COMESA Competition Commission
Kang'ombe House, 5th Floor
P.O. Box 30742
Lilongwe 3, Malawi
Tel: +265 111 772 466
Email - compcom@comesacompetition.org

Common Market for Eastern and Southern Africa

Case File No. CCC/MER/03/12/2024

Decision[1] of the 108th Meeting of the Committee Responsible for Initial Determinations Regarding the Proposed Acquisition by MIC UAE Investments 1 RSC Limited of a 100% shareholding in Kelix Bio Limited

ECONOMIC SECTOR: Pharmaceuticals

11 July 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 Where possible, the information omitted has been replaced by ranges of figures or a general description.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 30 April 2024, the COMESA Competition Commission (the "**Commission**") received a notification for approval of a merger involving MIC UAE Investments 1 RSC Limited ("**MIC UAE**" or the "**Primary Acquiring Firm**") and Kelix Bio Limited ("**Kelix**" or the "**Primary Target Firm**"), pursuant to Article 24(1) of the Regulations.

2. The proposed transaction concerns the acquisition by MIC UAE of a 100% shareholding in, and sole control of, Kelix. Immediately following the acquisition of Kelix by MIC UAE, and as part of an inter-related transaction, Kelix (through its wholly-owned subsidiary Kelix Bio Management (DIFC) Limited ("**Kelix UAE**")) intends to acquire: (a) 100% of the shares in Gulf Inject LLC ("**GI**"), Bioventure FZ LLC ("**BV**"), Bioventure Healthcare FZE ("**BVH**") and WellPharma Medical Solutions ("**WMS**") (together the "**GOHH Targets**"); and (b) 100% of the shares in Diabtec LLC ("**Diabtec**"). Kelix, the GOHH Targets and Diabtec are collectively referred to as the "**target firms**".

3. 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.

4. 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

MIC UAE (the acquiring firm)

5. The parties submitted that MIC UAE is an indirect wholly owned subsidiary of Mubadala Investment Company PJSC ("**Mubadala**"), a United Arab Emirates public joint stock company.

6. Mubadala is active in investing in a wide range of private and listed asset classes (e.g. private equity, ventures, growth, credit, real estate, infrastructure and listed equities). Mubadala's investment strategy is designed to build a resilient portfolio, diversified across asset classes and geographies. The MIC Group derives revenue from all COMESA Member States except Burundi, Comoros, Djibouti, Eritrea, and Seychelles. Mubadala and all firms controlled (whether directly or indirectly) by Mubadala are collectively referred to as the MIC Group.

7. The parties submitted that in the year 2023, the MIC Group had the following activities in the Common Market:

Table 1: MIC Group's activities in the Common Market

Member State	***Description of Activities***
*Democratic Republic of Congo ("**DRC**")*	*Broadband services*
Egypt	*Revenue is mainly derived from semiconductor wafer fabrication and sales of finished semiconductor wafers*
	Sales of gas condensate and sulphur
	Sale of gas
	Aircraft engine maintenance, repair and overhaul services
	Mobile and broadband services
	Banking services
	Distribution and marketing of petrochemical products
	Aluminium products
Ethiopia	*Mobile services*
Kenya	*Mobile and broadband services* *Distribution and marketing of petrochemical products*
Eswatini	*Broadband services*

Libya	*Mobile services* *Distribution and marketing of petrochemical products*
Madagascar	*Mobile services* *Distribution and marketing of petrochemical products*
Malawi	*Mobile services*
Mauritius	*Mobile services*
Rwanda	*Broadband services*
Somalia	*Mobile services*
Sudan	*Mobile and broadband services*
Tunisia	*Mobile services* *Operation and maintenance services to telecom operators* *Distribution and marketing of petrochemical products* *Aluminium products*
Zambia	*Mobile services*
Zimbabwe	*Broadband services*

8. It is noted that the CID has previously reviewed two transactions involving Mubadala as follows:

(a) The acquisition by Abu Dhabi National Energy Company - P.J.S.C. ("**TAQA**") of sole control, through a 43% stake, of Abu Dhabi Future Energy Company - P.J.S.C. ("**Masdar"**) (an entity wholly owned and controlled by Mubadala pre-merger[2]. Mubadala maintained a 33% interest in Masdar, and Abu Dhabi National Oil Company ("**ADNOC**") acquired the remaining non-controlling stake of 24%. The CID approved the merger, noting that the merger was not likely to substantially prevent or lessen competition in the generation and wholesale distribution of electricity in Egypt, being the relevant market identified in this transaction.

(b) The acquisition by ADNOC of a 24.9% shareholding in OMV Aktiengesellschaft ("**OMV**") and its direct and indirect subsidiaries from Mubadala Petroleum Petrochemicals Holding Company LLC ("**MPPH**"), a subsidiary of Mubadala. Post-merger, OMV would be jointly controlled by Österreichische Beteiligungs AG, one of the existing shareholders with 31.5% shareholding, and ADNOC. Mubadala thus exited OMV as a result of the transaction. The CID approved the merger as it was not likely to substantially prevent or lessen competition in the markets identified[3].

[2] Case File No. CCC/MER/08/36/2022- Proposed Acquisition of Sole Control of Abu Dhabi Future Energy Company – P.J.S.C. by Abu Dhabi National Energy Company – P.J.S.C. Decision issued on 19 December 2022

[3] The relevant markets identified were as follows as (i) the global exploration of oil and gas; (ii) the global wholesale supply of crude oil; (iii) the global production and supply of LPG; (iv) the supply of diesel in Egypt; (v) the supply of polypropylene and polyethylene, whose geographic scope was left open; and (vi) the global supply of urea.

Kelix (the primary target firm)

9. The parties submitted that the target firm, Kelix is a UK-incorporated, UAE-based biopharmaceutical business, which targets large, fast-growing and differentiated therapeutic areas through innovation and cost effectiveness. It focuses on selected therapy areas and product forms with high demand and growth potential such as oncology, diabetes, respiratory, inhalers, injectables and biosimilars. Kelix and all firms controlled (whether directly or indirectly) by Kelix are collectively referred to as "**Kelix Group**".

10. In COMESA, Kelix Group conducts its business operations through Adwia Pharmaceuticals ("**Adwia**"), a Cairo, Egypt based subsidiary of Kelix, and Celon Labs, an India-based subsidiary.

11. Adwia is a generics pharmaceutical company active in both the domestic market and exports. Adwia provides tailored treatments for both humans and animals, offering a wide range of products in various therapeutic classes. Adwia addresses over 10 therapeutic areas with brands in the central nervous system (CNS), men's health pain, and anti-infectives.

12. In the field of cardiovascular medications, Adwia produces drugs for hypertension (high blood pressure), anti-platelets (to prevent blood clotting), heart failure, lipid-lowering medications (to reduce cholesterol levels), and coronary medications (related to heart disease). For orthopedic conditions, Adwia offers non-steroidal anti-inflammatory drugs (NSAIDs) for pain relief, medications for neuropathic pain, and treatments for osteoporosis (a condition characterized by weak and brittle bones). In the urology segment, Adwia provides medications for benign prostatic hyperplasia (BPH), a condition that affects the prostate gland, and solutions for urinary incontinence (involuntary loss of urine).

13. Adwia also offers men's health products, including treatments for erectile dysfunction (difficulty achieving or maintaining an erection) and premature ejaculation. In the gastrointestinal category, Adwia produces medications such as anti-emetics (to prevent or relieve nausea and vomiting), antispasmodics (to relieve muscle spasms), and proton pump inhibitors (for the treatment of gastroesophageal reflux disease (GERD) and H. pylori infections). Adwia also manufactures Different classes of antibiotics for hospital-acquired infections and community-acquired infections, in addition to the production of central nervous system (CNS) solutions. Adwia holds an Egyptian Drug Authority license, which allows them to manufacture these medications at their facility located on the 10th of Ramadan City[4].

14. Celon Labs is a speciality pharmaceutical company that is at the forefront of research and manufacturing of high-quality, innovative and cost-effective formulations focused on oncology and critical care. Celon Labs commercialises over 110 oncology

[4] Adwia - Manufacturing

molecules and 85 critical care molecules. Its sales force covers over 2,500 hospitals across India. Additionally, it exports its products to over 40 countries across Latin America, Africa, the Middle East, the Commonwealth of Independent States (CIS) regions, and Southeast Asia.

15. The parties submitted that the Kelix Group has the following activities in the Common Market:

Table 2: Kelix's group activities in the Common Market

Member State	Description of Activities
Burundi	Human & Vet Medications
DRC	Human & Vet Medications
Djibouti	Human & Vet Medications
Egypt	Human & Vet Medications
Eritrea	Human & Vet Medications
Kenya	Human & Vet Medications
Libya	Human & Vet Medications
Mauritius	Human & Vet Medications
Sudan	Human & Vet Medications
Uganda	Human & Vet Medications
Zambia	Human & Vet Medications
Zimbabwe	Human & Vet Medications

GI, BV, BVH and WMS (the GOHH targets)

16. **GI** is a UAE-based manufacturer of sterile healthcare solutions for leading hospitals and healthcare facilities in the region. GI serves the United Arab Emirates and other Middle East markets with a portfolio of more than 65 products, including injectables, generic IV infusions, antibiotics, local anaesthetics, and hypertonic solutions to treat critical and chronically ill patients. GI's activities in the Common Market are through sales of intravenous infusion injectables and local anaesthetics, particularly in Libya and Sudan.

17. **BV** is a UAE-based biopharmaceutical company focused on biotech and a wide range of pharmaceutical activities. BV specializes in biotech and generics commercialization, technology transfer and in/out-licensing activities. BV's products include biosimilars, peptides, oncology, other therapeutic areas, and diabetes. BV out-licenses Adalimumab, Ustekinumab, Aflibercept, Golimumab, Denosumab, Pembrolizumab, Vedolizumab, Omalizumab, Ixekizumab, and Dupilumab. Under the license agreements, the licensees have an exclusive right to commercialize the products in each country of their territory. BV also supplies the products in bulk. For completeness, the parties submitted that specifically, BV has entered into sub-licensing agreements with licensees to provide an exclusive, royalty free right and license to use, market, promote distribute, store, repack, sell and import certain products as well as to use the dossier to obtain market authorization for the products

and to commercialize these products as a market authorization holder in the respective territories. The sub-licensing agreement grants the rights to the licensee upon payment of a lump sum amount as consideration, upon achieving or reaching certain milestones such as the obtainment of the market authorization.

18. The parties submitted that BV did not generate sales in COMESA in 2022. BV has as of June 2024 still not generated any revenue in the Common Market. BV applied for a marketing authorisation in the Common Market only in Egypt for Adalimumab through its sublicensee EVA Pharma.

19. **BVH** is a UAE-based pharmaceutical company producing dietary supplements and pharmaceutical products in soft gelatine capsules and gelatine enrobed tablets. BVH's product portfolio spans a wide spectrum of therapeutic areas, including biotech and generic pharmaceuticals, biosimilars, and target therapies. BVH has operations in one COMESA member state, namely Sudan, through the sale of vitamin D and cod liver oil.

20. **WMS** is a UAE-based pharmaceutical company that specializes in the production of intravenous ("**IV**") and dialysis products, as well as therapeutic products (including antipyretic, steroids and antiemetic). It offers a wide range of products and services, from generic drugs to biologics, from medical devices to diagnostics. WMS produces a total of 50 products, including 45 individual IV and dialysis products and 5 therapeutic products. WMS does not have any activities in the Common Market.

Diabtec (target firm)

21. The parties submitted that Julphar Diabetes Co LLC (**Julphar Diabetes**), upon completion of the proposed transaction will change its name to Diabtec LLC (**Diabtec**). Julphar Diabetes or Diabtec is a UAE-based entity, managing the manufacturing and commercialization of diabetes products including oral antidiabetics and insulin. In the Common Market, Diabtec is active in human medications (insulin products) in Libya and Tunisia.

Jurisdiction of the Commission

22. 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.*

23. The undertakings concerned have operations in two or more Member States. The undertakings derived a combined annual turnover in excess of the threshold of USD 50 million in the Common Market and both parties derived turnover of more than USD 10 million in the Common Market. In addition, the parties did not derive at least two-thirds of their respective aggregate COMESA-wide turnover within one and the same Member State. The Commission is thus satisfied that the transaction constitutes a notifiable transaction within the meaning of Article 23(5)(a) of the Regulations.

Details of the Merger

24. The parties submitted that the proposed transaction concerns the acquisition by MIC UAE and ultimately Mubadala, of a 100% shareholding in, and sole control of, Kelix from ADP III GP Limited ("**DPI**"), British International Investment PLC ("**BII**") and the European Bank for Reconstruction and Development ("**EBRD**") (together, the "**Kelix Sellers**"). Following the acquisition of Kelix by MIC UAE, and as part of an inter-related and inter-conditional transaction, Kelix (through its wholly owned subsidiary Kelix UAE), intends to acquire:

i. 100% of the shares in each of GI, BV, BVH and WMS from GOHH; and

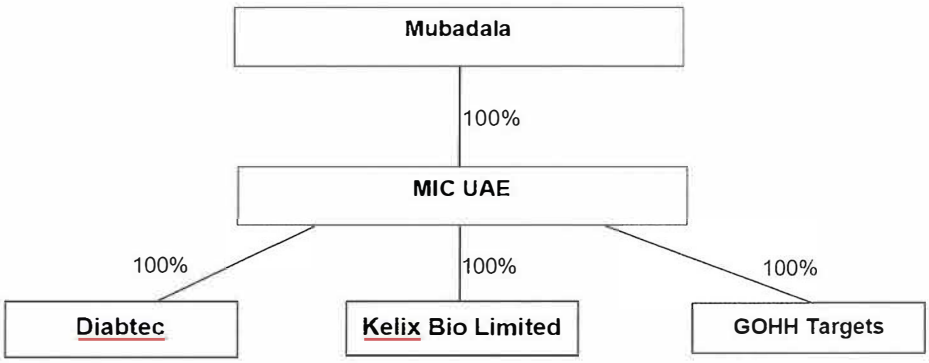
ii. 100% of the shares in Julphar Diabetes Co LLC (which as highlighted above will change its name to Diabtec). [5]

25. The acquisition of Kelix by MIC UAE is conditional on the execution of the GOHH Share Purchase Agreement (SPA) and the Julphar SPA. The acquisition of the GOHH Targets and Diabtec is therefore inter-related and inter-conditional with MIC UAE's acquisition of Kelix. Given that these transactions are conditional on each other, with the ultimate purchaser (at a group level) in each case being Mubadala, the Proposed Transaction constitutes a single concentration of unitary nature. The interconnected transaction is such that, MIC UAE will acquire 100% shareholding in Kelix. Kelix will then immediately acquire 100% shareholding in GOHH targets and Diabtec. MIC UAE will therefore control Kelix, the GOHH Targets and Diabtec.

26. Figure 1 below shows the intended structure of ownership and control after the completion of the merger.

[5] MIC UAE is only acquiring part of Diabtec LLC, namely a human insulin API plant.

Figure 1: The intended structure of ownership and control after the completion of the merger



27. The parties submitted the rationale for the proposed transaction, from the perspective of the acquiring and target firm, as follows:

    a) The proposed transaction will allow MIC UAE to expand its healthcare platform in North Africa and India and benefit from Kelix's expertise in the biopharmaceutical sector. The acquisition of the GOHH Targets and Diabtec will further expand the existing products portfolio of Kelix.

    b) The proposed transaction will provide Kelix, as well as the GOHH Targets and Diabtec, with a larger platform for growth and will facilitate their further development and expand innovation.

Competition Assessment

Consideration of the Relevant Markets

Relevant Product Market

28. Paragraph 7 of the COMESA Guidelines on Market Definition (the "**Market Definition Guidelines**") provides 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**".*

29. It is recalled that the acquiring group is an active investor in a wide range of private and listed asset classes (e.g. private equity, ventures, growth, credit, real estate, infrastructure and listed equities). Some of the acquiring group's activities in the Common Market include *inter alia*, provision of broadband services, mobile services, sales of gas condensate and sulphur, aircraft engine maintenance, repair and overhaul services, distribution and marketing of petrochemical products, aluminium products, and banking services.

30. It is further observed that within the Common Market, the primary target, Kelix is active in the manufacture and sale of human and vet medications. With regards to pharmaceutical products for human consumption, Kelix produces and sells:

a) Plain antispasmodics and anticholinergics (A3A)

b) Antiemetics and antinauseants (A4A)

c) Lipid regulators in combination with other lipid regulators (C10C)

d) Coronary therapy excl. calcium antagonists and nitrites (C1D)

e) Benign prostatic hypertrophy products (G4C)

f) Urinary incontinence products (G4D)

g) Erectile dysfunction products (G4E)

h) Anti-rheumatic, non-steroidal products (M1A), and

i) Anti-depressants and mood stabilisers (N6A).

31. GI manufactures and sells intravenous infusions injectables (such as Compound Sodium Lactate, Glucose 5%, Metronidazole I.V., Sodium Chloride 0.9% & Glucose 5%, Sodium Chloride 0.9%) and local anaesthetics.

32. BVH sells Dolcivit (Vitamin D3 (Cholecalciferol)) and Maxima Nutricod (Cod Liver Oil) while Diabtec is active in the supply of insulin products.

33. The CID noted that the status of Mubadala as a sovereign investor and that it holds interests in various companies globally. The CID took note of the parties' submissions that Mubadala does not have controlling shareholding interests in any company that has activities that are overlapping or complementary with those of the targets in the Common Market. The CID further noted the parties' submission that this investment is not being made in the knowledge or with the intention that it will create overlaps or synergies in the Common Market between the target and any of Mubadala's other controlled portfolio companies.

34. In view of the parties' submissions, given that the proposed transaction is not likely to affect the markets in which the acquiring group operates, the competitive assessment of this transaction focused on the activities of the target entities.

Pharmaceutical products

35. Pharmaceutical products also known as medicines or drugs are special preparations used in modern and traditional medicine that are essential for the prevention and treatment of diseases and the protection of public health.[6] Pharmaceutical products

[6] https://www.emro.who.int/health-topics/pharmaceutical-products/index.html

are chemical substances or compounds formulated to diagnose, treat, cure, prevent, or alleviate a medical condition or disease in humans or animals.

36. The CID has previously[7] 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-versa. Given this lack of substitutability between human and animal pharmaceutical products and coupled with the fact that Kelix is active in both the manufacturing and supply of human and animal pharmaceutical products, and further that the GOHH targets and Diabtec are active in pharmaceutical products for human consumption, the assessment focusses on both pharmaceutical products for human and animal consumption.

Pharmaceutical products for human consumption

37. Products within the broad pharmaceutical industry serve different purposes in terms of their therapeutic uses, and accordingly, not all products within the market for pharmaceutical products compete. The World Health Organization ("**WHO**") Anatomical Therapeutical Chemical ("**ATC**") classification system is a hierarchical and coded five-level system which classifies medicinal products according to their indication, therapeutic use, composition, and mode of action[8]. 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 indication, i.e. their intended use. 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[9].

38. The CID has previously held in ***DAWAA'A/Pharma Strategy (2022)***[10] that the products within a classification level can constitute distinct relevant product markets separate from the other classification levels. Pharmaceuticals at ATC3 class are grouped in terms of their therapeutic indication, i.e. their intended use. Using ATC3, the various pharmaceuticals produced by the target entities can be grouped in terms of their intended use as discussed below.

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[7] See paragraph 14 of Case File No. CCC/MER/12/31/2021: merger involving DAWAA'A Restricted Ltd and Pharma Strategy Partners GmbH

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

[9] https://www.who.int/tools/atc-ddd-toolkit/atc-classification.

[10] Case File No. CCC/MER/12/31/2021 Decision of the 82nd CID dated 3 May 2022.

Figure 2: WHO ATC classification system

39. According to WHO, plain antispasmodics and anticholinergics (A3A) are classified as drugs used to treat gastrointestinal disorders with examples being chlorbenzoxamine, trimebutine and alosetron.

40. *Antiemetics and antinauseants (A4A)* are medicines used to alleviate nausea and vomiting. Antiemetic drugs can help when nausea and vomiting stem from, for example: motion sickness, viral or bacterial infections- such as those responsible for the stomach flu, pregnancy, the effects of surgery, and other medications- such as chemotherapy. These medications work by blocking chemical messengers called neurotransmitters, which send information about nausea to the brain. Blocking their signals can keep a person from feeling nauseous and vomiting. Medicines such as antihistamines (used in motion sickness) can be classified here[11].

41. *Lipid regulators in combination with other lipid regulators (C10C)* are drugs that reduce levels of lipids (such as cholesterol and triglycerides) in the blood. Lipid regulators are also used to treat and prevent cardiovascular diseases, such as coronary artery disease, stroke, and peripheral artery disease, as well as to regulate homeostasis in lipid transport and metabolism through various signalling pathways,

[11] WHO ATC 2021 comparison Final 2021 for web site_0.pdf (ephmra.org)

to treat abnormal cholesterol levels[12]. Examples of medicines used as lipid regulators include atorvastatin, fluvastatin, lovastatin, pitavastatin,

42. *Coronary therapy excl. calcium antagonists and nitrites (C1D)* are medicines used to treat coronary artery disease or heart problems. These medicines are used to dilate blood vessels in people with coronary artery disease[13]. These medicines include dipyramidol, trimetazidine, ivabradine, and flosequinan[14].

43. *Benign prostatic hypertrophy products* are drugs used to treat a condition in which the flow of urine is blocked due to the enlargement of prostate gland. The symptoms include increased frequency of urination at night and difficulty in urinating. Benign prostatic hyperplasia is a health issue that becomes more common with age. An enlarged prostate can cause symptoms that may bother you, such as blocking the flow of urine out of the bladder. It also can cause bladder, urinary tract or kidney problems[15]. These medicines include alfuzosin, doxazosin, tamsulosin, prostate, dutasteride.

44. *Urinary incontinence Medicines (G4D)* are medicines used to treat Urinary incontinence (UI), also known as involuntary urination (uncontrolled leakage of urine)[16]. These medicines include xybutynin, myrbetriq and tolterodine.

45. *Erectile dysfunction products* are medications used to treat a consistent inability to sustain an erection sufficient for sexual intercourse. Medically, the term erectile dysfunction is used to differentiate impotence from other problems that interfere with sexual intercourse[17]. These medicines include sildenafil and tadalafil.

46. *Anti-rheumatic, non-steroidal products (M1A)* are drugs, which are used to treat the symptoms of rheumatoid arthritis and those that can modify the course of the disease. The drugs that help treat the symptoms such as pain and inflammation are aspirin, non-steroidal anti-inflammatory drugs. Drugs that can slow the progression of rheumatoid arthritis and help with pain, inflammation and stiffness are called disease modifying rheumatoid arthritis drugs[18]. These medicines include methotrexate, sulfasalazine and Hydroxychloroquine[19].

47. *Anti-depressants and mood stabilisers* are psychiatric medications used to treat mood disorders characterized by intense and sustained mood shifts, such as bipolar disorder[20] . They can help prevent manic episodes and depressive

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[12] Research progress in lipid metabolic regulation of bioactive peptides | Food Production, Processing and Nutrition | Full Text (biomedcentral.com)
[13] Calcium channel blockers - Mayo Clinic
[14] WHO ATC 2021 comparison Final 2021 for web site 0.pdf (ephmra.org)
[15] Benign prostatic hyperplasia (BPH) - Symptoms and causes - Mayo Clinic
[16] Adwia - Uripan XR
[17] List of 12 Erectile Dysfunction Medications Compared (drugs.com)
[18] List of Antirheumatics - Drugs.com
[19] Disease-Modifying Antirheumatic Drugs (DMARDS) (clevelandclinic.org)
[20] Bipolar disorder, previously known as manic depression, is a mental disorder characterized by periods of depression and periods of abnormally elevated mood that each last from days to weeks.

episodes. Antidepressants are medications used to treat depressive disorders. They work by increasing the levels of certain neurotransmitters in the brain[21]. These medicines include monoamine oxidase inhibitors and norepinephrine and dopamine reuptake inhibitors.

48. *Intravenous infusions* are fluids injected into a vein to prevent or treat dehydration. They're used in people of all ages who are sick, injured, dehydrated from exercise or heat, or undergoing surgery. These fluids include compound sodium lactate, glucose 5%, metronidazole I.V., sodium chloride 0.9% & glucose 5%, sodium chloride 0.9%[22].

49. *Local anaesthetics* are drugs which upon topical application or local injection cause reversible loss of sensory perception, especially of pain, in a restricted area of the body. They block generation and conduction of nerve impulse at all parts of the neurone where they come in contact, without causing any structural damage[23].

50. *Dolcivit (Vitamin D3 (Cholecalciferol)) and Maxima Nutricod (Cod Liver Oil)* are used as dietary supplements. Cholecalciferol is used as a dietary supplement in people who do not get enough vitamin D in their diets to maintain adequate health. Vitamin D is a nutrient that helps the body to absorb calcium, which is essential for bone health. Cod liver oil is a dietary supplement derived from liver of cod fish (Gadidae). As with most fish oils, it contains the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), and also vitamin A and vitamin D[24].

51. *Insulin* is a hormone that helps cells use glucose from food for energy and keeps blood sugar levels stable. Insulin products are medications that is used to treat diabetes. Diabetes is a condition characterized by sustained high blood sugar levels.

52. In view of the foregoing and noting the difference in intended use of the various pharmaceutical products supplied by the target entities, the different pharmaceutical products can be segmented into distinct markets based on ATC3 class or intended use. As such, using the ATC3 classification, it is possible to define distinct relevant products markets for plain antispasmodics and anticholinergics drugs, antiemetics and antinauseants; lipid regulators in combination with other lipid regulators; coronary therapy excl. calcium antagonists and nitrites; benign prostatic hypertrophy products; urinary incontinence medicines; erectile dysfunction products; anti-rheumatic, non-steroidal products; anti-depressants and mood stabilisers; intravenous infusions and local anaesthetics; and, dolcivit (Vitamin D3 (Cholecalciferol)) and Maxima Nutricod (Cod Liver Oil).

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[21] Mood Stabilizers vs Anti Depressants: Difference and Comparison (askanydifference.com)
[22] IV Fluids (Intravenous Fluids): Types & Uses (clevelandclinic.org)
[23] Local Anaesthetics - Classification, Chemistry, Mechanism of Action, Local Actions, Systemic Actions, Pharmacokinetics, Adverse Effects, Precautions, Interactions, Individual Compounds, Uses, Techniques | Pharmacology (pharmacy180.com)
[24] Vitamin D3: Health Benefits and Supplementation (verywellhealth.com)

Pharmaceutical products for animal consumption

53. The use of drugs in animals is fundamental to animal health and well-being and to the economics of the industry. However, drug use also is associated with human health effects[25]. Animal health products are mainly produced for the following groups of species: Ruminants (cattle, sheep and goats); Swine; Poultry (chickens and turkeys); Equine (horses); Companion animals (cats and dogs); and Aquaculture animals (farmed fish)[26].

54. The EC in its decisions has consistently divided animal health products into three main categories: (i.) biologicals (vaccines); (ii.) pharmaceuticals; (iii.) medicinal feed additives. The CID notes that the main activities of the parties relation to animal health are in the provision of pharmaceuticals for animal consumption as further discussed below[27].

55. Animal health pharmaceuticals are usually divided into: (i.) parasiticides- products that kill parasites that infest livestock, pets and other animals; (ii.) antimicrobials- including antibiotics, antivirals, antifungals, and antiparasitics – are medicines used to prevent and treat infectious diseases in humans, animals and plants[28]; (iii.) endocrine treatments- used to treat endocrine diseases which arise from several causes such as hormones being overproduced or underproduced, receptors malfunction, and normal pathways for hormone removal being disrupted[29]; (iv.) anti-inflammatory treatments- used to manage pain, inflammation, and high temperatures; and (v.) analgesics- used to relive pain[30]. The parties submitted that they produce animal medications which include but are not limited to medications under the following generic names, Doramectin (for the treatment of parasites such as gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites in cattle), Florfenicol (used as an antibiotic in veterinary medicine), Levamisole/ Abamectin (used to achieve fast animal curing), Erythromycin (used for the treatment of bacterial infections).

56. The EC has also previously held that when defining relevant product markets for the purposes of competition law in the area of animal health pharmaceuticals, the most important factors to be taken into account are the following[31].

    (i.) Animal species: Although many pharmaceuticals are multi-species, some are effective only for a particular species or group of species (such as companion animals).

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[25] Drugs Used in Food Animals: Background and Perspectives - The Use of Drugs in Food Animals - NCBI Bookshelf (nih.gov)
[26] m6205.doc (europa.eu)
[27] m5476_20090717_20212_en.pdf (europa.eu)
[28] Antimicrobial resistance (who.int)
[29] Endocrine Diseases in Animals - Endocrine System - Merck Veterinary Manual (merckvetmanual.com)
[30] m5476_20090717_20212_en.pdf (europa.eu)
[31] m5476_20090717_20212_en.pdf (europa.eu)

(ii.) Active substance: In some cases, the active substance is the main determinant for the product market definition, e.g. in antibiotics because the same active substance is effective against the whole range of pathologies.

(iii.) Target pathology/scope of effectiveness: Pathology is often at the core of the market definition. However, in some instances it is impossible to limit market demarcation to very narrowly defined pathologies. In the field of anti-microbials and parasiticides treatments against a single pathology may compete with alternative treatments that are effective against a whole spectrum of pathologies.

(iv.) Mode of administration: Most animal health pharmaceuticals are injectable (especially for production animals). For companion animals a large number of pharmaceuticals are administered orally (tablets, pastes and granules). There is a large number of additional modes of administration such as intra-mammary products for mastitis treatment in cows, anti-parasitic collars or spot-on drops for companion animals, etc.

(v.) Duration of efficacy: Farmers may demand products that remain active for long periods of time, usually for preventive purposes, e.g. anti-parasitic products or long-acting preventive antibiotics.

(vi.) Duration of the withdrawal period: For farm animals, the withdrawal period – i.e. the period after treatment during which an animal's meat or milk is deemed unsuitable for human consumption – is of large economic importance.

57. The CID notes that it is possible to further segment pharmaceuticals for animal consumption into distinct markets based on the factors highlighted above such as intended use, mode of administration etc.

58. Notwithstanding the possible segmentation within both human and animal pharmaceuticals into narrower submarkets, the CID observes that the transaction does not pose any overlaps between the activities of the targets and the acquirer, nor between the activities of the GOHH Target and Kelix. As such, any segmentation of the market will not alter the outcome of the competitive assessment.

59. The relevant product markets are hence construed as the manufacture and sale of the following:

i. Pharmaceutical products for human consumption such as plain antispasmodics and anticholinergics drugs, antiemetics and antinauseants, lipid regulators, coronary therapy, benign prostatic hypertrophy products, urinary incontinence medicines and erectile dysfunction products; and,

ii. Pharmaceutical products for animal consumption such as parasiticides, antimicrobials and endocrine treatments.

Relevant Geographical Market

60. The Commission's Market Definition Guidelines define the relevant geographic market as follows:

> ***"...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].

61. The EC has previously defined geographic markets for wholesale and retail pharmaceutical products as being national in scope, *inter alia* on the basis of the different national regulatory frameworks, authorisations procedures, reimbursement rules, governing different jurisdictions[33].

62. In its previous decisions[34], the CID has considered that the geographic market for pharmaceutical products was likely to be wider than national. The CID has considered that while licensing and importation restrictions differ per Member State, wholesale or retail distributors are not generally constrained in their ability to source products from a number of overseas jurisdictions, including outside the Common Market. In ***DAWAA'A/Pharma Strategy (2022)***[35]***,*** the CID 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.

63. 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 Egypt, Kenya, Uganda, and Zambia. Further, it is noted that the target, Kelix has a manufacturing plant in Cairo, Egypt, through which it manufactures and distributes pharmaceutical products both to wholesale and retail customers in Egypt as well as through exports to other countries. It is observed that key players in the pharmaceutical industry are generally multinational companies such as Sanofi, Roche, Pfizer and local companies such as Amoun, Pharco, EIPICO, Eva Pharmaall, all of which compete vigorously with the target firms.

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[32] Paragraph 8.
[33] Case No COMP/M.5778 – Novartis/Alcon, accessed at: m5778-6(2).doc (europa.eu)
[34] Case File No. CCC/MER/12/31/2021, CID decision in the merger involving DAWAA'A Restricted Ltd and Pharma Strategy Partners GmbH.
[35] *Ibid*

64. The above notwithstanding, the CID has also previously noted that the manufacturing and wholesale supply of drugs market may be constrained by qualification, certifications and regulatory requirements which may prevail at national level.[36]

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

Conclusion on Relevant Markets

66. On the basis of the foregoing assessment, and without prejudice to the CID's approach in similar future cases, the relevant markets are construed as the manufacture and sale of:

    i. Pharmaceutical products for human consumption such as plain antispasmodics and anticholinergics drugs, antiemetics and antinauseants, lipid regulators, coronary therapy, benign prostatic hypertrophy products, urinary incontinence medicines and erectile dysfunction products in a geographic market which is at least COMESA-wide; and,

    ii. Pharmaceutical products for animal consumption such as parasiticides, antimicrobials and endocrine treatments in a geographic market which is at least COMESA-wide.

Market Shares and Concentration

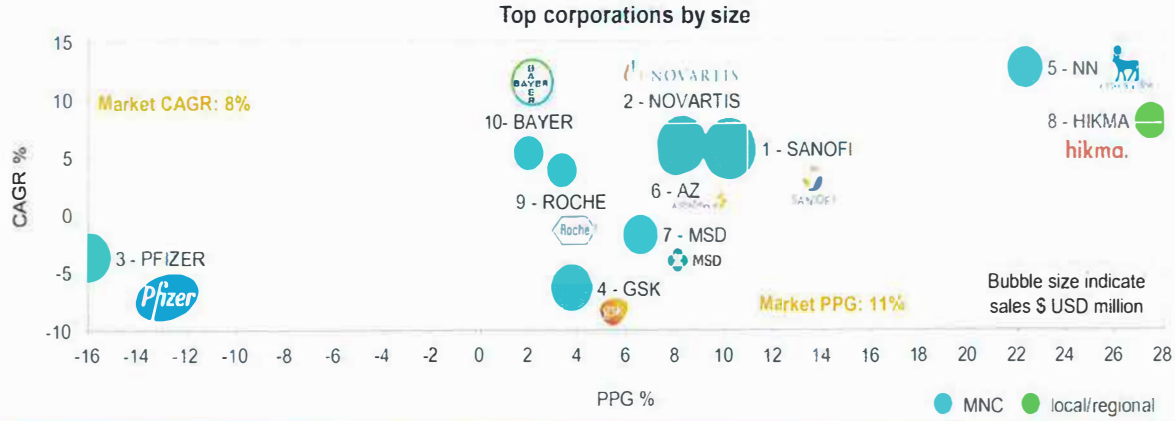
Pharmaceutical products for human consumption

67. According to IQVIA's Middle East and Africa Pharmaceutical Market Insights Report (2019), it was found that the major suppliers of pharmaceutical products in the Middle East and Africa (MEA) are as highlighted in the figure below[37].

[36] Case File. No. CCC/MER/4/10/2023, CID decision dated 12 October 2023 in the merger between Africa Capitalworks SSA 3 and Cipla Quality Chemical Industries Limited, paragraph 34.

[37] Middle East & Africa Pharmaceutical Market Insights (iqvia.com)

Figure 3: top 10 corporations in the pharmaceutical sector in MEA



Rank	Corporation	Sales[1]	Rank	Corporation	Sales[1]
1	SANOFI	1.675	6	AZ	698
2	NOVARTIS	1.410	7	MSD	685
3	PFIZER	1.075	8	HIKMA	590
4	GSK	996	9	ROCHE	524
5	NN	741	10	BAYER	506

[1]USD (M) MAT Q3 2018
Analysis based on Algeria, Egypt, Iraq, West Africa, Jordan, Kuwait, Lebanon, Morocco, Saudi Arabia, South Africa, Tunisia, UAE
Source: IQVIA Audited Data, MAT Q3 2018, includes IQVIA private, LPD, institutional data where available. Value sales at ex-factory price level without discount. Egypt sales at constant exchange rate and don't account for any currency fluctuation or devaluation
b: Base period MAT Q3 2017 Sales

68. The parties submitted their market shares and those of their main competitors, for the provision of various pharmaceutical products in Egypt, as per the table below.

Table 3: Market shares of the Kelix and its competitors in the provision of various pharmaceutical products in Egypt[38]

Market Player	Market Share
A3A ANTISPASM+ANTICHOL PLAIN	
Sedico	[20-30]%
Adwia	***[10-20]%***
Abbott	[10-20]%
Chemipharm	[10-20]%
Misr	[0-10]%
Others	[20-30]%
Total	**100%**
A4A ANTIEMETCS+ANTINAUSEANTS	
Adwia	***[40-50]%***
Nerhadou Int	[10-20]%
Globalpharma	[0-10]%
Merck & Co	[0-10]%

[38] IQVIA, 2023

Sunny Pharmaceutic	[0-10]%
Others	[20-30]%
Total	**100%**
C10C LIP.REG.CO.W.OTH.LIP.REG	
Marcyrl	[50-60]%
Xeedia Pharma	[20-30]%
Organon	[0-10]%
Pharmed Heal.Utopi	[0-10]%
Adwia	***[0-10]%***
Others	[10-20]%
Total	**100%**
C1D CORONRY THER EXC C AN+NI	
Servier	[60-70]%
Globalnapi	[10-20]%
Merck Kgaa	[0-10]%
October	[0-10]%
Adwia	***[0-10]%***
Others	[0-10]%
Total	**100%**
G4C BPH PRODUCTS	
Marcyrl	[30-40]%
Astellas Pharma	[10-20]%
Eva	[10-20]%
Adwia	***[10-20]%***
GSK	[0-10]%
Others	[20-30]%
Total	**100%**
G4D URINARY INCONTINENCE PRD	
Marcyrl	[20-30]%
Multiapex	[20-30]%
Astellas Pharma	[10-20]%
Adwia	***[10-20]%***
Fpi Utopia	[0-10]%
Others	[10-20]%
Total	**100%**
G4E ERECTILE DYSFUNCTION PRD	
Eva	[20-30]%
Adwia	**[10-20]%**
Lilly	[10-20]%
Viatris	[0-10]%
Multiapex	[0-10]%
Others	[20-30]%
Total	100%
M1A ANTIRHEUMATIC N-STEROID	
Novartis	[20-30]%

Kahira	[10-20]%
Minapharm	[0-10]%
Alexandria	[0-10]%
Pharco	[0-10]%
Adwia	***[0-10]%***
Others	[30-40]%
Total	**100%**
N6A ANTIDEPRESS & MOOD STAB	
Eva	[10-20]%
Lundbeck	[10-20]%
Fpi Utopia	[0-10]%
Novartis	[0-10]%
Multiapex	[0-10]%
Adwia	***[0-10]%***
Others	[50-60]%
Total	**100%**

69. The parties submitted that for the intravenous infusion injectables and local anaesthetics provided by the target GI in Libya and Sudan, market share data is not available. The parties however estimated GI's market shares to not exceed [0-10]% in the provision of the intravenous infusion injectables and local anaesthetics.

70. The parties submitted that with regards to Dolcivit (Vitamin D3 (Cholecalciferol)) and Maxima Nutricod (Cod Liver Oil) provided by the target BVH in Sudan, the market share data of competitors in respect of these products was not available. The parties however estimated the market shares of BVH to not exceed [0-10]% in the provision of Dolcivit and Cod Liver Oil.

71. With regards to the provision of insulin by Diabtec in Tunisia, the parties submitted the market shares as highlighted in the table below.

Table 4: Market shares of the Diabtec and its competitors in the provision of insulin in Tunisia

Market Player	Market Share
Novo Nordisk	[60-70]%
Sanofi	[20-30]%
Diabtec	***[0-10]%***
Medis	[0-10]%
Total	**100%**

Pharmaceutical products for animal consumption

72. With regards to the general market for pharmaceutical products for animal consumption, the parties submitted that Kelix does not have access to any databases

for animal health and is not aware of such data being available. The parties further submitted that Kelix's sales in this segment are very small and, in any case, would not amount to any significant market share.

73. The CID observes that the animal pharmaceuticals market is widespread, expanding itself to various regions including Asia-Pacific, Europe, North America, South America, and Middle East & Africa. North America has the largest market share by virtue of the pre-existing established pharmaceutical companies and the increasing consumption of meat and milk in the region. The major players in the global animal pharmaceutical sector are Zoetis Inc, Merck & Company Inc, Boehringer Ingelheim GmbH, Elanco Animal Health Inc., Vetoquinol SA, Virbac SA, Phibro Animal Health Corporation, Ceva Sante Animale S.A, Covetrus Inc., Biogenesis Bago SA, Neogen Corporation Ltd., Dechra Pharmaceuticals PLC, ImmuCell Corporation, Krka, tovarna zdravil, d. d., Novo mesto and ECO Animal Health Ltd[39].

74. From the tables above, the CID noted that while the acquisition of the different targets may enhance the product portfolio of the acquirer in the long run, having regard to the markets, the transaction is unlikely to result in significant change to the market structures in view of the absence of overlap between the acquirer and the targets, as well as between the GOHH Targets and Kelix, pre-merger.

75. While the market shares submitted by the parties for the narrower segments of the markets for the antiemetics and antinauseant drugs points to a significant market share of [40-50]% for the merging parties in Egypt, it is recalled that there will be no market share accretion post transaction. Pursuant to the implementation of the proposed transaction, the merged entity will continue to face competition from multinational companies such as Sanofi, Roche, Pfizer and local companies such as Amoun, Pharco, EIPICO, Eva Pharmaall, all of which compete with the target firms in the production of pharmaceutical products, and which will continue to exert competitive constraints on the parties post-transaction.

76. The CID noted that the pharmaceutical 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 at upstream level, and in terms of licensing and distribution network at downstream level. Notwithstanding the barriers to entry in the pharmaceutical sector, it is noted that the merger itself will not contribute to creating or heightening the barriers to entry in the relevant markets.

77. The CID further noted that through the transaction, the targets are likely to benefit from increased financial capacities which may improve its market position in the long run. However, it is unlikely that the proposed merger will result in the creation of a dominant position for the parties that would allow them to engage in unilateral

[39] Global Animal Pharmaceuticals Market Report 2021-2026 (prnewswire.com)

conduct in the market. It is similarly unlikely that the transaction would create incentives for collusive behaviour post-merger.

Consideration of Third-Party Views

78. In arriving at its determination, the CID also considered submissions from the National Competition Agencies of Eswatini, Kenya, Libya, DRC, Egypt, Mauritius, Madagascar and Zimbabwe which confirmed the absence of competition and public interest concerns.

Determination

79. 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.

80. The CID, therefore, approved the transaction.

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

Dated this 11th day of July 2024

Commissioner Dr Mahmoud Momtaz (Chairperson)

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