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Common Market for Eastern and Southern Africa

Case File No. CCC/MER/02/04/2024

Decision[1] of the 107th Meeting of the Committee Responsible for Initial Determinations Regarding the Proposed Acquisition of Control by AsterRx Holdings Over Allmed Medical Care Holdings Ltd.

ECONOMIC SECTOR: Health (Medical devices for dialysis)

20 May 2024

COMESA COMPETITION COMMISSION
20 MAY 2024

[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 Where possible, the information omitted has been replaced by ranges of figures or a general description.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 6 March 2024, the COMESA Competition Commission (the "**Commission**") received a notification for approval of the proposed acquisition of control by AsterRx Holdings ("**AsterRx**" or the "**acquiring firm**") over Allmed Medical Care Holdings Ltd ("**Allmed**" 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.

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The Parties

AsterRx (the "acquiring firm")

4. The parties have submitted that AsterRx is a Mauritian company and a special-purpose vehicle ultimately wholly owned and controlled by Alta Semper Ilera Fund I L.P ("**Alta Fund**"). Alta Fund is a limited liability partnership registered in Mauritius which is managed by Alta Semper Capital LLP ("**Alta Capital**"), a limited liability partnership registered in the United Kingdom.

5. The parties further submitted that AsterRx, Alta Fund, and Alta Capital, together "**Alta**" or the "**acquiring group**" is active in the pharmaceuticals market in the Common Market.

6. The acquiring group operates through the following entities with their respective activities, as presented in Table 1.

Table 1: The acquiring group entities and their respective activities within the Common Market

Member State	Name of Entity	Activity
Kenya	MyDawa (ION Kenya Ltd)	distribution of pharmaceutical products and personal care products
	MyDawa (ION Kenya Ltd)	Pharmacy/drug store- Retail sale of pharmaceutical products and personal care products (e.g., toothpaste, soap, and shampoo)
Uganda	Guardian Health Limited	Distribution of pharmaceutical products and personal care products
	Guardian Health Limited	Pharmacy/drug store- Retail sale of pharmaceutical products and personal care products (e.g., toothpaste, soap, and shampoo)

7. The parties have submitted that the pharmaceutical products distributed by the acquiring group are not intended for use in dialysis treatment nor in dialysis medical devices.

Allmed (the "target")

8. The parties submitted that Allmed is a corporation registered under the laws of England and Wales. Allmed, headquartered in the UK, operates a specialized and high-quality manufacturing facility for medical devices and pharmaceuticals for dialysis in Egypt, alongside its operations in Brazil and Germany. Allmed, along with its subsidiaries (collectively referred to as the "**target group**"), primarily

operates medical devices for dialysis and pharmaceutical products manufacturing subsidiary in Egypt, exporting a portion of its products to the Common Market.

9. The target group manufactures and supplies a wide range of medical devices for dialysis treatment, including dialyzers, bloodlines, fistula needles, acid concentrates, bicarbonate cartridges, and pharmaceuticals. The parties submitted that the pharmaceutical products for dialysis that the target is licensed to manufacture and supply include dextrose 5% injection, sodium chloride injection 0.9% injection, dextrose 5% & sodium chloride 0.9% injection, dextrose 5% & sodium chloride 0.45% injection, ringer's injection, lactated ringer's injection, heparin sodium (1ml ampoule), and sodium bicarbonate 650gm sachet.

10. Within the Common Market, the target group conducts its operations through various entities, each with distinct activities, as outlined in Table 2.

Table 2: The target group entities and their respective activities within the Common Market[2]

Member State	Name of Entity	Activity
Egypt	Allmed Middle East	Manufacturing of medical devices for dialysis
		Manufacturing of pharmaceutical products for dialysis
Ethiopia	Allmed Middle East	Supply of medical devices for dialysis
Kenya[3]	Allmed Middle East	Supply of medical devices for dialysis
Sudan	Allmed Middle East	Supply of pharmaceutical products for dialysis
Tunisia	Allmed Medical GmbH	Supply of medical devices for dialysis
Zambia	Allmed Middle East	Supply of pharmaceutical products for dialysis listed in para 10 above

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:

[2] Confidentiality of information claimed by the parties.
[3] The parties have submitted that the target group has suspended its activities in Kenya starting from financial year 2023.

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.*

12. The undertakings concerned have operations in two or more Member States. The undertakings concerned held a combined value of assets in excess of the threshold of USD 50 million in the Common Market and each of the parties held an asset value of more than USD 10 million in the Common Market. In addition, both of the parties did not hold more than two-thirds of their aggregate COMESA-wide value of assets from one and the same Member State.

13. The Commission 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

14. The parties submitted that the proposed transaction entails that AsterRx will acquire 85% of the share capital of Allmed while the current shareholder will remain with 15% shareholding. The parties further submitted that upon completion of the proposed transaction AsterRx will exercise a direct control over Allmed.

Competition Assessment

Consideration of the Relevant Markets

Relevant Product Market

15. Paragraph 7 of the Commission's Guidelines on Market Definition states that a *"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".*

16. The CID noted that the acquiring group is active in the distribution of pharmaceutical products not meant for treatment of dialysis and personal care products in Kenya and Uganda.

17. On the other hand, the target group, manufactures and supplies a wide range of medical devices for dialysis treatment, including dialyzers, bloodlines, fistula needles, acid concentrates, bicarbonate cartridges, as well as pharmaceutical products required for dialysis including dextrose 5% injection, sodium chloride injection 0.9% injection, dextrose 5% & sodium chloride 0.9% injection, dextrose 5% & sodium chloride 0.45% injection, ringer's injection, lactated ringer's injection, heparin sodium (1ml ampoule), and sodium bicarbonate 650gm sachet.

18. The CID limited its competitive assessment to the activities of the target group since the proposed transaction is not likely to affect the markets in which the acquiring group operates i.e., the acquiring group does not provide pharmaceutical products that are used by the target in respect of the treatment of dialysis.

The manufacturing and supply of medical devices and pharmaceuticals for dialysis

19. The target operates within the manufacturing and supply of medical devices utilized in renal (kidney) treatment therapies, along with associated pharmaceuticals required for dialysis. The kidneys perform a wide range of vital functions in the human body, including removing waste products and foreign chemicals from the blood, balancing water and electrolyte (salt) concentration, regulating blood pressure and acid-base balance, and producing hormones to support, inter alia, red blood cell production, and bone strength[4]. Renal Replacement Therapies ("RRT") are vital for patients grappling with kidney failures, a critical condition where the kidneys cease functioning adequately, necessitating treatments like dialysis or transplantation to sustain life[5].

20. Dialysis is a primary treatment for kidney failure which involves the removal of waste products and excess water from the blood[6]. Dialysis is an artificial process that performs the key functions of healthy kidneys: filtering the blood, controlling the blood's electrolyte composition, and balancing fluid levels[7]. It serves two categories of patients who require such therapies[8]: (i) chronic kidney disease/patients with an end-stage renal disease ("CKD") and (ii) acute kidney injury/patients facing a sudden kidney failure ("AKI").

21. CKD is usually caused by a long-term disease, such as high blood pressure or diabetes, that slowly damages the kidneys, resulting in permanent impairment over time, while AKI represents a sudden loss of kidney function, often reversible with appropriate intervention[9]. In both scenarios, compromised kidney function

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[4] https://comcom.govt.nz/__data/assets/pdf_file/0030/76269/Baxter-International-Inc-and-Gambro-AB-clearance-application-18-March-2013-public.PDF, accessed on 26 March 2024.
[5] https://www.anzdata.org.au/anzdata/for-patients/glossary-of-terms/, accessed on 26 March 2024.
[6] Ibid.
[7] https://ec.europa.eu/competition/mergers/cases/decisions/m6851_3812_2.pdf, accessed on 26 March 2024.
[8] Ibid.
[9] myhealth.alberta.ca accessed on 26 March 2024.

leads to the accumulation of toxins and waste products in the bloodstream, necessitating different therapeutic interventions.

22. The European Commission ("**EC**") identified three main therapeutic/dialysis treatments: peritoneal dialysis ("**PD**"), hemodialysis ("**HD**"), and continuous renal replacement therapy ("**CRRT**")[10].

23. The CID observed[11] that PD involves the introduction of dialysis fluid (known as dialysate) into the peritoneal cavity via a soft plastic tube called a PD catheter. PD is predominantly utilized in the treatment of chronic patients with CKD. HD entails the circulation of blood into a machine where it undergoes purification through an exchange with another fluid (dialysate or replacement fluid) across a membrane known as a dialyser, before being returned to the patient's body. HD is primarily employed in the treatment of chronic patients with CKD. CRRT employs similar principles of diffusion and/or convection to eliminate toxins and excess water from the blood while maintaining electrolyte (salt) balance. It is the primary treatment option for patients experiencing AKI.

24. The CID noted that these types of dialysis treatment use different medical devices and pharmaceutical products which play crucial roles in the dialysis process, helping to remove waste products and excess fluids from the blood in patients with kidney failure or impaired kidney function. The target's medical devices, which encompass dialyzers, bloodlines, fistula needles, acid concentrates, bicarbonate cartridges, and as well as pharmaceutical products, are utilized collectively in processes such as PD, HD, and CRRT. For instance,[12] pharmaceutical devices for PD comprise a small pumping machine known as a cycler, dialysate fluid bags, and various disposables like a transfer set that connects the catheter to the bag system. Pharmaceutical devices necessary for HD include a monitor, bicarbonates, concentrates, purified water, dialysers containing filtering membranes, bloodlines, tubing connecting the patient's bloodstream (via a fistula needle or catheter) to the machine. CRRT utilizes pharmaceutical devices including a dedicated CRRT monitor, dialysers, and bloodlines, which are often provided as a complete "set."

25. Bloodlines facilitate the connection between the patient's bloodstream, the dialyser, and the fluids. It is a critical component of haemodialysis equipment, used in the process of haemodialysis, a medical procedure for filtering waste and excess fluids from the blood when the kidneys are unable to perform this function adequately[13]. Fistula needles provide good blood flow for dialysis and are

[10] https://ec.europa.eu/competition/mergers/cases/decisions/m6851_3812_2.pdf, accessed on 26 March 2024.
[11] Ibid.
[12] https://ec.europa.eu/competition/mergers/cases/decisions/m6851_3812_2.pdf, accessed on 26 March 2024.
[13] Bloodline, accessed on 26 March 2024.

indicated for use in conjunction with connector of hemodialysis blood tubing set[14] while an acid concentrate is an essential component in the preparation of dialysis fluid, whereby the hemodialysis machine mixes liquid acid concentrate with powder bicarbonate concentrate and purified water[15].

26. A dialyzer is often referred to as an "artificial kidney", whose function is to remove the excess wastes and fluid from the blood when the patient's kidneys can no longer perform that task[16]. On the other hand, a bicarbonate cartridge is central to the dialysis fluid delivery system, offering a hygienic method of bicarbonate supply from a dry-concentrate cartridge, eliminating the risk of contamination and bacterial growth[17]. Preparation of fluids involves mixing two types of concentrate: acid concentrate, supplied in liquid form in bags, and base concentrate, generally bicarbonate-based and provided in powdered form in a cartridge. These concentrates are then diluted with pre-treated water under the supervision of the monitor.

27. The CID considered that from a demand perspective, medical devices and pharmaceutical products are different. While medical devices are the physical tools and equipment used directly in the dialysis treatment process, pharmaceuticals are medications and drugs administered to manage various aspects of kidney disease and its complications during dialysis. The CID observed that medical devices for dialysis are different from the pharmaceutical products used in the dialysis treatment process and therefore each can be classified as separate markets as medical devices for dialysis and pharmaceuticals for dialysis.

28. The CID considered that a further segmentation within the medical devices for dialysis and pharmaceuticals for dialysis can be made. For instance, within the medical devices segment; a bloodline functions as a tube connecting the patient to the dialysis machine, a fistula needle is used for accessing blood during hemodialysis while a bicarbonate cartridge is used in hemodialysis machines to regulate bicarbonate levels in the blood).

29. The above notwithstanding and given that there is no overlap in the activities of the parties, the CID considered that a further narrowing of the market was not necessary as any alternative market definition will not alter the competitive assessment with respect to **the Manufacturing and supply of medical devices and pharmaceuticals products for dialysis**. The CID noted that, similarly, the EC[18] has considered the possibility for further segmentation of each product market in terms of types of medical devices and consumables for dialysis although

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[14] Fistula needle, accessed on 26 March 2024.
[15] Acid concentrate, accessed on 26 March 2024.
[16] dialyzer, accessed on 26 March 2024.
[17] https://www.linkedin.com/pulse/bicarbonate-cartridge-one-step-towards-/
[18] Case No COMP/M.6851 - BAXTER INTERNATIONAL/ GAMBRO, para 26-39, Date: 22/07/2013

a precise market was not defined as the transaction was not likely to raise competition concerns.

30. Based on the foregoing assessment and without prejudice to the approach in similar future cases, the CID determined the relevant product markets as:

    a) **the manufacturing and supply of medical devices for dialysis; and**

    b) **the manufacturing and supply of pharmaceuticals for dialysis.**

Relevant Geographic Market

31. The Commission's Guidelines on Market Definition define the relevant geographic market as comprising:

    "...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"[19].

32. The CID noted that the target group has manufacturing facilities for medical devices and pharmaceuticals for dialysis (including dialyzers, bloodlines, fistula needles, acid concentrates, bicarbonate cartridges, and other pharmaceuticals) in Germany and Egypt, and export such products to Ethiopia, Kenya, Sudan, Tunisia, and Zambia. Further, the target group has a physical presence only in Egypt, but it does not have subsidiaries or territorial presence in the other COMESA Member States listed above but it exports some of its products to these Member States

33. The CID observed that Fresenius Medical Care AG & Co. KGaA, Baxter International Inc., B. Braun Melsungen AG, Nipro Corporation, DaVita Inc., MEDIVATORS Inc., Nikkiso Co. Ltd., Asahi Kasei Corporation, NxStage Medical Inc., etc. are among the top players in the manufacturing and supply of medical devices for dialysis globally[20].

34. The CID further observed that the major competitors of the target group in the manufacturing and supply of medical devices and pharmaceuticals for dialysis, include Fresenius Medical Care, based in Germany; Baxter International, based in the USA; BBraun Avitum, based in Germany; and Nipro Corporation, based in Japan. Further, these competitors export their medical devices for dialysis and

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[19] Paragraph 8

[20] https://www.skyquestt.com/report/dialysis-equipment-market#:~:text=Global%20Dialysis%20Equipment%20Market%20Insights,period%20(2023-2030) accessed on 29 March 2024.

pharmaceutical products for dialysis into the Common Market, particularly, Egypt, Ethiopia, Kenya, Sudan, Tunisia, and Zambia.

35. The CID also noted that the target group's connections to global markets is evidenced by its network of distributors across over 40 countries[21], including in the Common Market.

36. In view of the foregoing, the Commission considered the geographic scope for the manufacture and supply of medical devices for dialysis and pharmaceuticals for dialysis as likely to be broader than the Common Market and may extend to global given that manufacturers and sellers are global players. To this end, the CID determined the geographic scope for the relevant product markets as global.

Conclusion of Relevant Market Definition

37. For the purposes of assessing the proposed transaction, and without prejudice to its approach in future similar cases, the CID identified the relevant markets as the:

    a) ***the global market for the manufacturing and supply of medical devices for dialysis; and***

    b) ***the global market for the manufacturing and supply of pharmaceuticals for dialysis.***

Market Shares and Concentration

38. The CID considered the parties' submission of estimated market shares for competitors in the broader market for the supply of dialysis products market in the relevant Member States of the target's operation as follows.

Table 3: Estimated market share in the supply for dialysis products into the Common Market

Member State	Competitor Name	Product type	Estimated market shares (%)
Egypt	Fresenius Medical Care	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]
	Baxter International	Dialysis products	[redacted]
	BBraun Avitum	Dialysis products	[redacted]
	Nipro Corporation	Dialysis products	[redacted]

[21] https://allmedgroup.com/about/how-we-operate/, accessed on 29 March 2024.

	Total		100
Ethiopia	Fresenius Medical Care	Dialysis products	[redacted]
	Baxter International	Dialysis products	[redacted]
	BBraun Avitum	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]
	Total		100
Sudan	Baxter International	Dialysis products	[redacted]
	BBraun Avitum	Dialysis products	[redacted]
	Fresenius Medical Care	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]
	Total		100
Somalia	BBraun Avitum	Dialysis products	[redacted]
	Fresenius Medical Care	Dialysis products	[redacted]
	Nipro Corporation	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]
	Total		100
Tunisia	Fresenius Medical Care	Dialysis products	[redacted]
	Nipro Corporation	Dialysis products	[redacted]
	Baxter International	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]
	Total		100
Zambia	Fresenius Medical Care	Dialysis products	[redacted]
	Baxter International	Dialysis products	[redacted]
	BBraun Avitum	Dialysis products	[redacted]
	Allmed (the target)	**Dialysis products**	[redacted]

	Total	**100**

39. The CID observed that the target has a significant market share in Egypt ([redacted]%) while its market shares in the rest of the Member States is not significant, being less that [redacted]%. CID further noted that there is no product and geographic overlap in the parties' activities and their territorial nexus. Thus, the CID concluded that the existing market structure will not be altered following the proposed transaction.

40. The CID considered that the merged entity will continue to face significant competition from their competitors. Further, with there being no overlaps between the merging parties' activities, the proposed transaction will not result in market share accretion.

41. The CID also observed that global market for the supply of dialysis devices market was relatively fragmented and has a prevalent of competition from global players such as Fresenius Medical Care AG & Co. KGaA, Baxter International Inc., B. Braun Melsungen AG, Nipro Corporation, DaVita Inc., MEDIVATORS Inc., Nikkiso Co. Ltd., Asahi Kasei Corporation, NxStage Medical Inc[22].

42. In view of the foregoing, the CID considered that competition concerns were not likely to arise from the proposed transaction.

Consideration of Third-Party Views

43. In arriving at its determination, the CID also considered submissions from the National Competition Agencies of Egypt and Kenya which confirmed the absence of competition and public interest concerns.

Determination

44. 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.

45. The CID, therefore, approved the transaction.

[22] https://www.skyquestt.com/report/dialysis-equipment-market#:~:text=Global%20Dialysis%20Equipment%20Market%20Insights,period%20(2023-2030), accessed on 7 April 2024.

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

Dated this 20th day of May 2024

Commissioner Dr Mahmoud Momtaz (Chairperson)

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