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Common Market for Eastern and Southern Africa

Case File No. CCC/MER/11/46/2024

Decision[1] of the 116th Meeting of the Committee Responsible for Initial Determinations Regarding the Proposed Acquisition of sole control by Clayton, Dubilier & Rice Fund XII, L.P. of Opella Healthcare

ECONOMIC SECTOR: Pharmaceuticals

25 March 2025

[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 Where possible, the information omitted has been replaced by ranges of figures or a general description.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;

Having regard to the COMESA Merger Assessment Guidelines of 2014;

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;

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

Determines as follows:

Introduction and Relevant Background

1. On 9 December 2024, the COMESA Competition Commission ("**the Commission**") received a notification for a merger regarding proposed acquisition of sole control by Clayton, Dubilier & Rice Fund XII, L.P. ("**CD&R Fund XII**" or the "**acquiring firm**", together with its controlling and controlled affiliates, "**CD&R Group**" or the "**acquiring group**") of Opella Healthcare ("**Opella**" or the "**target firm**"), pursuant to Article 24(1) of the Regulations.

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

CD&R Fund XII (the "acquiring firm")

4. The parties submitted that CD&R Fund XII is a private equity fund forming part of the CD&R Group. The CD&R Group is a private equity investment group based in the U.S., which originates, structures and frequently acts as a lead equity investor in management buyouts, strategic minority equity investments and other strategic investments in a variety of economic sectors.

5. The parties submitted that in partnership with the management teams of its portfolio companies, the CD&R Group takes a long-term view of value creation and emphasizes positive stewardship and impact. The group invests in businesses that span a broad range of industries, including industrial, healthcare, consumer, technology and financial services end markets. The CD&R Group is privately owned by its partners and has offices in New York and London.

6. The parties submitted that the CD&R Group operates in all Member States, except Comoros and Somalia.

Opella (the "target firm")

7. The parties submitted that Opella, which is headquartered in France, a simplified joint stock company (société par actions simplifiée) incorporated under the Laws of France.

8. Opella employs over 11,000 people, operates in 100 countries and manages 13 manufacturing sites and four research and innovation centres. Opella is active in the supply of OTC medicines and vitamins, minerals and supplements.

9. The parties submitted that Opella's portfolio of brands includes (e.g.) Allegra, Doliprane, Dulcolax, Icy Hot and Novanight. Its broad product portfolio can be split into the following three main product categories:

   1) **Seasonal & pain**: Opella's seasonal & pain product portfolio, which accounts for approx. [redacted]% of its global sales, includes:

      (i) OTC allergy medications aimed at managing allergic reactions and symptoms,

      (ii) Cough, cold and flu (C&C) medication, targeting respiratory ailments, offering relief from C&C symptoms (e.g., cough, congestion, fever and sore throat), and

      (iii) OTC pain care medications designed to alleviate various types of pain, providing relief and improving overall well-being. Opella's brands in this product category are Allegra, Bisolvon, Doliprane, Dorflex, Eve, Icy Hot, Lizifen, Lizipaina, Mucosolvan, Novalgin and Rhinospray.

2) **Wellness:** Opella's wellness product portfolio, which accounts for approximately [redacted]% of its global sales, includes:

(i) Digestive wellness products promoting a healthy digestive system and supporting gastrointestinal health,

(ii) Physical wellness medication contributing to overall physical health and supporting physical well-being,

(iii) Mental wellness products focused on mental health, and

(iv) Men's sexual health pharmaceuticals treating erectile dysfunction. Opella's brands in this category are Buscopan, Cenovis, Cialis, Dulcolax, Enterogermina, Essentiale, MagnévieB6, Pharmaton and Qunol.

3) **Others**: In addition, Opella manufactures and distributes various Over the Counter (OTC) products addressing personal health needs, including skincare, oral hygiene, and general well-being. Those products account for approx. [redacted]% of its global sales and include (e.g.) Cortizone-10.

10. The parties further submitted that, within the Common Market, the target firm directly or indirectly controls entities operating in the Common Market, as presented in Table 1 below.

Table 1: the target firm's-controlled entities and their activities in the Common Market[2]

Member State	Company name	Country of incorporation
Egypt	Opella Healthcare Egypt LLC	Egypt
Libya	Opella Healthcare International[3]	France
Tunisia	Winthrop Pharma Tunisie, Opella Healthcare Tunisia SUARL	Tunisia

Jurisdiction of the Commission

11. 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:*

[redacted]

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".*

12. The undertakings concerned have operations in two or more Member States. The undertakings concerned derived a turnover of more than the threshold of USD 50 million in the Common Market and they each derived a turnover of more than USD 10 million in the Common Market. In addition, the parties do not hold more than two-thirds of their respective aggregate turnover or asset value in one and the same Member State. The CID was thus satisfied that the transaction constitutes a notifiable transaction within the meaning of Article 23(5)(a) of the Regulations.

Details of the Merger

13. The parties submitted that the transaction entails the acquisition of sole control by CD&R Fund XII over Opella.

Competition Analysis and Relevant Observations

Consideration of the Relevant Markets

Relevant Product Market

14. Paragraph 7 of the Guidelines on Market Definition stipulates that "*relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer/customer, by reason of the products' characteristics, their prices and their intended use".*

15. The CID noted the CD&R group invests in businesses that span a diverse range of industries, including industrial, healthcare, consumer goods, technology and financial services. With respect to healthcare or health related services, it is noted that within the Common Market the CD&R Group provides animal health services and distributes medical equipment and offers solutions and support to pharmaceutical and biotechnology companies in advanced clinical supply chain services and contract pharmaceutical packaging. The CID also noted that Opella is active in the supply of over-the-counter (OTC) medicines, vitamins, minerals and food supplement products in the Common Market. Opella supplies the following three main product categories:

(i) Seasonal & pain products – includes OTC allergy medications, cough, cold & flu treatments, and pain relief products. Key brands such as Allegra, Bisolvon,

Doliprane, Dorflex, Eve, Icy Hot, Lizifen, Lizipaina, Mucosolvan, Novalgin and Rhinospray.

(ii) Wellness products – covers digestive, physical, and mental wellness products, as well as men's sexual health pharmaceuticals treating erectile dysfunction. Key brands such as Buscopan, Cenovis, Cialis, Dulcolax, Enterogermina, Essentiale, MagnévieB6, Pharmaton and Qunol.

(iii) Other products – includes skincare, oral hygiene, and general well-being products, such as Cortizone-10.

16. The CID observed that from the products of the merging parties, the proposed transaction was not likely to raise horizontal overlaps since the merging parties do not provide similar products. The CID's assessment of the product market therefore focused on the products provided by Opella.

Supply of pharmaceutical products

17. According to the World Health Organization ("**WHO**"),[4] pharmaceutical products, such as medicines or drugs, are specialized formulations used in both modern and traditional medicine. The CID noted that the products are essential for disease prevention and treatment, positively contributing to overall public health. The CID further observed that pharmaceutical products comprise chemical substances or compounds specifically developed to address medical conditions in humans and animals.

18. In its previous decisions[5], the CID classified pharmaceutical products into two broad categories, namely those for human consumption and those for animal consumption. The CID determined that these categories are not interchangeable, as medications designed for human use cannot be administered to animals and vice versa. Given that Opella operates in the supply of pharmaceutical products for human consumption, the CID's assessment focused solely on pharmaceuticals intended for human use.

19. The CID observed that pharmaceutical products for human consumption cover a wide range of therapeutic products, not all of which compete within the same market. The CID noted the WHO's Anatomical Therapeutic Chemical ("**ATC**") classification system provides a structured framework for categorizing medicinal products based on therapeutic use, indication, composition, and mode of action. In the ATC classification system, the active substances are classified in a hierarchy with five

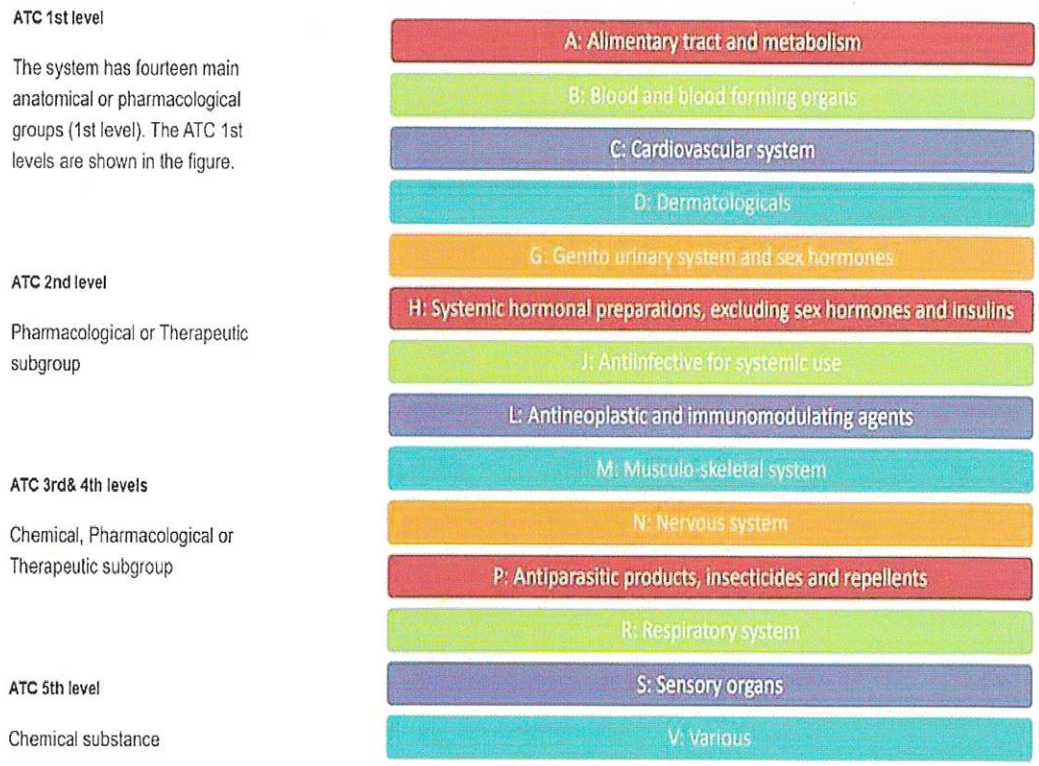
[4] See https://www.emro.who.int/health-topics/pharmaceutical-products/index.html
[5] see para. 36 of Case File No. CCC/MER/03/12/2024: merger involving MIC UAE Investments 1 RSC Limited and Kelix Bio Limited, decision dated 11 July 2024; and para. 14 of Case File No. CCC/MER/12/31/2021: merger involving DAWAA'A Restricted Ltd and Pharma Strategy Partners GmbH.

different levels,[6] each offering a progressively detailed classification of pharmaceutical products.

20. The CID noted that the five hierarchical levels of the ATC system are[7]: at ATC1 level, medical products are divided into 16 main anatomical groups. ATC2 classifies pharmaceutical products into pharmacological or therapeutic subgroups. ATC3 provides more refined classification based on specific therapeutic indications, i.e., their intended use. The ATC4 level is the most detailed one and for instance it distinguishes products by mode of action (e.g., distinction of some ATC3 classes into topical vs. systemic treatments depending on their way of treatment). ATC5 identifies the specific active chemical substances of medicinal products.

21. The CID observed that these five different levels of drugs classification systems are presented in Figure 1 below.

Figure 1: WHO ATC classification system[8]



[6] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[7] https://www.who.int/tools/atc-ddd-toolkit/atc-classification
[8] Ibid.

22. The CID observed that its previous decisional practice in ***MIC UAE/Kelix***[9] and ***DAWAA'A/Pharma Strategy***[10], it considered that pharmaceutical products within the same ATC classification level can constitute distinct relevant product markets, distinct from other classification levels. ATC3 classification groups pharmaceuticals based on their intended use, which can serve as a basis for market definition.

23. The CID noted that the pharmaceutical products supplied by Opella presented in the preceding paragraphs can potentially fall in different categorizations according to their intended use under the ATC classification system. The CID observed that Opella's products fall into OTC pharmaceutical products, vitamins, minerals, and dietary supplements, which are integral to consumer health, focusing on preventive and maintenance care. Their ATC classifications include *analgesics (N02), cough & cold preparations (R05), gastrointestinal treatments (A03), urologicals (erectile dysfunction drugs) (G04B), vitamins (A11), minerals (A12),* and d*ietary supplements (A16 – other alimentary tract and metabolism products).*

24. The CID noted that cough and cold preparations treat symptoms such as nasal congestion, runny nose, and cough, often containing combinations of decongestants, antihistamines and cough suppressants.[11]

25. The CID also noted that analgesics, or painkillers, include general analgesics and antipyretics that relieve various types of pain, from headaches to arthritis, by reducing inflammation or altering pain perception.[12]

26. The CID further noted men's sexual health pharmaceutical products, particularly those treating erectile dysfunction, fall under urologicals.[13] For instance, Opella sells Cialis (tadalafil), a medication primarily used to treat erectile dysfunction and symptoms of benign prostatic hyperplasia. The CID observed that medications, such as Opella's Cialis (tadalafil) address erectile dysfunction and symptoms of benign prostatic hyperplasia.[14]

27. The CID considered that given the differences in intended use, the pharmaceutical products supplied by Opella can be segmented into distinct product markets based on ATC3 classification or intended therapeutic use. The CID thus considered that the relevant segmentation should include analgesics and antipyretics, cough and cold preparations, gastrointestinal treatments, erectile dysfunction treatments,

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[9] Case File No. CCC/MER/03/12/2024, Decision of the 108th CID dated 11 July 2024 regarding the Proposed acquisition by MIC UAE Investments 1 RSC Limited of a 100% shareholding in, and sole control of, Kelix Bio Limited.

[10] Case File No. CCC/MER/12/31/2021, Decision of the 82nd CID dated 3 May 2022 regarding the Proposed Acquisition of Sole Control Over Pharma Strategy Partners GmbH by DAWAA'A Restricted Ltd

[11] https://www.mayoclinic.org/drugs-supplements/antihistamine-decongestant-and-anticholinergic-combination-oral-route/description/drg-20069979

[12] https://my.clevelandclinic.org/health/drugs/21483-analgesics

[13] See para. 45 of Case File No. CCC/MER/03/12/2024, decision of the 108th CID dated 11 July 2024.

[14] https://medlineplus.gov/druginfo/meds/a604008.html#:~:text=Tadalafil%20(Cialis)

vitamins and minerals and dietary supplements under which the products supplied by Opella in the Common Market fall.

28. The CID noted that the above identified potential segmentations present peculiar characteristics and intended use for each type of product such that substitution between these categorises is not possible. The CID thus observed that for instance, in the event of a 5 – 10% increase in the price of products under the cough and cold preparations, it was unlikely for a patient to shift and purchase an analgesics and antipyretics product given different intended usage.

29. Notwithstanding the potential narrower market segmentations based on their intended therapeutical use, the CID observed that the transaction does not result in any overlap between the activities of the merging parties. As such, the CID noted that any further segmentation of the pharmaceutical products for human consumption market will not alter the competitive assessment of this transaction.

30. To this end, the CID considered the relevant product market as the **supply of pharmaceutical products for human consumption, comprising OTC medicines, vitamins, minerals, and dietary supplements, with the potential for further segmentation by therapeutic use.**

Relevant Geographic Market

31. The Guidelines on Market Definition define the relevant geographic market as follows:

> "*The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas*".

32. The CID considered that the geographic market for the supply of pharmaceuticals for human consumption, such as OTC medicines, vitamins, minerals, and dietary supplements, is likely broader than the national market. The CID noted that most of these products are sourced from multiple suppliers operating outside the national markets. For instance, the CID noted from the parties' submission that Opella itself is primarily located outside of the Common Market and it exports the pharmaceutical products into the Common Market for further distribution. The CID observed that in Libya, Opella supplies its products to customers from its subsidiary Healthcare International, a company incorporated and based in France. The CID considered that entities located outside of the Common Market are able to effectively enter into and compete within the Common Market. The CID noted that suppliers from outside the national market actively participate in the supply of these products, justifying the identification of a broader market than national.

33. Similarly, in ***DAWAA'A and Pharma Strategy***[15], the CID considered that the geographic market for pharmaceutical products is likely to extend beyond national borders. The CID observed that pharmaceutical wholesale and retail distributors generally have the flexibility to source pharmaceutical products from multiple overseas jurisdictions, including countries outside the Common Market. The CID was of the view that these factors suggest that national markets do not impose strict barriers that would limit the supply of these products within individual Member States.

34. Further, while the CID acknowledged that the manufacturing and wholesale supply of pharmaceutical products may be subject to specific national-level regulatory requirements, such as certification and qualification criteria, the CID's decisional practice supports a broader geographic market definition. Similarly, in ***Africa Capital/Cipla***[16], the CID determined that the relevant geographic market for pharmaceuticals was COMESA-wide, given that a significant proportion of these products were sourced from various suppliers beyond national markets.

35. In view of the forging considerations and recognizing that the transaction under review does not raise competition concerns under any alternative market definition, the CID defined the relevant geographic market for the supply of pharmaceutical products for human consumption, comprising OTC medicines, vitamins, minerals, and dietary supplements with the potential for further segmentation by therapeutic use to be at least the Common Market.

Conclusion on Relevant Markets

36. For the purposes of assessing the proposed transaction, and without prejudice to the CID's approach in future similar cases, the CID has defined the relevant market as **the supply of pharmaceutical products for human consumption, comprising OTC medicines, vitamins, minerals, and dietary supplements with the potential for further segmentation by therapeutic use in at least Common Market.**

Consideration of Substantial Lessening of Competition or "Effect" Test

Market Shares and Concentration

37. The determination of market shares and concentration provides a first indication of whether a change in market structure could create or facilitate the exercise of market power. Market power is defined as the ability of a firm profitably to increase and sustain the price of a product above competitive levels or restrict output or reduce product quality independently of its competitors, customers, and consumers. The

[15] Case File No. CCC/MER/12/31/2021, decision of the 81st CID dated 3 May 2022.
[16] Case File No. CCC/MER/4/10/2023, decision of the 98th CID dated 12 October 2023.

Commission is unlikely to find concern in non-horizontal mergers, be it of a coordinated or of a non-coordinated nature, where the market shares post-merger of the new entity concerned in each of the markets concerned is below 30% and the sum of the market shares of the top three firms is less than 70%.[17]

38. The CID noted the parties' submissions that Opella has limited knowledge in relation to the competitive landscape in the Common Market since it operates only in Egypt, Tunisia and Libya. The CID further noted that given the absence of horizontal and vertical overlaps between the parties' activities, the proposed transaction will not result in any market share accretion or change in market structure.

39. The CID further noted the parties' submissions on the estimated market shares of Opella and its five largest competitors in the supply of OTC medicines, vitamins, minerals, and supplements in Egypt and Tunisia, being Member States where Opella has a local presence and sells its products, as presented in Tables 2 and 3 below.

Table 2: the target and its top competitors market shares in the supply of pharmaceutical products for human consumption, such as OTC medicines, vitamins, minerals, and dietary supplements in Egypt[18]

Competitors	Market shares (%)	
	Pre-merger	**Post-merger**
Haleon	[5-10]	[5-10]
Pharco	[5-10]	[5-10]
Amoun (APC)	[5-10]	[5-10]
Opella (the target)	***[0-5]***	***[0-5]***
AUG Pharma	[0-5]	[0-5]
Eva	[0-5]	[0-5]
Other players	[65-70]	[65-70]
Total	**100**	**100**

40. The CID observed that the competitive landscape of pharmaceutical products in Egypt, including in OTC medicines, vitamins, minerals, and dietary supplements, is characterized by a fragmented market structure. The CID observed the low level of concentration which confirmed the presence of intense competition within the sector.

[17] The COMESA Merger Assessment Guidelines paragraph 8.9.
[18] Confidentiality of information claimed by the parties.

41. The CID was of the view that the high level of market fragmentation suggested that the merged entity will continue to face competition pressures from the existing and new competitors in Egypt.

42. The CID noted the parties' further submissions on the target and its top competitors' estimated market shares in Tunisa, as presented in Table 3 below.

Table 3: the target and its top competitors market shares in the supply of pharmaceutical products for human consumption, such as OTC medicines, vitamins, minerals, and dietary supplements in Tunisia[19]

Competitors	Market shares (%)	
	Pre-merger	**Post-merger**
Opella (the target)	***[5-10]***	***[5-10]***
Recordati	[5-10]	[5-10]
Kaleon	[0-5]	[0-5]
Boiron	[0-5]	[0-5]
Pierre Fabre	[0-5]	[0-5]
Hikma Pharma	[0-5]	[0-5]
Other players	[70-75]	[70-75]
Total	**100**	**100**

43. The CID observed that the Tunisian market for pharmaceutical products, including OTC medicines, vitamins, minerals and dietary supplements, is highly fragmented.

44. The CID noted that despite Opella having the largest market shares in Tunisia, it still had relatively low market share. The CID was of the view that Opella will continue to face competitive pressure from other players such as Recordati, Boiron and Pierre Fabre. The CID further noted that the structure of the pharmaceutical market in Tunisia will remain unchanged.

45. The CID observed that Tunisia's pharmaceutical industry has been growing steadily, reaching a valuation of USD 1.5 billion in 2021.[20] Its strategic location near Europe and free trade agreements with Africa, the Middle East, and the European Union enhance its market accessibility. The CID further noted that there are over 120 pharmaceutical companies in Tunisia with 39 of them involved in drug manufacturing.[21] The leading pharmaceutical firms in Tunisia include Sanofi-Aventis, Pfizer, Inc., TERIAK Laboratory, UNIMED Laboratories, Adwya, SIPHAT, MEDIS, Taha Pharma, OPALIA PHARMA and Cytopharma. The CID further noted

[19] Confidentiality of information claimed by the parties.
[20] https://pharmchoices.com/full-list-of-pharmaceutical-companies-in-tunisia/
[21] Ibid.

that Tunisia is a major pharmaceutical player in Africa alongside Egypt, Morocco, South Africa, Kenya and Nigeria and it exports most of its pharmaceutical products to other Francophone countries in Africa and the Middle East.[22]

46. The CID considered that the merged entity will continue to face competition from numerous existing players and potential new entrants. The CID was therefore of the view that the proposed transaction was unlikely to negatively impact competition in the relevant market.

Consideration of Third-Party Views

47. In arriving at its determination, the CID also considered submissions from the national competition authorities of DRC, Egypt, Eswatini, Kenya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Tunisia, Zambia and Zimbabwe which confirmed the absence of competition and public interest concerns.

Determination

48. 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 will it be contrary to public interest. The CID further determined that the transaction is unlikely to negatively affect trade between Member States.

49. The CID, therefore, approved the transaction.

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

Dated this 25th day of March 2025

Commissioner Dr Mahmoud Momtaz (Chairperson)

Commissioner Lloyds Vincent Nkhoma **Commissioner Vipin Naugah**

[22] Ibid.