THE FUTURE OF AFRICAN PHARMACEUTICAL MARKET HARMONIZATION: A COMPARED ANALYSIS BETWEEN THE EUROPEAN AND CHINESE APPROACH TO AFRICAN MEDICINES AGENCY ESTABLISHMENT

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Abstract

With the widening gap between medicines demand and local supply, the African medicines market currently presents relevant investment opportunities for foreign stakeholders. Its attractiveness is, however, challenged by some of Africa's endemic features, such as inadequate local health infrastructure, fragmented regulatory systems and the inability to handle direct aid from the international community. Against this backdrop, the ongoing harmonization process and the introduction of the African Medicines Agency in 2019 have been particularly welcomed and received international support, especially from China and the EU. This paper, after outlining the initiatives taken within the African harmonization process, takes a comparative look at the actions taken by China and the EU and attempts to indicate which initiatives have proved to be and will be most useful to AMA establishment and African regulatory stability in the prospect of investment attraction.[1]

Keywords.
AfCFTA, medicines, pharmaceutical market, economic integration, AMA, foreign investment

I. INTRODUCTION

Due to the continued growth of Africa's population, the recent rise of middle-class demanding quality healthcare, and the increased need for specialized treatments and therapies, the demand for medicines has been growing exponentially across the Continent. Nonetheless, the African medicines market remains outside the radar of foreign manufacturers and investors.

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1 We are grateful to Angelo Forte for the comments on the early drafts of the paper.

After first addressing the reasons behind the lack of investments in the sector, this paper will analyse the initiatives which have been taken to address market challenges and, in particular, the actions taken by China and the EU, attempting to indicate which initiatives have proved to be and are expected to be most beneficial to regulatory stability and the stabilization of the recently established African Medicines Agency (AMA).

II. OPPORTUNITIES AND CHALLENGES FOR FOREIGN INVESTORS IN THE AFRICAN MEDICINES SECTOR IN LIGHT OF THE REGULATORY HARMONIZATION PROCESS

Before delving into the details of the support provided by China and EU to the African regulatory harmonization process and – particularly – AMA's establishment (see Section III *infra*), this section will provide a wide-ranging overview of the current opportunities offered by the African medicines sector **(2.1.)** as well as the challenges likely to be faced by foreign investors when approaching the market **(2.2.),** and outline the initiatives adopted by African countries to harmonize the pharmaceutical regulatory framework, with reference, in particular, to AMA establishment in the attempt to make the market more attractive to investors **(2.3).**

A. Current opportunities for investment in the African medicines sector: a complex but emerging market

As Africa's population is expected to reach 2.5 billion by 2050,[2] the middle class is expanding across the Continent,[3] and the main burden of diseases in Africa is shifting from communicable to non-communicable diseases,[4] the demand for quality healthcare and specialized treatments and therapies is highly increasing, surpassing the inadequate local production.[5] As noted by a 2019 McKinsey report, only a handful

2 Andrew Stanley, *African Century*, 60 F&D 16 (2023), www.imf.org/en/Publications/fandd/issues. All links in this article are updated as of November 5, 2023.

3 United Nations Office of the Special Adviser on Africa, *Growing Middle Class and Import Substitution: Connecting the Dots to Unlock Made in Africa*, 2 Africa Dialogue Series 8 (2023), www.un.org/osaa/sites/www.un.org.osaa/files/ads2023_policy_brief_2.pdf.

4 Hebe N. Gouda, et al., *The Rising Burden of Non-Communicable Diseases in Sub-Saharan Africa*, (2019) 7 The Lancet Global Health e1375 (2019).

5 Yusuff A. Adebisi, et al., *Revisiting the Issue of Access to Medicines in Africa: Challenges and Recommendations*, (2022) 1 Public Health Challenges e9ff (2022). This is due to due to (i) the limited number of pharmaceutical industries, (ii) the insufficiency of upstream R&D, the production of excipients and active pharmaceutical ingredients, as well as (iii) the high costs of raw materials

of African-located manufacturers engage in drug production,[6] with their operations that, in most cases, fall short of meeting.[7] Moreover, only 3% of demand is met by intra-African trade, with a large share of medicines being supplied by international agencies.[8]

In light of the above, African governments have started considering medicine supply as a national security issue and have, therefore, taken steps towards sustainable, long-term market growth, coordinating their actions to harmonize the regulatory framework. Notable examples in this regard are the Africa Medicine Regulatory Harmonization (AMRH) initiative, the recent conclusion of the African Continental Free Trade Area (AfCFTA) agreement and the establishment of the African Medicines Agency (AMA). The efforts of African governments to harmonize the regulatory framework and the introduction of frictionless trade in Africa, which the pharmaceutical industry is likely to be among the prime beneficiaries of, are meant to attract foreign investors to fill the gap between local demand and medicines' local supply.[9]

B. Market challenges and disincentives to potential investment

Despite its potential attractiveness, foreign investors might find that the African pharmaceutical market is particularly complex to navigate due to some of its inherent features. One of the main challenges that investors may face when first entering and then operating within the African pharmaceutical market is the absence of regulatory predictability and uniform legislative and regulatory tools.[10] As market stakeholders are normally accustomed to dealing with well developed and sophisticated regulatory systems, dealing with a fragmented, non uniform and unstable regulatory system might represent a considerable challenge.[11]

6 Michael Conway, et al., *Should sub-Saharan Africa make its own drugs?*, McKinsey & Company (Jan. 10, 2019), https://www.mckinsey.com/industries/public-and-social-sector/our-insights/should-sub-saharan-africa-make-its-own-drugs. The report shows, in particular, that against a population of 1.3 billion, there are roughly 375 drug manufacturing industries across the Continent, mostly located in North Africa. In the sub Saharan area, drug manufacturers are largely clustered in a small number of countries (*i.e.,* Kenya, Ghana, Nigeria and South Africa), and with operations that do not meet international standards.

7 *Id.*

8 More specifically, against a pharmaceutical market estimated to be worth between USD 40 and 65 billion annually and projected to reach USD 56 billion to USD 70 billion by 2030, 60-90% of the total amount of packaged medicines is imported, while 36% is locally produced and not traded.

9 Landry Signé & Chido Munyati, *In Africa's Free Trade Area, Investment in Pharmaceuticals Means Impact and Profit*, The European Sting (Mar. 29, 2023), https://europeansting.com/2023/03/29/in-africas-free-trade-area-investment-in-pharmaceuticals-means-impact-and-profit/.

10 United Nations Office of the Special Adviser on Africa, *supra* note 3, at 7.

11 Yusuff A. Adebisi, et al., *supra* note 5, at 12.[12]In most sub-Saharan countries, pharmaceutical imports comprise as much as 70–90% of the total drugs consumed, indeed, there is only one small-scale manufacturer of active pharmaceutical ingredients located in Ghana. See Abigail A. Ekeigwe, *Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation*, 5 AAPS Open 1 (2019), https://doi.org/10.1186/s41120-019-0032-x.

A second element that may represent an important challenge for foreign investors and market stakeholders, in general, is the fact that raw materials and equipment needed for drug production are highly expensive in Africa, as they are mostly imported and are often of poor quality.[12]

Further elements to be taken into account as compromising the productivity of the African pharmaceutical market are the lack of investment in research and development and the fact that many international companies do not register patents in African jurisdictions, limiting to commercialise generic equivalents after the relevant patent have expired.[13]

Lastly, investors shall also take into consideration that the African pharmaceutical market is characterised by the presence of poor supply chain systems,[14] the absence of adequate infrastructure and low manufacturing capabilities.[15]

C. The harmonization of the pharmaceutical regulatory framework in Africa and the establishment of AMA

Every country needs a guaranteed supply of safe, effective, good quality and affordable medical products to promote public health and patient care. To achieve these goals, it is common to establish a National Medicines Regulatory Authority (NMRA) entrusted with providing adequate mechanisms to ensure the quality, safety, and efficacy of medical products throughout their product life cycle.[16]

12 In most sub-Saharan countries, pharmaceutical imports comprise as much as 70–90% of the total drugs consumed, indeed, there is only one small-scale manufacturer of active pharmaceutical ingredients located in Ghana. See Abigail A. Ekeigwe, *Drug manufacturing and access to medicines: the West African story. A literature review of challenges and proposed remediation*, 5 AAPS Open 1 (2019), https://doi.org/10.1186/s41120-019-0032-x.

13 William Fisher, Ruth L. Okediji & Padmashree Gehl Sampath, *Fostering Production of Pharmaceutical Products in Developing Countries*, 43(1) Mich. J. Int'l L., 21-24, 26-30 (2022), https://doi.org/10.36642/mjil.43.1.fostering.

14 Anna Schöpperle, *Analysis of challenges of medical supply chains in sub-Saharan Africa regarding inventory management and transport and distribution*, University of Westminster, London Westminster Business School 19-32, (2013), https://iaphl.org/wp-content/uploads/2016/05/Medical-Supply-Chain-Challenges.Masterthesis.ASchoepperle.pdf.

15 Stella C. E. Anyangwe & Chipayeni Mtonga, *Inequities in the Global Health Workforce: The Greatest Impediment to Health in Sub-Saharan Africa,* 4(2) International Journal of Environmental Research and Public Health 93-100 (2007), https://doi.org/10.3390/ijerph2007040002.

16 The most advanced NMRAs develop regulatory systems capable of correctly applying globally accepted standards while using good risk management approaches that ensure a level of control proportionate to risks to public health. To be considered robust and functional, good regulatory systems should have five main characteristics: they should be responsive, results-oriented, predictable, risk-proportionate and independent.

While African jurisdictions are not an exception to the foregoing rule,[17] it is worth noting that African NMRAs are usually afflicted by low effectiveness and efficacy standards.[18] In 2015, only 7% of African NMRAs had developed a moderate capacity to be functional and achieve their goals, whereas over 90% had minimal to no capacity due to the often limited resources.[19] Among African NMRAs, only Egypt, Ghana, Nigeria, South Africa and Tanzania have reached a level 3 maturity under the WHO Global Benchmarking Tool (GBT) – and not even for every product.[20]

In addition to the above, African NMRAs are further characterised by ineffective intra-continental collaboration,[21] which translates into sensibly different market approval and

17 All African countries, excluding the Sahrawi Republic, have an NMRA or an administrative unit conducting some or all expected NMRA functions.

18 On medicines sector regulation in Africa, see, among the others, Yusuff A. Adebisi, *supra* note 5; Sakhile Dube-Mwedzi, et al., *A Rapid Assessment of the National Regulatory Systems for Medical Products in the Southern African Development Community*, 13, 64 J of Pharm Policy and Pract (2020), https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00255-x; Sopein-Mann Oluwafunmike, et al., *Medicines Regulation in West Africa: Current State and Opportunities*, 11 BIRS Africa Technical Report Papers (2021), http://dx.doi.org/10.5703/1288284317443; Mark Ncube Bakani, Dube Admire & Kim Ward, *Establishment of the African Medicines Agency: Progress, Challenges and Regulatory Readiness* 14, 29 J of Pharm Policy and Pract (2021), https://doi.org/10.1186/s40545-020-00281-9; Iain Barton, et al., *Unintended Consequences and Hidden Obstacles in Medicine Access in Sub-Saharan Africa*, 7:342 Front. Public Health (2019), https://doi.org/10.3389%2Ffpubh.2019.00342; Margareth Ndomondo-Sigonda, et al., *National medicines regulatory authorities financial sustainability in the East African Community*, 15(7): e0236332 PLoS ONE (2020), https://doi.org/10.1371/journal.pone.0236332; Abbie Barry, et al., *Comparative Assessment of the National Pharmacovigilance Systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania*, 43 Drug Safety 339-350 (2020), https://doi.org/10.1007/s40264-019-00898-z; Naima Nasir, et al., *Medical device regulation and oversight in African countries: a scoping review of literature and development of a conceptual framework*, 8:e012308 BMJ Glob Health (2023), https://gh.bmj.com/content/8/8/e012308; Sarah Hubner, et al., *The evolving landscape of medical device regulation in East, Central, and Southern Africa*, 9(1) Glob Health Sci Pract. 136-148 (2021), https://doi.org/10.9745/ghsp-d-20-00578.

19 Mark Ncube Bakani, Dube Admire & Kim Ward, *supra* note 18, at 2.

20 The GBT is a global standard for objectively assessing regulatory capacity for medicines and vaccines. The standard provides for 4 maturity levels, the first as a lower level and the fourth as a higher and more mature level. At this stage, none of the African countries reached level 4. The WHO's list of NMRAs operating at levels 3 and 4 of maturity is available at https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4. On the subject, see Javier Guzman, et al., *The WHO Global Benchmarking Tool: a game changer for strengthening national regulatory capacity*, 5:e003181 BMJ Global Health, https://gh.bmj.com/content/5/8/e003181.citation-tools.

21 *Id* at 20. As to marketing authorization, the foregoing is a main issue for African Countries. Marketing authorization is an official document issued by a regulatory authority that allows a product to be marketed or distributed after it has been evaluated for safety, efficacy, and quality. The marketing authorization timeline is the period between when a medicines manufacturer submits a marketing authorization application and when a regulatory authority issues its decision. In some areas of the world, medicines manufacturers can submit a single marketing authorization application to an organization that has the ability to grant marketing authorization for a large number of countries. For example, a manufacturer that submits an application to the European Medicines Agency (EMA) can obtain marketing authorization for a large number of European countries. However, it is more typical for a manufacturer to have to submit individual applications to the NMRA for each country they would like to market or distribute their product in. This process, which often involves preparing an extensive application specific to the country, paying a fee to the country's NMRA, and engaging in back and forth with the NMRA to answer

supervising/regulatory frameworks among African countries, including neighbouring ones and members of the same Regional Economic Communities (RECs).[22]

The main consequence of this fragmentation is a lack of substantial intra-continental trade flows and, hence, African countries' failure to create regional or sub-regional economies of scale.

i. Regulatory Harmonization Initiatives

Since the 2000s, in order to address the latter issues, several initiatives have been put forward in the African context to attract both direct and indirect foreign investment, create economies of scale and build a harmonized and robust regulatory framework, often looking at non-African experiences – such as the European one.

The first major initiative on medicine sector improvement is the African Union's (AU) Pharmaceutical Manufacturing Plan for Africa (PMPA), which still constitutes the ground for most of the supranational initiatives put forward by African countries and organizations in the years to now. The action is aimed at building a strategic map of the goals and technical solutions to improve the African pharmaceutical market while contributing to the Universal Health Coverage, AU Agenda 2063, and Sustainable Development Goals (SDG) targets.[23]

questions, may take years. In addition, manufacturers may have little incentive to submit applications to countries that they feel do not represent lucrative markets. As a result, after a novel medicine is approved for the first time, usually in a high-income country such as the United States, it takes an average of 4 to 7 years for that medicine to be approved in sub-Saharan African countries. See, on the topic, Vincent Ahonkhai, et al., *Speeding access to vaccines and medicines in low- and middle-income countries: A case for change and a framework for optimized product market authorization*, 11(11):e0166515 PLoS One, https://doi.org/10.1371/journal.pone.0166515.

22 RECs are sub-regional grouping of African countries construed with the aim of achieving greater economic integration. They are the building blocks of both the African Union and the New Partnership for Africa's Development, having also a relevant role within the new African Continental Free Trade Area. The following separate regional communities constituted based on international treaties are currently operational: Arab Maghreb Union (AMU), Common Market for Eastern and Southern Africa (COMESA), Community of Sahel-Saharan States (CEN-SAD), East African Community (EAC), Economic Community of Central African States (ECCAS), Economic Community of West African States (ECOWAS), Intergovernmental Authority on Development (IGAD), and the Southern African Development Community (SADC). The foregoing are the RECS acknowledged by the African Union. It should be noted that other regional integration treaties are operating in the African context, such as the Union Economique Et Monétaire Ouest-Africaine (UEMOA).

23 The challenges considered within the PMPA include: "*1) access to affordable financing, 2) access to technology and technical know-how, 3) inadequate human resource capacity, 4) small fragmented markets and poor market intelligence, 5) fragmented and weak regulatory systems, 6) fragmented and poor procurement and supply chain systems, 7) policy incoherencies across trade, industry, health, and finance, 8) poor business to business linkages and collaboration, 9) low investments in research and development as well as intellectual property*". In this regard, see Janet Byaruhanga, *The Pharmaceutical Manufacturing Plan for Africa*, Nepad (Aug. 24, 2020), https://www.nepad.org/news/pharmaceutical-manufacturing-plan-africa. See also: African Union, *Pharmaceutical Manufacturing Plan for Africa – Business Plan* 18 (2012), https://au.int/sites/default/files/pages/32895-file-pmpa_business_plan.pdf.

The African Medicines Regulatory Harmonization Initiative (AMRH) was established in 2009 as part of the PMPA initiative. Specifically, the AMRH is a response to many challenges faced by NMRAs in Africa,[24] and its main aim is to provide an enabling environment by establishing a harmonized regulatory framework, reducing duplication of efforts and speeding up the registration process for medicines. To achieve its aim, the AMRH – working through RECs[25] and, particularly, the activities of expert working groups, technical working groups,[26] and steering committees at regional levels – focuses on four specific areas: (i) harmonizing policies and regulatory frameworks; (ii) enhancing human and institutional capacity for regulation of medical products and technologies; (iii) facilitating and coordinating research and knowledge management on medicines regulation at country, regional and continental levels; and (iv) coordination of regulatory activities with the African Medicines Agency (AMA).[27]

Following the establishment of AMRH in 2009, in 2016, the AU Heads of State and Governments endorsed the AU Model Law on Medical Products Regulation.[28] The Regulation provides a template for African countries to harmonize their regulatory frameworks, and it outlines the key functions and standards that should form part

24 As mentioned, these challenges include, among others, weak or inconsistent legislative frameworks (which creates technical barriers to the pharmaceutical trade), sluggish medicine registration processes and subsequent delayed approval decisions, inefficiency and limited technical capacity, patients' poor access to priority essential medicines and excessive medicines prices. These circumstances are exacerbated by African NMRAs operating independently, with limited capacity and resources.

25 The AMRH Initiative has so far been implemented in 5 RECs namely, EAC, SADC, ECOWAS, ECCAS and IGAD. At the higher level, the African Medicines Regulators Conference serves as the AMRH Assembly and provides a platform for sharing best practices on regulatory matters and a mechanism for generating technical information to guide AU decision-making processes

26 The AMRH has ten technical committees. They include the African Medicines Quality Forum on quality assurance and post marketing surveillance; the African Medical Devices Forum; the African Vaccines and the African Vaccines regulatory Forum for clinical trials and ethics oversight; Pharmacovigilance; the African Blood Regulators Forum; Medicines Policy and Regulatory Reforms; Regulatory Capacity Development and Good Manufacturing Practice; Registration and Marketing Authorisation and Information Management System

27 For an overview of the results obtained by the AMRH, see: African Medicines Agency, *Ama Infographics*, Nepad, https://www.nepad.org/publication/ama-inforaphics. In the mentioned recent study: Margareth Ndomondo-Sigonda, et al., *supra* note 18, issued on the topic of the implementation of the AMHR initiative, the following major themes emerge with reference to criticalities and best practices in the market: 1. Transparency and reliability are critical; 2. Reliance is essential for smart regulation; 3. Multiple successful strategies for NMRA capacity building have been identified; 4. Communication between heads of agencies is essential; 5. Cooperation at the regional level is not possible without leadership at the NMRA level; 6. Sustainable funding remains challenging; and 7. Industry has important insights. With regard to the RECs, their main aim is to support a regulatory workforce that enhances human and institutional capacity and contributes to improved healthcare delivery, regulatory standards, and practices in Africa. See: Nepad, *Understanding the role of Regional Centres of Regulatory Excellence in strengthening medicines regulation in Africa*, Path (Nov. 2016), https://www.path.org/resources/understanding-the-role-of-regional-centres-of-regulatory-excellence-in-strengthening-medicines-regulation-in-africa/.

28 African Union, *African Union Model Law on Medical Products Regulation*, https://kyokuhp.ncgm.go.jp/library/regulation/PDF_JPG/AUmodellaw_e.pdf.

of the regulatory system.[29] Through the process of AU Model Law domestication, African countries can either adopt the model law as is or adapt it so that it is consistent with their constitutional principles and legal system, as well as amend or repeal any inconsistent national laws.[3031]

More significant steps in terms of harmonization were, however, taken in 2019 with the establishment of AfCFTA.[32]

The AfCFTA agreement was indeed entered into force on 30 May 2019, establishing the world's largest (by number of members) free trade area, bringing together the countries of the AU and the 8 RECS for the creation of a unified market of 1.3 billion people and pursuing the goal of increased intra-African trade, including of pharmaceutical products.[33] The agreement aims, in particular, to create a liberalized market for goods and services in the African continent, deepen its economic integration, enhance the competitiveness of member states' economies, and lay down the foundations for the establishment of a Continental Customs Union.

AfCFTA is expected to have a relevant impact on the economy and development of the Continent. More specifically, AfCFTA might greatly impact the pharmaceutical sector by addressing the challenge of small and fragmented markets in order to create a positive cycle of increased regional manufacturing, research and local talent.[34] In this

29 Mark Ncube Bakani, Dube Admire & Kim Ward, *supra* note 18, at 2. The AUDA-NEPAD is coordinating capacity-building and providing technical assistance to enable countries to review their legislation in place on medical products regulation in order to align them with the AU Model Law. The respective RECs are actively involved in facilitating this process. See, on the topic: Noxolo Luthuli & Wilberto Robles**, *Africa Medicines Regulatory Harmonization Initiatives*'**, Wcg 12 *(Apr. 18, 2017)* https://catalystglobal.org/wp-content/uploads/2022/01/White-Paper-on-Africa-Harmonization-Initiatives-FINAL-041817-1.pdf.

30 Auda-Nepad, *A Guidance Document for Domestication of the African Union Model Law on Medical Products Regulation*, 10 (2020), https://www.nepad.org/publication/guidance-document-domestication-of-african-union-model-law-medical-products.

31 Despite the fact that the goal set of 25 countries domesticating the Model Law by 2020 was not reached, several African countries did manage to adopt or adapt the model by the target date, potentially offering lessons and best (worst) practices that can be emulated (or avoided) when revising national medicines regulatory systems. However, there is still a need to understand the current status of AU Model Law domestication and implementation in order to provide a foundation for identifying the existing gaps and opportunities for improving the regulation of medical products in Africa, public health protection and promotion, and pharmaceutical industry advancement on the Continent. See: Mark Ncube Bakani, Dube Admire & Kim Ward, *supra* note 18, at 12.

32 African Union, *Agreement Establishing the African Continental Free Trade Area*, (2019), available at https://au.int/en/treaties/agreement-establishing-african-continental-free-trade-area. The AfCFTA is one of the flagship projects of "AU Agenda 2063: The Africa We Want". The scope it is to create a comprehensive economic integration within the entire African region. See: African Union, *Agenda 2063: The Africa We Want*, https://au.int/en/agenda2063/overview.

33 As of 6 November 2023, the AfCFTA has been signed by 54 AU Member states, and ratified by 46 states.

regard, a continental market could sustain greater economies of scale, which will help businesses achieve higher production volumes. Regional markets may further allow for specialization, which ultimately could enable regional procurement markets that are beneficial for investors.[35]

ii. The African Medicines Agency (AMA)

In addition to the above-described initiatives, the establishment of AMA certainly stands out as a potential game-changer for an improved pharmaceutical ecosystem in Africa, also in terms of foreign investment attraction.

With AMRH paving the way for the treaty establishing AMA, the relevant AMA treaty was signed in 2019 and entered into force on 5 November 2021, following the receipt of the 15th instrument of ratification[37]

The need for an AMA-like institution was already expressed in the African Health Strategy (AHS) 2016–2030,[38] where the importance of an African regulatory mechanism for medicines and medical products was highlighted to ensure, in compliance with the concept of UHC developed by the WHO, that people must have access to high-quality essential health services, secure, reliable, and affordable essential medicines, and vaccines, as well as financial security.[39] Following the Covid-19 pandemic, the AMA was hailed as a key tool for enhancing regulatory oversight of medicines and vaccines across the continent's 54 countries.[40] Indeed, the pandemic highlighted the

34 According to Landry Signé & Chido Munyati, *supra* note 9, at 14, the pharmaceutical industry is likely to be among the prime beneficiaries of the introduction of frictionless trade in Africa.

35 Stella C. E. Anyangwe & Chipayeni Mtonga, *supra* note 15. See also Alison Buckholtz, *Why Pharma Investors Are Looking at Africa "with New Eyes"*, International Finance Corporation (Jun. 2021), https://www.ifc.org/en/stories/2021/pharma-investors-looking-at-africa-with-new-eyes-en.

36 Blaise Mwizerwa Nkubito & Yves Geysels, *The African Medicines Agency: Impacts on the Continent's Clinical Trials Regulation*, Applied Clinical Trials (Jun. 20, 2023), https://www.appliedclinicaltrialsonline.com/view/the-african-medicines-agency-impacts-on-the-continent-s-clinical-trials-regulation.

37 As of September 2023, 32 countries have signed the AMA treaty, 21 countries have ratified and deposited. Among the countries that have not ratified the instrument there are both Nigeria and South Africa. As to the further milestone of the initiative, in April 2021, the AU has appointed Michel Sidibé, former Executive Director of UNAIDS and former Malian Minister of Health, as its special envoy for the establishment of the AMA. In July 2022, the AU Council voted Rwanda as the host of its future headquarters.

38 African Union, Department of Social Affairs, *Africa Health Strategy 2016 – 2030* at 26, https://au.int/sites/default/files/documents/24098-au_ahs_strategy_clean.pdf.

39 Universal health coverage (UHC) is a concept developed within the World Health Organization and it is one of the objectives to be reached within the Sustainable Development Goals. UHC means that all people should have access to the full range of quality health services they need, when and where they need them, without financial hardship. See, on the subject: World Health Organization, *Universal health coverage (UHC)*, Who (Oct. 5, 2023), https://www.who.int/news-room/fact-sheets/detail/universal-health-coverage-(uhc).

need for a regulatory body such as the AMA to fill gaps and correct inconsistencies in the current complex patchwork of regulations, initiatives, and competencies.[41]

The aim of AMA, which qualifies as a specialized agency of the AU, is to promote the adoption and harmonization of medical products' regulatory policies and standards, as well as provide scientific guidelines and coordinate existing regulatory harmonization efforts in the African Union with the ultimate purpose of improving access to safe, effective, affordable, and qualitative medical products across African countries. AMA also aims to develop common standards and regulations, coordinate reviews of clinical trial applications, evaluate medical products and pharmaceutical ingredient manufacturing sites, and share information about products authorized for marketing. Aligning technical requirements for developing and marketing medicines across the countries has the potential of building a unified regulatory framework and developing regulatory competence, strengthening governance, and building collaboration, emphasizing continual improvement and transparency. The agency's action is supposed to focus on coordinating and strengthening medicine regulatory harmonization initiatives across the continent, examining regional policies, finding new financing sources, and making an effort to simplify the complex requirements from regional and international standards and recommendations.[42]

The core idea behind the AMA treaty is that – if adequately implemented - it could catalyse all the different initiatives undertaken to date but also create a positive cycle through which AMA will be able to foster the growth of domestic production as well as facilitate trade across the Continent and also accelerate the entry of new products into the healthcare system, the decrease of costs of medicines, the increase of access to medicines, and the expulsion of fake, substandard, and harmful products out of the market. This all happens in a historical moment where all data suggest that over the next five years, Africa's healthcare sector, especially local pharmaceutical production, will be a critical economic driver for the whole region.[43]

As a potential game-changer among all harmonization initiatives, AMA has also received broad (direct and indirect) international support from the EU and China.

In the following Sections, we will analyse the action and the approach taken by the EU and China in this regard and will attempt to indicate, as a result of a comparative

40 Paul Adepoju, *Ratification of Africa Medicines Agency Treaty Inches Forward—Africa CDC Head Calls It 'Much-Needed'*, Health Policy Watch (Oct. 16, 2020), https://healthpolicy-watch.news/ratification-of-africa-medicines-agency-treaty-inches-forward-africa-cdc-head-calls-it-much-needed/.

41 Blaise Mwizerwa Nkubito & Yves Geysels, *supra* note 36.

assessment, which initiatives are more likely to provide the best outcome for AMA establishment and regulatory stability in general.

III. ANALYSING EU AND CHINA'S APPROACH AND INITIATIVES TOWARDS AMA AND REGULATORY STABILITY IN AFRICA: A COMPARATIVE ASSESSMENT

The EU and China are both active in Africa, with different approaches and different historical ties. Over the last decades, while the relationship between the EU and Africa has focused more on the development of aid and cooperation in governance, as well as sustainable development and trade, through various economic partnership agreements, the Chinese engagement in the Continent has been driven primarily by resource extraction and infrastructure investment.

In terms of investment, while on a global scale, China outpaces the EU for overseas investments,[44] when focusing on Africa - particularly Sub-Saharan Africa - the situation becomes less straightforward. China has entered into agreements totalling over $ 303 billion in investments and construction contracts between 2006 and 2020. From this standpoint, the EU's commitment of Euro 150 billion within a span of just five years holds considerable weight.

A. The European Union and Global Health Collaboration with Africa

The Africa – EU Partnership is guided by the dialogue between the EU and the African Union, in which also non-state and civil society actors, societies, bodies, companies and organizations taking part into. The institutional forum where strategies and cooperation mechanisms are developed is the Africa – EU Summit, in the context of which EU and AU's heads of state and governments meet – usually every three years – to provide political guidance for further work.

On the occasion of the 6th EU – AU Summit, which took place at the beginning of last year and where EU and AU leaders agreed upon a joint vision for a renewed partnership, the EU and the AU also committed to supporting "the full-fledged African health sovereignty, in order for the continent to respond to future public health emergencies" through "a common agenda for manufacturing vaccines, medicines, diagnostics,

42 Molly Unoh Ogbodum, et al., *African Medicines Agency: How it will change the landscape of medicines in Africa*, 2:e96 Public Health Chall. 3 (2023), https://doi.org/10.1002/puh2.96.
43 Yusuff A. Adebisi, et al., *supra* note 5.
44 China has mobilized over two trillion dollars for almost four thousand investment and construction

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".[45]

These declarations of intent fall within the scope of the EU global health strategy[46] and, more specifically, the EU intervention policy in support of the African health sector that has already been in place for some years.

Such intervention has been developed along three lines, i.e. harmonization of the regulatory framework, support of the resilient local health systems and development of local manufacturing hubs.[47]

The above investments are consistent with the Global Gateway Africa-Europe Investment Package, which was regarded as one of the key deliverables of the 6th EU – AU Summit[48] and which constitutes the regional implementation of the EU's Global Gateway Investment Strategy.[49]

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projects abroad since 2005. See: Emilie Bel, *The EU global investment initiative that could close Africa's infrastructure gap*, Atlantic Council (May 5, 2023), https://www.atlanticcouncil.org/blogs/africasource/the-eu-global-investment-initiative-that-could-close-africas-infrastructure-gap/.

45 Press release, European Council, *Sixth European Union - African Union Summit: A Joint Vision for 2030*, (Feb. 18, 2020), https://www.consilium.europa.eu/en/press/press-releases/2022/02/18/sixth-european-union-african-union-summit-a-joint-vision-for-2030/.

46 The EU global health strategy has the overarching goal of improving global health security and ensuring better health for all. It was first adopted in 2010, and it was lastly updated in November 2022. See: European Commission - Directorate-General for Health and Food Safety - Directorate-General for International Partnerships, *EU Global Health Strategy - Better Health For All in a Changing World*, (Nov. 30, 2022), https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en#details. See also: Gabija Leclerc, *New EU global health strategy, a recalibrated agenda*, European Parliamentary Research Service, (Jan. 2023), https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/739306/EPRS_BRI(2023)739306_EN.pdf.

47 To achieve the latter, the EU has provided/supported the development of the following investment package: A mobilisation of more than 100 million euros by the European Commission, the EMA, EU Member States — Belgium, France and Germany — and the Bill & Melinda Gates Foundation (BMGF) by 2027 to support the recently established AMA and other African medicines regulatory initiatives at regional and national levels, with the declared purpose of strengthening regulatory capacity; A mobilisation of 1 billion euros by the WHO and the European Investment Bank (EIB), in close cooperation with the European Commission (EC) and the African Union, with the aim of supporting health systems strengthening in Africa with a focus on Primary Health Care (PHC). See: Joint Statement, World Health Organization & European Investment Bank, *EIB pledges 500 million euro under a partnership launched by WHO and the EIB, with the support of the EU, for stronger and more resilient health systems in Africa*, (Feb. 17, 2022), https://cdn.who.int/media/docs/default-source/primary-health-care-conference/who-eib-joint-declaration-17february2022.pdf?sfvrsn=27ba7b9b_5. As to the 134 milion euros funds, this mobilisation was announced at the Global Gateway Forum which took place in Brussels on 26 October 2023. See: Press release, European Commission, *Global Gateway: EU steps up support for global health and equitable access to health products and local manufacturing, (*Oct. 26, 2023), https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5278.

48 European Commission - Directorate-General for Health and Food Safety - Directorate-General for International Partnerships, *supra* note 46.

The Africa-Europe Investment Package is an investment strategy/plan of at least Euro 150 billion, which aims to support Africa for a strong, inclusive, green and digital recovery and is composed of an Investment, a Health and an Education section.[50] To implement the Package, EU and AU have agreed upon the following tools: (i) leverage of public funds to stimulate private investments; (ii) promote accountable, transparent, inclusive and responsive governance to boost efforts towards improving investment and the business climate as well as towards unlocking and increasing responsible and sustainable African and European investments; (iii) use of Official Development Assistance and financial tools such as infrastructure trusts and capital market instruments; (iv) support and partnership from international and national financing development institutions, including the European Investment Bank, the African Development Bank, and public/private partnerships; (v) boost regional and continental economic integration, particularly through the African Continental Free Trade Area.[51]

All the above actions have been carried out and will be implemented with a "Team Europe" approach, meaning with the involvement of the European Union, EU Member States — including their implementing agencies and public development banks — as well as the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). Among the Team Europe Initiatives relevant to our research, the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV +) must be mentioned.

The MAV+ initiative was first launched by the European Commission in May 2021 to respond to the call of African leaders asking for help with local manufacturing of vaccines in Africa, along with the Partnerships for African Vaccine Manufacturing launched by the African Union.[52] The initiative has the objective of offering "a

49 Global Gateway is the European strategy to boost smart, clean and secure connections in digital, energy and transport sectors, and to strengthen health, education and research systems across the world. Global Gateway aims to mobilise up to €300 billion in investments and operates through a 'Team Europe approach', meaning that it will bring together the EU, its Member States and their financial and development institutions to mobilise the private sector to leverage investments.

50 European Commission, *EU-Africa: Global Gateway Investment Package*, https://international-partnerships.ec.europa.eu/policies/global-gateway/initiatives-region/initiatives-sub-saharan-africa/eu-africa-global-gateway-investment-package_en#strengthening-health-and-pharmaceutical-systems.

51 European Commission - Directorate-General for Health and Food Safety - Directorate-General for International Partnerships, *supra* note 46.

52 MAV+ is an initiative adopted as part of the "Team Europe approach", *i.e.* as part of a coordinated action taken by the European Union, EU Member States — including their implementing agencies and public development banks — as well as the European Investment Bank (EIB) and the European Bank for Reconstruction and Development (EBRD). See: Press release, European Council, *supra* note 45;

comprehensive, 360-degree approach to tackle barriers on both supply and demand sides" by "creating an enabling environment for sustainable local manufacturing in Africa through 3 dimensions: the supply side, the demand side and the enabling environment".[53]

In synthesis, the initiative, revolving around three key dimensions (supply side, demand side and enabling environment), is aimed at incentivising, both at the national and regional level, investments into local pharmaceutical companies, facilitating market integration and supporting local agencies (such as the recently established AMA) by helping them fighting, also with EMA's help, counterfeit product and increasing trust in local production.

In alignment with the EU pharmaceutical strategy, MAV+ has already approved and put under implementation the allocation of EUR 1.114.000.000, encompassing both loans and other financial instruments from European Development Financial Institutions (EDFIs) as well as grants, budget support and blended finance.

At a continental level, the funding has been directed toward strengthening the regulatory framework and the stabilization of the AMA's action across the continent, the WHO's mRNA technology transfer hub, and the PAVM,[54] hosted by the Africa Centres for Disease Control and Prevention (ACDC).

The Africa-EU Partnership focuses primarily on cooperation at a continental level and specifically on the relationship between the European and African Unions. As such, it complements the EU's existing frameworks at a national level. For example, at the country level, the EU support packages are contributing to the MADIBA project led by Institut Pasteur in Senegal and local production in South Africa while also enabling the right ecosystem for investments in Rwanda and Ghana.

Press release, European Commission, *€1 billion Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa,* (May 21, 2021), https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594.

53 European Commission, *Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa*, https://international-partnerships.ec.europa.eu/policies/team-europe-initiatives/team-europe-initiative-manufacturing-and-access-vaccines-medicines-and-health-technologies-africa_en#initial-results.

B. China and the implementation of Africa's Health Diplomacy

China and African countries have a long history of cooperation in the healthcare sector.[55]

Chinese engagement in African healthcare dates back to the 1960s when China started to send medical teams[56] to Africa to provide direct care, build local capacity, train personnel, and construct hospitals.[57] Since then, China's health diplomacy towards Africa has experienced periods of contraction (1980s-1990s) and expansion (since the 2000s). Since the first Forum on China-Africa Cooperation in 2000, China's relations with Africa in every field, including health, have expanded noteworthy.[58] Indeed, China's direct investment into Africa increased from $75 million in 2003 to $5 billion in 2021;[59] moreover, it must be underlined that the investment level increased to $4.2 billion despite the COVID-19 pandemic. As it has been the case for the EU – Africa relationship, the adversities of endemic COVID-19 have provided an opportunity to build upon these and strengthen these ties.[60]

It is worth noting that these relations quickly became a starting gate for commercial activities, with China hoping to expand trade and investment activities on the continent. Hospital construction, supply procurement, drug distribution and production, and other health-related projects in Africa became more and more linked to commercial projects – rather than being merely grant-based. Indeed, aid remained a very small percentage of China's engagement with Africa ($3.3 billion in 2018 – $28 billion 2008-2018) if compared to loans ($16 billion in 2017, down sharply from $29 billion in 2016 – $136 billion 2007-2017) and trade ($185 billion in 2018 – $1.657 billion 2008-2018).[61]

54 The major objective of PAVM, which has been adopted in 2021, is to scale up local vaccine manufacturing capacities and meet at least 60% of local demand by 2040, especially regarding: (i) legacy diseases, (ii) expanding diseases, and (iii) outbreak diseases.

55 Daniel Large, *As the beginning ends: China's return to Africa*, in African Perspectives on China (Firoze and Marks & Stephen eds., 2007).

56 Sending medical teams abroad has traditionally been the most visible part of the PRC's health diplomacy. In 2006, then Chinese Communist Party (CCP) General Secretary Hu Jintao underlined that, of all cooperation projects with countries in Africa, sending medical personnel "*has the longest history, involves the largest number of countries, and is the most successful*". See: Yanzhong Huang, *Pursuing Health as Foreign Policy: The Case of China*, 17(1) Indiana Journal of Global Legal Studies 105–146 (2010), https://www.repository.law.indiana.edu/ijgls/vol17/iss1/6/.

57 Maddalena Procopio, *China's Health Diplomacy in Africa: Pitfalls Behind the Leading Role*, Ispi Online (Apr. 7, 2020), https://www.ispionline.it/en/publication/chinas-health-diplomacy-africa-pitfalls-behind-leading-role-25694.

58 *Id.*

59 China Africa Research Initiative, *Data: Chinese Investment in Africa*, https://www.sais-cari.org/chinese-

With reference to the healthcare sector, Chinese Diplomacy has been mainly implemented through the Forum on China-Africa Cooperation (FOCAC), which was established in 2000 as a partnership platform between China and 53 African states, creating a form of multilateralism in which all countries are equal partners.[62]

Following an initial phase where FOCAC primarily concentrated on enhancing trade engagement, China progressively broadened the economic collaboration within the partnership. From 2006, it extended beyond trade to include foreign aid, direct investment, development finance, and, since 2013, the construction of continental-scale infrastructure under the Belt and Road Initiative.[63] In 2007, the China-Africa Development Fund was established,[64] boosting China's foreign direct investment (FDI) across Africa.

Investment in health is an essential component of the FOCAC. Since its establishment in 2000, each FOCAC summit has launched several initiatives to strengthen health cooperation, mainly implemented with bilateral partnerships. For example, in the 2018 Forum, China pledged to build on previous commitments to improve health care on the continent, including promises to upgrade medical facilities, invest in the Africa Centres for Disease Control and Prevention (Africa CDC), and train medical specialists.[65] In general, FOCAC initiatives have been developed alongside the following directives:[66]

- Sending medical teams and short-term expert groups to Africa;
- Building medical infrastructure in Africa;
- Providing medical supplies;
- Training medical specialists;

investment-in-africa.

60 Maddalena Procopio, *supra* note 57.

61 Id.

62 Shirley Ze Yu, *What is FOCAC? Three stages in the new China-Africa relationship*, Africa at LSE (Feb. 3, 2022), https://blogs.lse.ac.uk/africaatlse/2022/02/03/what-is-focac-three-stages-the-new-china-africa-relationship-trade-economics/.

63 The Belt and Road Initiative (BRI) is a global infrastructure development strategy proposed by China in 2013 to promote economic cooperation and connectivity between China and the world, with investments in more than 150 countries. The 'Belt' refers to a network of overland transportation connecting China with Europe, and the 'Road' refers to a sea-based network of shipping lanes and ports connecting China, Africa, and Europe.

64 It is China's first equity fund focusing on investment in Africa, aiming at boosting Africa's industrialization process and enhancing Africa's sustainable development capacity through investment. CADFund was officially launched in June 2007 and undertaken by China Development Bank (CDB). With a capital amount of 10 billion US dollars, CADFund is headquartered in Beijing and has five representative offices in South Africa, Ethiopia, Zambia, Ghana and Kenya.

65 Andrew Green, *Forum on China-Africa Cooperation: what it means for health*, 392 The Lancet 998-999

- Helping strengthen Africa's public health system against the threat of infectious diseases
- Encouraging Chinese pharmaceutical enterprises to invest and produce in Africa for larger capacity and more cooperation.[67]

It is worth specifying that the commitments and initiatives agreed upon within FOCAC, which are then implemented in subsequent bilateral partnerships, are the result of broader investment strategies, such as - in the Chinese case - the Belt and Road Initiative (BRI) and the Health Silk Road (HSR).

Particularly, the HSR has brought a change in China's approach to investments also in the healthcare sector, which in its traditional form was linked to conventional infrastructure projects (e.g., hospitals, hardware facilities) and significant state-level engagement such as unilateral government aid, which has continued till today, especially in the fight against COVID-19.[68] The HSR brought two major changes to the old BRI: the shift to service-oriented and high-tech sectors and the increasing participation of private-owned enterprises.[69]

This last point is also reflected in the last FOCAC, held in 2021 in Senegal, where many observers correctly underlined that Chinese commitments paled compared to previous rounds. This was due to China's first-time decision to decrease its state capacity as a direct financier for African projects. The State was, however, replaced by Chinese private companies, who positioned themselves to take a leading role in future economic engagements, given that China pledged that the private sector would invest $10 billion in Africa in the following three years. In any event, China still deepened its commitment as Africa's public goods provider. It promised 1 billion doses of COVID vaccines, of which 600 million would be gifted and 400 million produced by Chinese companies and joint ventures on the continent. China promised to send 1,500 medical and public health professionals to support the pandemic recovery.[70]

(2018), https://doi.org/10.1016/S0140-6736(18)32285-2.

66 Zeng Aiping, China-Africa Health Silk Road: Practices, Challenges and Solutions, 87 China Int'l Stud. 114-118 (2021).

67 Examples of Chinese healthcare investment initiatives in specific African countries since 2000 can be found here: Olivia J. Killeen, et al., *Chinese Global Health Diplomacy in Africa: Opportunities and Challenges*, 12(2) Glob Health Gov. 25-29 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6447313/.

68 Nader Habibi & Hans Yue Zhu, T*he Health Silk Road as a New Direction in China's Belt and Road Strategy in Africa*, 1(2021) GDS Working Paper Series 4-8 (2021), https://heller.brandeis.edu/gds/pdfs/working-papers/china-africa-2021.pdf.

In conclusion, it is possible to identify some common elements with respect to China's approach to healthcare investment in Africa.

Firstly, the Chinese investment focus is not 'institutional' but operational. Between 2000 and 2017, China funded 1339 health-related aid projects. According to the OECD framework, the priority focus areas of these projects were medical services, such as specialty equipment and tertiary services (n=489, 37%); basic health care, such as basic medical services and drugs (n=251, 19%); malaria control (n=234, 18%) and basic health infrastructure (n=178, 13%).[71] Indeed, only the Forum on China-Africa Cooperation Dakar Action Plan (2022-2024) of FOCAC 2021 makes reference to the regulatory harmonization process of the African continent, stating that "China will help accelerate the establishment of the African Medicines Agency (AMA) and support the African Medicines Regulation and Harmonization (AMRH) program to improve the effectiveness of the medical products regulatory systems".[72]

Secondly, China has a predominantly bilaterally-oriented health diplomacy, through which it implements, among others, FOCAC's commitments and BRI – HSR strategies.[73]

Moreover, unlike financial assistance from Western countries and from the EU, Chinese aid is distributed without political conditions.[74] The only condition attached to the aid is that usually, about 70% of each project financed is contracted to Chinese enterprises that use a workforce composed of Chinese labourers brought directly from China. The remaining 30% of the value of each project is normally assigned to companies which are joint ventures between Chinese and local African enterprises.[75]

69 *Id.*

70 Shirley Ze Yu, *What is FOCAC? Three stages in the new China-Africa relationship*, Africa at LSE (Feb. 3, 2022), https://blogs.lse.ac.uk/africaatlse/2022/02/03/what-is-focac-three-stages-the-new-china-africa-relationship-trade-economics/.

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73 Andrew Green, *Forum on China-Africa Cooperation: what it means for health*, 392 The Lancet 998-999 (2018), https://doi.org/10.1016/S0140-6736(18)32285-2.

74 Zeng Aiping, China-Africa Health Silk Road: Practices, Challenges and Solutions, 87 China Int'l Stud. 114-118 (2021).

Lastly, China has a horizontal approach in its health assistance to African nations,[76] which aims to improve the health of populations through comprehensive initiatives targeting the underlying societal-level issues and systems contributing to health. While horizontal health assistance can have greater long-term impacts on the public's health, it can be difficult to measure the short-term impact of preventative systems and upstream determinants of health.[77]

IV. IMPACT OF EU AND CHINA'S APPROACH AND INITIATIVES ON THE ESTABLISHMENT OF AMA AND ON REGULATORY STABILITY IN AFRICA

In this Section, the strengths and weaknesses of the two above-described approaches will be addressed in a comparative way so that in Section V, an attempt will be made, also in light of the Chinese experience, to elaborate proposals to improve and complement the European approach.

A. The European Approach

Many of the initiatives adopted by the EU with a focus on strengthening the continent's regulatory stability have been recently established, and it is therefore not easy to make a comprehensive assessment of their current and mid-term future impact. What can be assessed and analysed, however, are the approaches and instruments with which the objective is pursued.

First of all, it should be pointed out that the amount of EU investment is significant and has increased dramatically in recent years. While historically and in terms of volume, the European Union has not been among the top investors in Africa, recent figures - if confirmed and sustained over time - are likely to prove a new counter-trend.[78]

Second, and evidently, AMA and regulatory harmonisation constitute one of the central pillars of the EU's investment strategy in Africa's healthcare sector. Focusing on AMA as an investment strategy may prove to be successful for two reasons: first,

75 Salvatore Mancuso, *China in Africa and the Law,* 18:1 Annual Survey of International & Comparative Law 245 (2012), https://digitalcommons.law.ggu.edu/annlsurvey/vol18/iss1/10/?utm_source=digitalcommons.law.ggu.edu%2Fannlsurvey%2Fvol18%2Fiss1%2F10&utm_medium=PDF&utm_campaign=PDFCoverPages.

76 Erica Penfold & Pieter Fourie, *Ebola and Cultures of Engagement: Chinese versus Western Health Diplomacy*, Council on Foreign Relations – Council of Councils, (Oct. 3,2014), https://www.cfr.org/councilofcouncils/global-memos/ebola-and-cultures-engagement-chinese-versus-western-health-diplomacy.

77 Olivia J. Killeen, et al., *supra* note 67, at 15-16.

78 As seen above, these figures are at least Euro 150 billion in the context of the Africa-Europe Investment Package, including more than Euro 1 billion allocated to the Team Europe Initiative on Manufacturing

AMA's success in achieving its objectives – or even a part of them – would constitute a turning point for the entire continent, and second, the EU is in the perfect position to support AMA on its purpose, as the latter was modelled after the EMA. Working in cooperation with AMA for its development would more easily allow for the development of health diplomacy between AU - EU and AMA - EMA aiming at cooperation, for example, in providing infrastructural, technological, administrative, and regulatory support to successfully establish AMA in Africa.[79]

Another aspect to be noticed and praised is the use of the "Team Europe" approach in carrying out this investment strategy. The concept is commonly understood as a strategic and practical way of redefining how the EU jointly engages with international partners. The approach seeks to strengthen cooperation among and joint action between various stakeholders, including the EU, its member states, financial institutions, implementing agencies, partner countries, civil society and the private sector.[80] In this regard, MAV+ appears to be quite promising if compared to other Team Europe Initiatives in different sectors: differently from other initiatives, coordination meetings at the headquarters level to steer national engagement have been significantly frequent, and the exchange with other involved member states and the EU has been continuous. Moreover, MAV+ has been able to initiate and keep the dialogue with key civil society organisations and interaction with interested private sector actors going. To be praised also with respect to other initiatives is the fact that half of the financial resources involved are also contributed by member states and that strong shared ownership is present among MAV+ members. This is confirmed, among others, by the fact that all member states can speak on behalf of the MAV+, whereas the EU does not act as a spokesperson in this respect.[81]

On the other hand, the European approach may also expose itself to certain weaknesses that could undermine or diminish its relevance.

The first risk is embedded in the Global Gateway dimension of the MAV+. As Global Gateway initiatives are the result of a shared effort among all actors on the European 'side', the risk is that African counterparts may be left out of the shared dialogue and

and Access to Vaccines, Medicines and Health Technologies in Africa - MAV + (which includes, among its key goals, the strengthening of AMA and of regulatory frameworks), as well as more than Euro 100 million to support the establishment of AMA and other African medicines regulatory initiatives at regional and national levels.

79 Vijay Kumar Chattu, et al., *Advancing African Medicines Agency through Global Health Diplomacy for an Equitable Pan-African Universal Health Coverage: A Scoping Review*, 18(22) Int. J. Environ. Res. Public Health 11758 (2021), https://www.mdpi.com/1660-4601/18/22/11758.

80 Niels Keijzer, Iliana Olivié & María Santillán O'Shea, *Working better together? A comparative assessment of*

that initiatives are adopted with a "top-down" or vertical approach. The adoption of a vertical approach, in which the investment priority is mostly set by the investor, would risk thwarting the considerable scale of the amounts invested, especially in light of the specificities and complexity of African legal systems. As the role of receiving countries remains unclear in the context of the Global Gateway strategy,[82] the capacity of EU institutions and agencies to dialogue effectively with the AU, AMA and AU member states will play a pivotal role in the appropriate allocation of resources and the ability of investments to have a real impact.

Moreover, it should be considered that while, on the one side, having a 'centralised' interlocutor – be it the AU or the AMA itself – might have the benefit of facilitating the dialogue and easing the process of implementing investment initiatives aimed at enhancing regulatory harmonisation, on the other side, it may crash on the complexity and stratification of legal systems on the African continent. Suffice it to mention that, for instance, in Nigeria alone, an estimated 300 traditional legal systems coexist, and, more broadly, in all of sub-Saharan Africa, the legal climate remains of an uncertain nature and written laws often remain dead letters.[83] The risk, therefore, is that by projecting the European experience and its standards, methods of action, and mechanisms into a reality that may not necessarily be capable of embracing them for reasons that are primarily cultural, even before being legal. In particular, it is to wonder whether an EMA-like model could work in a context such as the African one. Lastly, in light of the density and complexity of the information provided on the latter initiatives, there might be a potential clarity issue on the intended reach of EU and Team Europe's initiatives, goals, funding, timelines and long-term operational (and added) value. Although this downside more directly refers to an issue of visibility and communication, it may have a direct impact on the effectiveness and development of the above-described initiatives.[84]

Some confusion on the balance of elements within each initiative might then derive from the above; this, paired with insufficient monitoring mechanisms or an insufficient involvement of key stakeholders, might have the further negative result of

five Team Europe Initiatives, Royal Institute Elanco - Elcano Policy Paper 7 (Nov. 2023), https://media.realinstitutoelcano.org/wp-content/uploads/2023/11/policy-paper-working-better-together-a-comparative-assessment-of-five-team-europe-initiatives.pdf.

81 *Id.* at 34.

82 Farwa Sial & Xavier Sol, *The Emperor's New Clothes - What's new about the EU's Global Gateway?*, Counter Balance 19 (Sep. 2022), https://counter-balance.org/uploads/files/EU-global-gateway-report-FINAL.pdf.

83 Rodolfo Sacco, Le droit africain—Anthropologie et droit positif, 136 (2009).

relegating the private sector to a marginal role.[85] The latter's role is indeed crucial in the harmonization process and their exclusion might impair the investments made: if it is believed that regulatory harmonisation – in order not to remain a dead letter – shall be accompanied by a strengthening of the health systems that can support it, then private actors might have great impact, especially if African governments will decide to make greater use of public-private partnerships, for example in the form of regional procurement pooling mechanisms or production triangles.

B. The Chinese Approach

The African continent has been figuring very prominently in Chinese foreign policy. During the last couple of years, the multilateral cooperation between China and African countries has grown exponentially.

In general, as it has been outlined above, a major difference with the EU approach can be found in the subject matter of investments. So far, starting from the launch of China's Africa policy in 2006[86] but also through the China Africa Health Silk Road, China has developed many kinds of aid programs to Africa, through which it has sent medical teams and short-term expert groups to the continent, helped build medical infrastructure, donated medical supplies, trained medical personnel, and strengthened African public health systems against the threat of infectious diseases.[87]

What appears then to be lacking in investment policy, therefore, is a significant commitment in terms of 'institutional' aid – similar to what the EU has done – to the pharmaceutical regulatory harmonisation process in Africa, as well as to the AMA establishment.[88] Focus on more concrete and less 'institutional' policies might not necessarily be a negative element. It could be argued, in fact, that before strengthening African pharmaceutical regulators and bodies, it would be appropriate to strengthen African public health systems and facilities, the lack of which would, in any case, prevent entities such as AMA from adequately fulfilling their function.

84 Critics of the Global Gateway argue that the initiative has overly long timelines, that the EU communicates poorly about it, and that the goals are difficult to discern; some critics also say that some of the funding was already mobilized for existing projects and that, in the end, the initiative amounts to no more than rebranding. See: Emilie Bel, *supra* note 44.

85 Niels Keijzer, Iliana Olivié & María Santillán O'Shea, *supra* note 80, at 43.

86 Vijay Kumar Chattu, et al., *supra* note 79.

87 Zeng Aiping, *supra* note 66.

88 It is interesting to note that, despite the long investment relationship between China and Africa, only

Moreover, this approach has been favourably received by market insiders. In this regard, it has been said, for example, by an infectious disease specialist from Cameroon that: "For all the high-level talk…the impact is much more felt at the community level. […] [The Chinese Government] does not focus on training high-level people but on training local people who are able to sustain the programme. […] "Beyond disease-specific interventions, we are seeing a lot of emphasis on health systems strengthening", he said. "It is not super sexy, but it is really important stuff. Stuff we need to prevent the next epidemic from happening."[89]

Another relevant element of China's investment policy is that China's investments have impacted the continent through mutually beneficial cooperation, without interference in domestic politics and internal affairs. In other words, China has heavily invested in Africa's significant efforts to export its governance model.[90] This strategy removes most of the problems associated with the African rule of law and the complexity of the legal systems of the Continent as well as of single states. Indeed, the latter problems may come to the surface – mainly – when attempting to combine investment with the implementation of a certain governance mechanism or cooperation system. This aspect also benefits the political-communication aspect of China's investment initiatives. In contrast to the Western "North-South cooperation", China has successfully developed a narrative of "South-South cooperation", which, unlike the Western approach, relies upon equality, common development, and the concept of a partnership of equals, also due to China's greater similarities to the continent than Western countries. Among other things, it is emphasised that Western aid is always subordinated to unilaterally (or almost unilaterally) established conditions and, in any case, interferes in the internal affairs of individual states. The Chinese South–South approach, instead, helps to leverage donor-recipient cooperation and leads to a win-win and self-reliant development situation, with a strong commitment to non-intervention in African domestic affairs and a determination to build partnerships which are less exploitative and more relevant to local needs.[91]

Lastly, China has been doing a comprehensive job of integrating, at least in part, the private sector into the public flow of support to the African continent. As mentioned in FOCAC 2021, China pledged that the private sector would invest $10 billion in Africa in the following three years. During the pandemic, for example, private players

in the latest FOCAC 2021 is this mentioned, agreeing that: "*China will help accelerate the establishment of the African Medicines Agency (AMA) and support the African Medicines Regulation and Harmonization (AMRH) program to improve the effectiveness of the medical products regulatory systems*". See: Ministry of Foreign Affairs of the People's Republic of China, *supra* note 72.

89 Andrew Green, *supra* note 65.

have also been part of Chinese health diplomacy. Private actors have contributed immensely to the African countries to combat the pandemic. The same has provided several thousands of detection kits, PPE face masks, infrared thermometers, surgical masks, hand gloves, and extraction kits. Several Chinese companies have played an active role in the region by donating to local charity institutions, non-governmental organizations, and civil societies.[92]

The Chinese approach, however, also leaves itself open to some criticism.

Some of the criticisms raised concern the 'debt trap' and the creation of 'overdependence' upon Chinese aid.[9394]A debt trap is construed when the creditor country or institution extends debt to a borrowing nation partially or solely to increase the lender's political leverage. The creditor country extends excessive credit to a debtor country with the intention of extracting economic or political concessions when the debtor country becomes unable to meet its repayment obligations. China's financing approach raises then concerns about the debt sustainability of participating countries,[95] particularly those with high debt levels or limited capacity to service their debt.[96] Unsustainable debt levels may lead to economic instability, fiscal constraints, and reduced policy space for partner countries, potentially undermining the long-term benefits of the HSR projects. Indeed, in several BRI countries the host government has been unable to service its debt, and it has had to either reschedule the payments or convert them into equity sales to Chinese investors.[9798]

90 *Id.*

91 Richard Asante, *China and Africa: Model of South-South Cooperation?*, 04:02 China Quarterly of International Strategic Studies 262 (2019), https://www.worldscientific.com/doi/epdf/10.1142/S2377740018500124.

92 For instance, see the role of the Alibaba Foundation in Vijay Kumar Chattu, et al., *supra* note 79.

93 Marcus Vinicius de Freitas, *The Impact of Chinese Investments in Africa: Neocolonialism or Cooperation?*, 23 Policy Brief - Policy Center for the New South 3 (2023), https://www.policycenter.ma/sites/default/files/2023-08/PB_30-23_Marcus%20Freitas.pdf.

94 Evan Hsiang, *Chinese Investment in Africa: A Reexamination of the Zambian Debt Crisis*, Harvard International Review (Jan. 25, 2023).

95 Yuan Shaoyu, *The Health Silk Road: A Double-Edged Sword? Assessing the Implications of China's Health Diplomacy*, 4(2) World 338-339 (2023), https://doi.org/10.3390/world4020021.

96 Deborah Brautigam, *A critical look at Chinese 'debt-trap diplomacy': the rise of a meme*, 5:1 Area Development and Policy 1-14, 10.1080/23792949.2019.1689828.

97 Nader Habibi & Hans Yue Zhu, *supra* note 68, at 4-5.

98 The composition of Chinese financing also supports this thesis. Given that China pronounced that it has fulfilled its pledged $60 billion of financing to Africa under the 2015 FOCAC commitment, (including $5 billion for grants and zero-interest loans), and given the Chinese foreign direct investment to Africa in 2016 ($3.3 billion) and in 2017 ($3.1 billion) totalled $6.4 billion. Indeed, the numbers manifest that the overwhelming majority of Chinese financing to Africa are neither grants nor investment, but loans of various forms. China may not be the biggest creditor of Africa, but this serves to substantiate the widespread conviction that China is creating more debt for Africa (although the Chinese counterargument

Another critique that has been raised pertains to inadequate coordination with the international community and international legal mechanisms. China's emphasis on bilateral health assistance has been rooted in the concern that adherence to the multilateral system could transfer state authority to intergovernmental or nongovernmental entities. Despite this foundational stance, China's involvement in multilateral health governance has notably expanded in recent years. Experts are urging China to progressively incorporate its funding into other international systems. This approach could potentially elicit sustained commitments and enhance the measurability of the impact of its funding.[99][100]

Furthermore, despite the existence of FOCAC, China – as mentioned above – has a method of approaching investments, at least as far as the African continent is concerned, generally based on a bilateral approach, i.e. based on individual BITs with African countries or individual partnerships. In addition, cooperation mechanisms are also internally fragmented, so that a united decision-making and implementation mechanism – within China – has yet to be developed.[101] This approach runs the risk – instead of fostering harmonisation of investments and initiatives within the continent – of exacerbating differences between African countries, contributing to further fragmentation and differentiation in the quality of health facilities, the capacities of regulatory agencies, and the level of progress of health systems in general.

The above could also be potentially amplified by the recent Chinese trend in terms of private (against public) investment. Unguided private investment, in fact, tends to

has been that the long-term economic capacity building effect of the Chinese loans significantly outweighs their downsides). See: Yun Sun, *China's 2018 financial commitments to Africa: Adjustment and recalibration*, Brookings Edu (Sept. 5, 2018), https://www.brookings.edu/articles/chinas-2018-financial-commitments-to-africa-adjustment-and-recalibration/.

99 Andrew Green, *supra* note 65.

100 In that spirit, in 2018, China launched its first agency dedicated to foreign assistance, the China International Development Cooperation Agency (CIDCA). However, the role of the CIDCA is still being fine-tuned and the agency remains, as of today, relatively small and rather inexperienced in coordinating efforts. See: Marina Rudyak, *The Ins and Outs of China's International Development Agency*, Carnegie Endowment for International Peace (Sept. 2, 2019), https://carnegieendowment.org/2019/09/02/ins-and-outs-of-china-s-international-development-agency-pub-79739.

101 Zeng Aiping, *supra* note 66. For example, public health aid programs and medical teams to Africa, after complicated evolution in history, are currently managed and deployed by the National Health Commission. As for human resources training, the Ministry of Education is responsible for managing academic degree education for African students in China, including medical students. The Ministry of Commerce is responsible for training programs for health officials and specialists, building African medical facilities, managing donations of medical equipment and supplies, and helping African countries strengthen their health systems against the threat of infectious diseases. The Ministry of Foreign Affairs and the Ministry of Finance are involved in health diplomacy and budget support, respectively.

102 Shirley Ze Yu, *supra* note 70.

103 Chinwe Esimai, *Chinese Investments in Africa: Four Anti-corruption Trends to Watch,* Knowledge at

yield better outcomes in larger economies that have more stable governments and offer short-term returns. However, not all African economies can provide such conditions.[102]

Lastly, it must be emphasised that the fact that China does not provide conditions or stringent reporting requirements for guaranteeing its aid corruption in Africa might foster bribery and unfair business practices to secure business transactions.[103] More generally, due to the lack of transparency and the absence of reporting activities, there are concerns about the quality, sustainability, and safety of the infrastructure and services provided under the HSR. Indeed, ensuring that the investments lead to long-term improvements in healthcare systems requires adherence to high standards of construction, management, and maintenance.[104]

V. FINAL REMARKS: WHAT CAN THE EU DO BETTER?

Having compared the two approaches and having analysed their strengths and weaknesses, it is worthwhile to dwell on some concluding remarks and proposals aimed at complementing the current European approach in its support of regulatory stability in the pharmaceutical sector in Africa and the establishment of AMA.

First of all, it is believed that the EU's strategy to invest in AMA will likely prove a good bet. There has never been a more pressing need for Africa to have its own regulatory body for medicines and medical products than in the aftermath of the COVID-19 era, which has exposed the limitation of dependence on other nations' goodwill. In this context, AMA may play a stronger role on multiple fields and become the default regulator for African countries, which are still far behind in creating their national capacity in the pharmaceutical sector's regulatory affairs.[105] A few potential key roles that the AMA could fulfil are listed here below:

- leading to an expanded market for poor-quality, inadequately regulated pharmaceuticals crossing multiple borders without sufficient oversight;
- serving as a reliable partner for the expansion of pharmaceutical manufacturing capacity in Africa under licenses from European and North American companies;
- serving as a reliable partner for various regional and global stakeholders, including regulatory authorities, funding agencies, multilateral, and national governments.

Wharton (Sep. 19, 2019), https://knowledge.wharton.upenn.edu/article/chinese-investments-africa-four-anti-corruption-trends-watch/.

104 Yuan Shaoyu, *supra* note 95, at 339.

105 Vijay Kumar Chattu, et al., *supra* note 79.

106 Morgan Pincombe & Javier Guzman, *Striking While the Iron is Hot: Setting the African Medicines Agency*

To serve the latter purposes, AMA could be further strengthened by establishing a formal partnership with EMA (which AMA was essentially set up to mirror) to help channel the funds already invested at the European level. This partnership could envisage, for example, the possibility of developing triangular relations with European pharmaceutical companies, allowing them to manufacture in Africa products with EU marketing authorisation, under certain conditions and with certain guarantees, and, for example, stipulating in special trilateral agreements that part of the production located in Africa shall be destined for the African population. Cooperation should not be developed – however - with the objective of guaranteeing AMA the capillarity and regulatory agility that is typical of the EMA, which, as mentioned, is difficult to replicate in Africa due to factors such as the complexity of the legal system. Instead, the partnership with EMA should, at an early stage, aim and seek "quick wins" so as to prove its value, demonstrate impact, and, thus, secure additional support from the international community. For example, AMA could focus, also relying on the eventual partnership with EMA,[106] on:

- improving the market authorization process, which will yield significant and visible results, pooling the expertise needed to review product dossiers, publishing guidelines for industry and regulators, and streamlining the process for approving medical products;
- accelerating access to essential medicinal products and vaccines by partnering with countries seeking to expand vaccine manufacturing capacity that have already ratified the AMA treaty — such as Ghana, Rwanda, and Tunisia — as well as with international partners, also ensuring the vaccines produced in one member state can be procured in others.

Moreover, the EU should not overlook the value of investments that can directly and more immediately strengthen the health systems of African countries. The strengthening of regulatory-institutional initiatives must necessarily be coordinated with a 'bottom-up' approach, increasing the solidity of the systems by making them progressively more adapted to complex governance mechanisms such as that of the AMA. After all, it would be unthinkable to imagine a fully operational AMA without hospitals, doctors, and health infrastructures. On this, the European Union may have something to learn from the Chinese approach, which has carried out these types of investments since the 1960s with great practical and communicative effectiveness.

Up for Success, Center For Global Development (Apr. 22, 2022), https://www.cgdev.org/blog/striking-while-iron-hot-setting-african-medicines-agency-success.

107 The EABF brings together, among others, multinational companies and key players, large corporations,

In order to do this, learning from China's recent initiatives in this regard, as embodied in FOCAC 2021, the EU could, among other things, boost private involvement. The European Union already has fora that can be strengthened and enhanced for this purpose, such as, for example, the EU-Africa Business Forum (EABF), which brings together African and European business leaders and key players[107] to discuss how to improve the business and investment climate. The EU must make the most of these instruments, and, at the same time, advocate for a greater use of public-private partnerships by African institutions and countries.

Another improvement that the EU can implement is to increase the inclusiveness of the decision-making mechanisms behind investment initiatives. The success of investment and the EU-Africa relationship will depend on the capacity of EU institutions and agencies to dialogue effectively with AU member states. The challenges to be addressed in this regard are the differences between EU and AU internal decision-making processes and mechanisms and the timing at which such dialogue takes place.[108] Indeed, African actors are usually involved only after EU member states have agreed internally on a specific investment proposal. This, of course, leaves limited time and margin to the AU and its member states to react and risks to cause the development of initiatives and projects that do not respond to the real needs and priorities of the investment beneficiaries themselves.

To facilitate the dialogue, the governance model of the Global Gateway and, in general, of Team Europe Initiatives would need to be reviewed – learning from the Chinese approach, for which priorities are usually agreed upon in advance with the African state(s) - to ensure democratic ownership of development strategies and meaningful participation of African counterparties, both public and private, thus ensuring ensure transparency of decision-making, process and structure of European investment initiatives.[109]

In the context of the Global Gateway, another thing that is better ensured by China than the EU is communication. As also seen above, Global Gateway, Team Europe, and the various EU initiatives need to be communicated in a simpler and more effective manner. It has been argued that the Global Gateway is a mere rebranding

small and medium-scale enterprises and confederations, as well as multilateral and regional institutions. See: European Commission, *Africa-EU Partnership*, International Partnerships, https://international-partnerships.ec.europa.eu/policies/africa-eu-partnership_en.

108 Farwa Sial & Xavier Sol, *supra* note 82, at 21.

109 *Id.*

110 Chloe Teevan, *Global Gateway as new approach, not simple funding pot*, Euractive (Apr. 3, 2023),

of existing initiatives. Although this is not the case, even the most sophisticated investment law instrument must be accompanied by adequate communication. The EU must, therefore, streamline and simplify the framework of the various initiatives, which often risk overlapping, and put in place a clear, simple and precise institutional communication, not only for Europeans but also for worldwide beneficiaries.[110]

Lastly, it would be worth experimenting with existing, functioning platforms that could bring added value and concrete support even in the short term, such as the Africa Medical Supplies Platform, launched by the AU, partially with the help of the Chinese government,[111] in June 2020 to enable all African governments to procure key medical supply in the fight against the COVID-19 pandemic.[112] The Platform unlocks immediate access to an African and global base of manufacturers and procurement strategic partners and enables African Union Member States to purchase certified medical equipment such as diagnostic kits, PPEs and clinical management devices with increased cost-effectiveness and transparency. Purchasing through the AMSP is restricted to governments, national health systems, NGOs and donor organisations.[113] The Platform already envisages among its partners, among others, France, China, the WTO, and the Bill & Melinda Gates Foundation. The EU could incorporate this project into the scope of action of Team Europe MAV+ by entering into a partnership with the Platform and: (i) use this opportunity to set up initial 'tests' of cooperation with the Chinese government; and (ii) work to broaden the scope of this platform, which worked very well in the Covid phase, to enable it to become over time a procurement centre for medicines, medical devices and health products in general manufactured in Africa, dedicated to institutional actors, under the AMA's monitoring.

https://www.euractiv.com/section/development-policy/opinion/global-gateway-as-new-approach-not-simple-funding-pot/.

111 The AMSP, however, is funded by the African Export-Import Bank (Afreximbank) and run by the Africa Centers for Disease Control and Prevention through the African Union (AU), with support from the UN Economic Commission for Africa. See: Zachary Donnenfeld, *Africa Medical Supplies Platform: a model for the world?*, Institute for Security Studies – Africa (May 13, 2021), https://issafrica.org/iss-today/africa-medical-supplies-platform-a-model-for-the-world.

112 Nader Habibi & Hans Yue Zhu, *supra* note 68, at 15-16.

113 Zachary Donnenfeld, *supra* note 111.