania, Uganda
Southern African Development Community (SADC)	2015	Angola, Botswana, Lesotho, Malawi, Mozambique, Swaziland, United Republic of Tanzania, Zambia, Zimbabwe
Economic Community of West African States (ECOWAS)	2015	Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, The Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, Togo
Economic Community of Central African States (ECCAS)	2015	Angola, Burundi, Cameroon, Central African Republic, Chad, Republic of Congo, the Democratic Republic of the Congo, Equatorial Guinea, Gabon, Rwanda, São Tomé and Príncipe
Intergovernmental Authority on Development (IGAD)	2016	Djibouti, Ethiopia, Kenya, Somalia, Sudan, Uganda

Despite the East African Community's AMRH initiative being presented as a model venture, barriers subsist such as funding, fees charged for manufacturers in each MRNA, the lack of a binding framework for the recognition of assessments in each member state, the unequal progress of MRNAs in the region, differing assessment timelines, understaffing and high staff rotation. The thorny

question of the lack of sustained funding provided by member states for the AMRH initiative, necessitated the input of external multilateral funding whilst a fee-based system was being put in place (Mashingia et al., 2020, pp. 9-13). The continued lack of a "harmonized, transparent system with common requirements and standards" (Arik et al., 2020, p. 7), implies continued dependency on technical assistance from WHO and EMA to improve regulatory systems, regulatory expertise, and staff qualifications. EACs ambitions to move from a pilot programme to permanent institutions, and the establishment of its own regional medicines agency (Arik et al., 2020), is expected to further deepen its mid-term dependency on donor funding.

Overall, however, the East African Community's AMRH, the most integrated of the three RECs discussed here, serves as a benchmark for other initiatives, such as that of the SADC (Calder, 2016, pp. 31-32). The great diversity of national regulatory systems and asymmetry of resource capacities in the SADC – which contrast with greater similarities between EAC member states – constitute a serious challenge for closer cooperation. Also, harmonisation initiatives involving a substantial number of regional members (16 in SADC and 15 in ECOWAS) tend to be more demanding. Whereas a joint health policy framework (2000) has facilitated collaborations, several obstacles such as distinct regulatory systems, requirements, and provisions as well as distinct levels of human, technical and financial resources have hampered progress. Supranational initiatives by particular member states offer opportunities for developing closer regulatory cooperation, for example through the ZaZiBoNa (Zambia, Zimbabwe, Botswana, and Namibia) pilot project launched in 2013. Notwithstanding its operation in an advisory capacity without centralised procedural arrangements (Sithole et al., 2020), the projects' work-sharing has reduced approval times through timely setting of annual schedules for joint assessments (Ndomondo-Sigonda et al., 2023, p. 7), while centring on priority diseases and promoting joint inspections (Calder, 2016, p. 19). Benefiting from WHO-PQP support, over time, other SADC member states have joined the project, including South Africa, the Democratic Republic of Congo and Mozambique, whilst financial support has further diversified to include national and multilateral partners.

In the case of the SDAC-led AMRH initiative, other than varying legal frameworks, bureaucratic tangles, and the dearth of effective regional coordination, limited human resources, differing development levels, limited available expertise and varying review times have been signalled (Sithole et al., 2020). Distinct demographic, socio-economic and epidemiological country profiles can also impact differential NRAs decisions on medicinal products. Crucially, the depend-

ency upon external technical assistance, the lack of local expertise and funding problems have acted as barriers to the efficacy of the trans-national regulatory system. Despite its diversified financial resources, fees, country budget allocations and industry have – yet – to cover the initiative's costs without recourse to significant donor contributions. Besides cultural and linguistic differences, political complications posed by the safeguarding of national interests and health sovereignty have also played a role in slowing harmonisation processes (Calder, 2016, p. 45).

Conclusions

EU's ambitions to become a global health actor are relatively recent (Jørgensen & Schvartzman, 2016), whereas AU's focus on international partnerships and its assertive regionalism have typically been associated with a New or Post-Cold War setting with bio-securitarian (Badmus, 2015) and geopolitical dimensions (Fazal, 2020). WHO's legitimacy, somewhat tarnished by the initial phase of the COVID-19 pandemic as a global reference for health standards, regulation, and information, was instrumental in the process of multilateral capacity building programmes with EU support. The latter bolstered its international projection by connecting with global partnerships and their expertise in health diplomacy and governance beyond its borders. The outbreak of the COVID-19 pandemic constituted an opportunity for the EU to enhance its reputation as a global health player, launching various novel initiatives (Langan, 2022).

The 6th AU-EU Summit was presented as a significant step forward in the inter-regional relations between Africa and Europe, while upgrading the Joint Africa-EU Strategy (2007), from which health was conspicuously absent. Serving as a catalyst for 6th AU-EU Summit, the pandemic imprinted greater urgency upon EU's inter-regional health diplomacy, testing its capacity to respond to health crises. The different strands of EU-AU funding in health contained in five programmes (the Global Gateway Package, TEAM Europe, the Strengthening of Health Systems, the African Medicines Agency, and Vaccine Dose Sharing) represent a multilateral package deal destined to reinforce the AU and its institutions. Despite EU's lofty narratives on public health internationalism, its bloc protectionism and member countries' privileged relations with COVID-19 vaccine manufacturers, caused cracks to appear in the "gloss of harmony" embellishing the EU's "renewed partnership" with the AU. Insufficient attention has been paid to historical antecedents regarding disease control, public health and epi-pandemic responses, and the decolonisation of inter-regional relations. Thus,

unresolved tensions between bio-securitarian related, and public health and human rights dimensions inherited from the colonial era tend to be neglected in the literature. While the AMA treaty explicitly recognises its bio-securitarian and risk-management responsibility, it also emphasises a strong commitment to health as a human right.

The EU's declared and reiterated support for the establishment of the African Medicines Agency (AMA) forms a key pillar of the restyled AU-EU common agenda, for which EMA serves as a model and benchmark. EU universalism is reflected in AMA's structure, model law, coordination of regulatory procedures and standards, and oversight over NMRA networks. Inspired by WHO's role regarding the setting of global standards and development goals, EU's exporting of the flagship EMA model – which constitutes a global reference for authorisations – working through WHO and AUDA-NEPAD, constitutes a test-case for its capacity to leverage and shape regional African institutions. AMA's case suggests that the EU has succeeded in exercising significant leverage – together with its international partners – over its design and implementation within a donor-recipient relationship. Despite notions of "equality and shared ownership," the transposition of the exogenous "designed for purpose" EU organisational and business model to Africa heralds a rather dependent form of health sovereignty (Kell & Vines, 2020) for an "African-owned institution" (AU, 2022b, p. 9).

One of the major challenges in implementing this multilateral project is the tension between national and supranational goals and targets for regulatory control (Schrama, 2023). To attenuate potential barriers, AU's project expounding the notion of pan-African solidarity and cooperation attributed the coordination of these regulatory networks to five of Africa's regional economic communities (RECs). In sub-Saharan Africa, the Economic Community of West African States (ECOWAS), the East African Community (EAC), and the Southern African Development Community (SADC) exhibit distinct track records regarding the pace and depth of economic integration. Having developed separately from the OAU, they became building blocks of the AU. African countries' regional cooperation to contain the COVID-19 pandemic demonstrated their potential to manage health crises (Medinilla et al., 2022). However, RECs success as integrative agencies has been rather limited and fraught with obstacles. Given that some countries are members of more than one community, overlaps occur which complicate the coordination of regional policies and their outcomes (Nagar & Nganje, 2016).

AMRH reviews in the EAC, SADC and ECOWAS appear to suggest that despite (slow) progress, moving towards harmonisation may be too ambitious at

the present stage and that convergence should precede it (Calder, 2016, p. 65). Most NMRAs in Africa lack the capacity to effectively carry out their statutory regulatory responsibilities. The need for regulatory competence, the lack of human resources, the skills gap, high staff turnover, the inability to inspect manufacturers, the costs of regulation and donor dependent funding, as well as differentials in the comparative performance of NMRAs have been identified as barriers (Ncube et al., 2022; Ncube et al., 2023).

Despite – or maybe because of – the tutelage of AUDA-NEPAD and WHO, with EU support, significant aspects of local and regional diplomacy are obfuscated by positive metanarratives on AU-EU's renewed partnership. Given that a "one size fits all approach" is ill-fitted to achieve AMRH's goals (Ncube et al., 2023), the non-synchronous and diverse regional building blocks challenge AMA's imagined model playbook. In practice, EAC and ZaZiBoNa have emerged as home-grown models for other regions (Calder, 2016, pp. 50-52). While one of the "secrets" of EAC's success is that "each country brings different strengths to the regulatory harmonization process" (Ndomondo-Sigonda et al., 2023, p. 16), the endogenous dynamics of diplomatic culture underpinning intra-regional institutional reforms remain largely invisible (Anderson, 2018). More in-depth research is needed to better understand the role of African health agency in the less visible but particularly diverse dynamics shaping AMA's fragile building blocks beneath the gloss of (regulatory) harmonization.

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