COMESA Competition Commission
Kang'ombe House, 5th Floor
P.O. Box 30742
Lilongwe 3, Malawi
Tel: +265 1 772 466
Email- compcom@comesacompetition.org

Common Market for Eastern and Southern Africa

Case File No. CCC/MER/4/10/2023

Decision[1] of the Ninety-Eighth (98th) Meeting of the Committee Responsible for Initial Determinations Regarding the Proposed Acquisition of Sole Control by Africa Capitalworks SSA 3 over Cipla Quality Chemical Industries Limited

ECONOMIC SECTOR: Pharmaceutical

12 October 2023

COMESA COMPETITION COMMISSION
12 OCT 2023

[1] In the published version of this decision, some information has been omitted pursuant to Rule 73 of the COMESA Competition Rules concerning non-disclosure of business secrets and other confidential information. Where possible, the information omitted has been replaced by ranges of figures or a general description.

The Committee Responsible for Initial Determinations,

Cognisant of Article 55 of the Treaty establishing the Common Market for Eastern and Southern Africa (the "**COMESA Treaty**");

Having regard to the COMESA Competition Regulations of 2004 (the "**Regulations**"), and in particular Part 4 thereof;

Mindful of the COMESA Competition Rules of 2004, as amended by the COMESA Competition [Amendment] Rules, 2014 (the "**Rules**");

Conscious of the Rules on the Determination of Merger Notification Thresholds and Method of Calculation of 2015;

Recalling the overriding need to establish a Common Market;

Recognising that anti-competitive mergers may constitute an obstacle to the achievement of economic growth, trade liberalization and economic efficiency in the COMESA Member States;

Considering that the continued growth in regionalization of business activities correspondingly increases the likelihood that anti-competitive mergers in one Member State may adversely affect competition in another Member State,

Desirability of the overriding COMESA Treaty objective of strengthening and achieving convergence of COMESA Member States' economies through the attainment of full market integration,

Having regard to the COMESA Merger Assessment Guidelines of 2014,

Determines as follows:

Introduction and Relevant Background

1. On 2 May 2023, the COMESA Competition Commission (the "**Commission**") received a notification for approval of a merger involving Africa Capitalworks SSA 3 ("**ACW SSA 3**") and Cipla Quality Chemical Industries Limited ("**CiplaQCIL**"), pursuant to Article 24(1) of the Regulations. In terms of the proposed transaction, ACW SSA 3 will acquire 51.18% of the share capital of CiplaQCIL.

2. Pursuant to Article 26 of the Regulations, the Commission is required to assess whether the transaction between the parties would or is likely to have the effect of substantially preventing or lessening competition or would be contrary to public interest in the Common Market.

3. Pursuant to Article 13(4) of the Regulations, there is established a Committee Responsible for Initial Determinations, referred to as the CID. The decision of the CID is set out below.

The Parties

ACW SSA 3 (the acquirer)

4. ACW SSA 3, a newly established firm for purposes of the proposed transaction, is a company registered in accordance with the corporate law of Mauritius. ACW SSA 3 is controlled by Africa Capitalworks Holdings ("**ACW**") and does not have any ongoing business activities being a newly established entity. ACW is a company registered in Mauritius, which provides permanent equity capital and complementary skills to mid-market companies across Sub-Saharan Africa. ACW SSA 3, the firms it controls, the firms that control it, and all the firms controlled by its controllers are referred to as the Acquiring Group.

5. Within the Common Market, the Acquiring Group operates in Djibouti and Ethiopia. Wingu.Africa Group Limited ("**Wingu**") is the only firm in the Acquiring Group that has presence in the Common Market and provides data center services to several information and communications technology companies, content distribution networks and content providers.

CiplaQCIL (the target)

6. CiplaQCIL is a public company listed on the Uganda Securities Exchange and incorporated under the laws of Uganda. CiplaQCIL is active in the pharmaceutical sector, and its activities include the following:

    - Manufacturing and supplying antiretrovirals ("**ARTs**") used in the treatment of human immunodeficiency virus ("**HIV**") and acquired immunodeficiency syndrome ("**AIDS**"); and
    - Manufacturing and supplying artemisinin-based combination therapies ("**ACTs**") used in the treatment of antimalaria; and
    - Manufacturing and supplying medication used in the treatment of hepatitis B; and
    - Serving as a logistics and distribution provider in relation to the following products: asthma, chronic obstructive pulmonary disease, diabetes, infections, gastroenterology, and cardiovascular disease.

7. Within the Common Market, CiplaQCIL operates in Kenya, Uganda, and Zambia.

Jurisdiction of the Commission

8. Article 24(1) of the Regulations requires 'notifiable mergers' to be notified to the Commission. Rule 4 of the Rules on the Determination of Merger Notification Thresholds and Method of Calculation (the "**Merger Notification Thresholds Rules**") provides that:

Any merger, where both the acquiring firm and the target firm, or either the acquiring firm or the *target firm, operate in two or more Member States, shall be notifiable if:*

a) the combined annual turnover or combined value of assets, whichever is higher, in the Common Market of all parties to a merger equals or exceeds USD 50 million; and

b) the annual turnover or value of assets, whichever is higher, in the Common Market of each of at least two of the parties to a merger equals or exceeds USD 10 million, unless each of the parties to a merger achieves at least two-thirds of its aggregate turnover or assets in the Common Market within one and the same Member State.

9. The undertakings concerned have operations in two or more Member States. The merging parties hold a combined asset value in excess of the threshold of USD 50 million in the Common Market. In addition, the parties do not hold more than two-thirds of their respective aggregate COMESA-wide asset within one and the same Member State. The notified transaction is therefore notifiable to the Commission within the meaning of Article 23(5)(a) of the Regulations.

Details of the Merger

10. In terms of the Share Purchase Agreement entered between the parties[2] dated 14 March 2023, ACW SSA 3 will acquire 51.18% of the share capital of CiplaQCIL. As a result of the proposed transaction, ACW SSA 3 will acquire sole control over CiplaQCIL.

COMPETITION ASSESSMENT

Consideration of the Relevant Markets

Relevant Product Market

11. The acquiring group, through Wingu, provides data center services to enterprise customers, information and communications technology companies, content distribution networks, and content providers in the Common Market.

12. CiplaQCIL is active in the manufacturing and wholesale supplying of pharmaceutical products. It manufactures and supplies antiretrovirals used in the treatment of HIV, artemisinin-based combination therapy medication used in the treatment of antimalaria, and medication used in the treatment of hepatitis B – being its main activities. Accordingly, there is no overlap in the activities of the acquirer and the target.

[2] The parties to the sale purchase agreement are: Meditab Holdings Limited, CIPLA (EU Limited); Africa Capitalworks Limited; CIPLA Limited; and Africa Capitalworks SSA 3.

13. Since the proposed transaction is not likely to affect the markets in which the acquiring group operates, the competitive assessment has focused on the products provided by CiplaQCIL.

Manufacturing and wholesale supply of pharmaceutical products

14. The CID has previously[3] considered that pharmaceutical products can be broadly categorised into pharmaceutical products for human consumption and animal consumption where each category of the pharmaceutical product cannot be administered to the other category of use, i.e., a medication intended for human consumption cannot be administered on animals and vice-vice. Given this lack of substitutability between human and animal pharmaceutical products and coupled with the fact that the target is active only in the manufacturing and supply of human pharmaceutical products, the assessment focussed only on the pharmaceutical products for human consumption.

15. The World Health Organization ("**WHO**") provides for a classification system (the Anatomical Therapeutical Chemical ("**ATC**")) which groups medicinal products according to their indication, therapeutic use, composition, and mode of action[4]. In the first and broadest level ATC1, medicinal products are divided into the 16 anatomical main groups. The second level, ATC2, is either a pharmacological or therapeutic group. The third level, ATC3, further groups medicinal products by their specific therapeutic indications. Finally, the ATC4 level is the most detailed one and refers for instance to the mode of action (e.g., distinction of some ATC3 classes into topical and systemic depending on their way of action) or any other subdivision of the group[5]. The CID has previously held[6] that the products within a classification level can constitute distinct relevant product markets separate from the other classification levels. The target's products fall under the 4th ATC classification level.

16. The CID considered that the antiretrovirals for treatment of HIV and AIDS, medicines for the treatment of antimalaria, and hepatitis are separate product markets due to their different molecular structures, their application, and functionality as discussed below.

Antiretrovirals for treatment of HIV infections

17. The "J05AR" is a code in the 4th ATC hierarchical classification system (**J** Anti-infectives for systemic use → **J05** Antivirals for systemic use → **J05A** Direct acting antivirals → J**05AR** Antivirals for treatment of HIV infections, combinations) that represents a specific therapeutical/pharmaceutical subgroup i.e., antiretrovirals for

[3] See paragraph 14 of Case File No. CCC/MER/12/31/2021: merger involving DAWAA'A Restricted Ltd and Pharma Strategy Partners GmbH
[4] https://www.who.int/tools/atc-ddd-toolkit/atc-classification, accessed 3 August 2023.
[5] Para 11 ibid n. 16
[6] See paragraph 17 of Case File No. CCC/MER/12/31/2021.

treatment of HIV infections, combinations, within the "J05A" therapeutical/pharmacological main group[7].

18. According to the WHO, HIV is an infection that attacks the body's immune system, specifically the white blood cells called CD4 cells[8] which help the immune system fight off infections. CD4 Cells are targeted by HIV which destroys them and leading to a weakened immune system and development of AIDS.

19. Antiretroviral drugs refer to the medicines used to treat HIV while antiretroviral therapy refers to the use of a combination of three or more antiretroviral drugs for treating HIV infection[9]. HIV treatment using combined antiretroviral therapy is required to effectively suppress the viral load (amount of HIV in the bloodstream), increase/preserve (or improve) the CD4 cell count or immune function and reduce the risk of opportunistic infections and cancers commonly associated with HIV[10]. The combination antiretroviral therapy involves using a combination of antiviral drugs from different classes to target the virus at multiple stages of its life cycle[11].

20. CiplaQCIL produces and supplies different doses of combination antiretroviral therapies that are used to fight AIDS such as a 3-in-1 fixed dose combination (Stavudine + Lamivudine + Nevirapine), Lamivudine, Zidovudine & Nevirapine; Lamivudine and Zidovudine; Lamivudine and Tenofovir Disoproxil Fumarate; Efavirenz, Lamivudine & Tenofovir Disoproxil Fumarate; and Dolutegravir (as Sodium), Lamivudine & Tenofovir Disoproxil Fumarate. From a supply side, manufacturers can produce and supply different antiretroviral combinations.

21. Given that there is no overlap in the activities of the parties, a consideration of further segmentation of the market is not necessary as any alternative market definition will not alter the competitive assessment with respect to the supply of antiretrovirals for the treatment of HIV infections.

Artemisinin used for the treatment of antimalaria

22. The "P01BE" is a code in the 4th ATC hierarchical classification system (**P** Antiparasitic products, insecticides, and repellents → **P01** Antiprotozoals → **P01B** Antimalarials → **P01BE** Artemisinin and derivatives) that represents a specific therapeutic/pharmacological subgroup i.e., Artemisinin and derivatives, within the "P01B" therapeutic/pharmacological main group, which is " Antimalarials"[12].

23. WHO recommends artemisinin-based combination therapies for the treatment of uncomplicated malaria caused by Plasmodium falciparum[13]. "*Artemether,*

[7] https://www.rxreasoner.com/atccodes/J05A, accessed on 4 August 2023.
[8] https://www.who.int/health-topics/hiv-aids#tab=tab_1, accessed on 4 August 2023.
[9] file:///C:/Users/HP/Downloads/9789241549684_eng.pdf, page 15, accessed on 29 August 2023.
[10] https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/treatment, accessed on 4 August 2023.
[11] https://www.thewellproject.org/hiv-information/hiv-drugs-and-hiv-lifecycle, accessed on 10 August 2023.
[12] https://www.rxreasoner.com/atccodes/P01BE, accessed 5 August 2023.
[13] *https://www.who.int/docs/default-source/documents/publications/gmp/who-cds-gmp-2018-26-eng., accessed on 5 August 2023.*

artemisinin, artemotil, artenimol, and artesumate are the active ingredients of artemisinin-based combinations…artemether is an antimalarial agent used to treat acute uncomplicated malaria while artemisinin is used in the treatment of antimalaria due to species Plasmodium. On the other hand, artemotil, also known as β-arteether, is a semi-synthetic derivative of artemisinin and a fast-acting blood schizonticide specifically indicated for the treatment of chloroquine-resistant plasmodium falciparum malaria and cerebral malaria cases. Artenimol is an artemisinin derivative and antimalarial agent used in the treatment of uncomplicated plasmodium falciparum infections while artesunate is a semi-synthetic artemisinin derivative, indicated for the initial treatment of severe malaria in adults and children".[14]

24. Anti-malarial medications work by eliminating the parasite – known as Plasmodium parasites – that has infected the red blood cells of the patient[15]. Further segmentation can be possible since there are multiple antimalarial medications with various chemical structures, with each one damaging the disease-causing parasite in a different way, but generally via killing the parasite enzymes or activities within infected erythrocytes. Different types of antimalarial medications exist, each with its own mechanism of action, efficacy, and potential side effects, which could limit substitutability from demand side. However, further segmentation is not necessary as any alternative market definition will not alter the competitive assessment given that there is no overlap in the parties' activities.

Antiviral medications for the treatment of hepatitis

25. CiplaQCIL is active in the manufacturing and wholesale supply of antiviral medications used to treat hepatitis B, which is under the nucleoside and nucleotide reverse transcriptase inhibitors molecular classification[16].

26. The "J05AF" is a code in the 4th ATC hierarchical classification system (**J** Antiinfectives for systemic use → **J05** Antivirals for systemic use → J**05A** Direct acting antivirals → **J05AF** Nucleoside and nucleotide reverse transcriptase inhibitors) that represents a specific therapeutical/pharmaceutical subgroup i.e., Nucleoside and nucleotide reverse transcriptase inhibitors, within the "J05A" therapeutical/pharmacological main group, which is Direct acting antivirals[17].

27. Hepatitis is treated by medications classified under nucleoside and nucleotide reverse transcriptase inhibitors. "*Hepatitis is an inflammation of the liver that is caused by a variety of infectious viruses and non-infectious agents leading to a range of health problems, some of which can be fatal…there are five main strains of*

[14] https://www.rxreasoner.com/atccodes/P01BE, accessed 5 August 2023.
[15] https://www.pharmaceutical-technology.com/data-insights/innovators-anti-malarial-compositions-pharmaceutical/, accessed on 6 August 2023.
[16] https://www.who.int/health-topics/hepatitis#tab=tab_1, accessed on 4 August 2023.
[17] https://go.drugbank.com/categories/DBCAT002376, accessed on 4 August 2023.

the hepatitis virus, referred to as types A, B, C, D, and E. While they all cause liver disease, it is important to note that each type of hepatitis is caused by a different virus, and can have different modes of transmission, symptoms, prevention methods, and long-term effects. For instance, hepatitis A is usually spread through contaminated food and water or close contact with an infected person while hepatitis B is transmitted through contact with infected blood, semen, or other body fluids".[18]

28. The target produces different types of drugs such as Entecavir and Tenofovir disoproxil fumarate used for the treatment of Hepatitis B[19]. Different types of antivirals are used to treat different hepatitis viruses depending on the specific types of viruses, severity of the disease, the patient's health status and other factors. For instance, Entecavir and Adefovir dipivoxil are nucleoside analogue used in the treatment of chronic hepatitis B for patients with active viral replication, histological evidence of active disease, or persistent elevations in liver transaminases[20] while sofosbuvir and daclatasvir are used to treat hepatitis C[21]. From a demand side, each drug targets different viruses and could have distinct mechanisms of action, such that there might not be substitutability, indicating the possibility of further segmentation.

29. In view of the foregoing, and having regard to the products offered by the target, the CID considered that for the purpose of this transaction, the relevant market can be construed as the manufacture and supply of antiviral medications for the treatment of hepatitis B.

30. The CID further observed that the target's customers are government agencies, non-profit organisations and pharmaceutical suppliers/distributors. The CID considered that the conditions of supply at wholesale level is likely to differ from supply to retail customers, having regard to national regulations, financial capacity, and volumes of supply.

31. Based on the foregoing assessment and without prejudice to its approach in similar future cases, the CID considered that the relevant product markets are the manufacture and wholesale supply of:

    a) antiretrovirals for the treatment of HIV infections.

    b) artemisinin for the treatment of antimalaria; and

    c) antivirals for the treatment of hepatitis B.

[18] https://www.who.int/health-topics/hepatitis#tab=tab_1, accessed on 4 August 2023.
[19] https://ciplaqcil.co.ug/our-offerings/hepatitis, accessed on 30 August 2023.
[20] https://go.drugbank.com/drugs/DB00442, accessed on 4 August 2023.
[21] https://www.who.int/news-room/fact-sheets/detail/hepatitis-c, accessed on 13 August 2023.

Relevant Geographic Market

32. The parties referred to the CID's decision in ***DAWAA'A/Pharma Strategy***[22] where it considered that the market for pharmaceuticals is global in scope given the presence of pharmaceutical products by global suppliers which signifies the presence of competition from the global market. The parties argued that the pharmaceutical geographic market is global because the target's main activities are global, and its competitors are generally active in different countries across the global market including Kenya, Uganda, and Zambia.

33. In line with its previous decisions, the CID considered that the geographic market for the relevant markets identified are indeed likely to be broader than national, since the majority of these products are sourced from different suppliers outside of national markets. In ***Elgon/Westlands***[23], the CID noted that for the upstream supply of pharmaceutical products, wholesale suppliers are not generally constrained in their ability to source products from several overseas jurisdictions, including outside the Common Market and that the major distributors of pharmaceutical products are global players. The CID ultimately left the definition of the relevant market open since the transaction was not likely to raise competition concerns.

34. In the current transaction, it is observed that CiplaQCIL supplies its products to its customers in Zambia from its production facility in Uganda, and at the time of the filing was exporting to 13 countries in Africa (of which three are in the Common Market) and two in Southeast Asian Countries. Whilst at least 79% of antimalarial drugs consumed on the African continent are reported to be imported from India and China[24], it should be noted that the manufacturing and wholesale supply of drugs market may be constrained that qualification certifications and regulatory requirements which may prevail at national level.

35. In view of the above and noting that the transaction will not raise concerns under any alternative market definition, the geographic scope for the relevant products identified is construed to be at least COMESA-wide.

Conclusion on Relevant Markets

36. Based on the foregoing assessment, and without prejudice to the CID's approach in similar future cases, the relevant markets have been identified as the manufacture and wholesale supply of:

    a. **antiretrovirals for treatment of HIV infections in a geographic market which is at least COMESA-wide.**

---

[22] Case File No. CCC/MER/12/31/2021: merger involving DAWAA'A Restricted Ltd and Pharma Strategy Partners GmbH.
[23] See paragraph 30, Case File No. CCC/MER/03/07/2023, proposed merger involving Elgon Healthcare Limited and Westlands Heights Limited.
[24] https://www.afdb.org/en/news-and-events/malaria-is-bad-for-business-invest-in-the-local-manufacturing-of-low-cost-generic-medicines-president-adesina-tells-african-leaders-17802, accessed on 16 August 2023.

b. **artemisinin for the treatment of antimalaria in a geographic market which is least COMESA-wide; and**

c. **antivirals for the treatment of hepatitis B in a geographic market which is which is at least COMESA-wide.**

Market Shares and Concentration

37. The merging parties submitted that the size of the pharmaceutical industry in Kenya, Uganda, and Zambia is approximately valued at USD 1 billion, USD 400 million, and USD 260 million, respectively, with the possibility that these values are understated. Based on the above market sizes, the target's estimated market shares in the pharmaceutical markets in Kenya, Uganda and Zambia would be approximately less than 15%.

38. The CID noted there would be no change in the existing market structure post-merger in view of the absence of overlap pre-merger and further that the merged entity would continue to face competition from the existing competitors which include global players such as Viiv Heal care, Gilead Sciences, Janssen Pharmaceuticals, inc., and Merck Sharp & Dogme Crop in the supply of antivirals[25] and Sanofi, KPC Pharmaceuticals, Kerui nanhai, Guangxi xiancaotang, Guilin Pharmaceutical, Natural Bioengineering, BIONEXX, CAT KHANH, BEEPZ, and Novanat Bioresource in the supply of antimalaria products[26].

39. As observed in previous decisions[27], the pharmaceutical and medical equipment market is typically characterised by significant barriers to entry in terms of the research and testing which is required to introduce new products, intellectual property rights on the products, licensing, and registration requirements for pharmaceutical products.

40. Given the absence of product and geographic overlap in the activities of the acquirer and the target, the CID noted that there will not be any change in the relevant market structure post-merger, and there is no risk of the proposed merger resulting in the creation of a dominant position for the parties that would allow them to engage in unilateral conduct in the market.

Consideration of Third-Party Views

41. The CID considered submissions from the competent authorities of Kenya, Ethiopia, and Zambia which confirmed that the transaction was not likely to raise competition and public interest concerns post-merger. This is consistent with the CID's findings, as discussed above.

---

[25] https://www.fortunebusinessinsights.com/industry-reports/hiv-aids-drugs-market-101115 accessed on 7 August 2023.
[26] https://extranet.who.int/pqweb/medicines/prequalified-lists/sf-quality-control-labsl, accessed on 16 August 2023.
[27] See paragraph 40, Case File No. CCC/MER/03/07/2023, proposed merger involving Elgon Healthcare Limited and Westlands Heights Limited.

Determination

42. Based on the circumstances of the case and having regard to the foregoing assessment, the CID determined that the merger is not likely to substantially prevent or lessen competition in the Common Market or a substantial part of it, nor be contrary to public interest. The CID further determined that the transaction is unlikely to negatively affect trade between Member States. The CID, therefore, approved this transaction.

43. This decision is adopted in accordance with Article 26 of the Regulations.

Dated this 12th day of October 2023

Commissioner Dr Mahmoud Momtaz (Chairperson)

Commissioner Lloyds Vincent Nkhoma **Commissioner Islam Tagelsir Ahmed Alhasan**