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PUBLIC VERSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

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Subject: **Case M.10997 – NB / ARDIAN / MEDIOLANUM / NEOPHARMED**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

[1] OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.

[2] OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

Dear Sir or Madam,

(1) On 31 January 2023, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which NB Renaissance Partners Holdings S.à r.l. ("NBRPH"), Ardian France S.A. ("Ardian"), and Mediolanum Farmaceutici S.p.A. ("Mediolanum"), through a jointly controlled special purpose vehicle, Neon Topco S.p.A. ("Topco"), will indirectly acquire joint control within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation of Neopharmed Holding S.p.A. and its 100% subsidiary Neopharmed Gentili S.p.A., as well as the latter's 100% subsidiary Valeas S.p.A (all together the "Target" or "NeoGen") (the "Transaction").[3] NBRPH, Ardian, and Mediolanum are referred to as the "Notifying Parties" (and together with the Target, as the "Parties").

1. THE PARTIES

(2) NBRPH is part of the Neuberger Berman group, which is ultimately controlled by Neuberger Berman Group, LLC ("NB LLC"). NB LLC is a US-based manager of equity, fixed income, private equity and hedge fund portfolios for institutions and advisors worldwide, which provides a broad range of investment solutions.

(3) Ardian is a French private equity company, which currently manages around USD 140 billion of assets worldwide. As a management company, Ardian manages and advises, through its subsidiaries, a number of investment funds, which have direct or indirect interests in numerous companies active around the world.

(4) Mediolanum is an Italian-based holding company. Mediolanum is active, through its subsidiaries, in the pharmaceutical and contract manufacturing organisation ("CMO") sectors, and, more marginally, in the (i) real estate, (ii) hotel and catering, and (iii) agriculture and farming sectors.

(5) NeoGen is an Italian pharmaceutical company engaged in the commercialisation of finished dose pharmaceuticals ("FDPs") and supplements in various therapeutic areas and, more marginally, in the sale of medical devices and cosmetics. NeoGen is currently subject to sole control by Ardian.

2. THE CONCENTRATION

Joint control

(6) Pursuant to a sale and purchase agreement ("SPA"), and a co-investment and shareholders' agreement ("SHA") entered into by the Parties on 8 November 2022, post-Transaction, the Target will be indirectly jointly controlled by: (i) NeonCo S.r.l. ("NeonCo"), a newly incorporated company indirectly and jointly controlled by NBRPH and Ardian on a 50%-50% basis,[4] which will be holding 86% of the

[3] Publication in the Official Journal of the European Union No C 048, 8.2.2023, p. 44.

[4] Pursuant to the Investment and Shareholders' Agreement relating to the investment in NeonCo, each of NBRPH and Ardian will have veto rights over a number of reserved matters, including (i) approving the budget and the business plan, as well as any material amendments or changes to or material deviations thereof, and (ii) appointing the managing director or CEO and other senior management of NeoGen. Form CO, Annex 13.

shares in the Target and (ii) Mediolanum, which will be holding the remaining 14% of the shares.[5]

(7) The SHA foresees a number of veto rights for Mediolanum, which in the context of this case, as described in paragraphs 8-10 below are equivalent to veto rights over the annual budget or the business plan. These veto rights will enable Mediolanum to exercise decisive influence in relation to the strategic business behaviour of the Target.[6]

(8) In particular, Mediolanum will have veto rights over any acquisition of companies, going concerns, licenses, rights to market and/or IP rights (including patents and trademarks) or joint-venture agreements relating to any of the Target's products, regardless of their value.[7] In light of the fact that in the pharmaceutical sector licensing of IP plays an important role and takes place rather frequently, e.g. in the context of licensing market authorisations,[8] the fact that Mediolanum has a veto over any IP license agreement by the Target regardless of the value of such agreement goes beyond the level of financial protection that is typically accorded to non-controlling minority shareholders.[9] Furthermore, the business plan of the Target provides for continued M&A activities in Italy, internationalisation and entry into new products by inorganic growth,[10] which would, according to the above-mentioned veto rights, also require the approval of Mediolanum.[11] Therefore, Mediolanum will enjoy veto rights over the concrete actions that are necessary to implement the business plan's set goals.

(9) Moreover, Mediolanum will have veto rights over the start, change or interruption of business lines of the Target that contribute more than EUR 1 million to the annual turnover of the Target, which according to the Notifying Parties, is also very important to remain competitive in the pharmaceutical market.[12] Indeed, despite the fact that no start or interruption of new business lines occurred in the past three years, the Commission considers that Mediolanum's veto rights over the Target's business lines appear even more important in the context of the current business plan, which includes: (i) new launches for the period 2022-2027 and (ii) the entry into new markets.[13]

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5 Form CO, paragraph 94 and Annex 12.

6 See Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (2008/C 95/01), paragraphs 67-68, 71 and 72.

7 Form CO, paragraph 69.

8 In response to a pre-notification RFI of 27 January 2023, Questions 2 and 5, the Notifying Parties listed past investments in intangible assets in the last three years, which included *inter alia* patents, trademarks, marketing authorisations etc, as well as the acquisition of rights to use the dossier of pharmaceutical products in the last five years, all of which would have been captured by Mediolanum's veto rights.

9 From CO, paragraphs 69 and 78.

10 Form CO, Annex 16, "Ardian Investment Memorandum", Chapter 6.

11 Mediolanum will also enjoy veto rights over any capital expenditure of a value exceeding EUR 1 million each or EUR 10 million as a whole per year. On the basis of NeoGen's capex relating to investments in 2021 and 2022, Mediolanum would indeed have the power of co-determination over the commercial policy of NeoGen. See Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (2008/C 95/01), paragraph 71.

12 Form CO, paragraph 79. In response to pre-notification RFI 3 of 23 January 2023, the Notifying Parties indicated that almost all of the Target's existing lines of business contribute more than 1 million euros to the Target Groups' annual turnover.

13 Form CO, Annex 16, "Ardian Investment Memorandum", Chapter 6.

(10) In addition, Mediolanum would have veto rights over the appointment and dismissal of managers with a gross salary exceeding EUR 500,000,[14] except for the CEO.[15] Despite the lack of a formal veto right over the CEO, the initial appointment of the CEO has been determined in the SHA[16] by both NeonCo and Mediolanum *[…]* while the subsequent CEO will be appointed based on the common will of all Notifying Parties.[17]

(11) Therefore, on balance, the Commission considers that each of the Notifying Parties will exercise joint control over the Target, within the meaning of Article 3(1)(b) of the Merger Regulation.

Full functionality

(12) The Target will be a full-function joint venture performing on a lasting basis all functions of an autonomous economic entity.[18] Firstly, NeoGen has sufficient resources to operate independently on the market with its own management and customers. Secondly, NeoGen has an autonomous presence on the pharmaceutical markets and its operations go beyond any specific function of the Notifying Parties. Lastly, NeoGen is already (since the 1970s') a full-function undertaking, designated to operate on a lasting basis.[19]

(13) In light of the above, the Target will be full-functional within the meaning of Article 3(4) of the Merger Regulation. The Transaction is thus a concentration within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation.

3. UNION DIMENSION

(14) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million (NBRPH: EUR *[…]*; Ardian, including NeoGen: EUR *[…]*; Mediolanum: EUR *[…]*; NeoGen: EUR 250.4 million, all in 2021)[20]. The aggregate EU-wide turnover of each of at least two of the undertakings concerned is more than EUR 250 million (NBRPH: EUR *[…]*; Ardian, including NeoGen: EUR *[…]*; Mediolanum EUR *[…]*; NeoGen: EUR *[…]*, all in 2021). Not each of the undertakings concerned achieves more than two-thirds of its aggregate EU-wide turnover within one and the same Member State.

(15) The Transaction therefore has an EU dimension according to Article 1(2) of the Merger Regulation.

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14 According to the Notifying Parties, there are no Target managers that currently earn a gross salary of more than EUR 500,000 per year, but it cannot be ruled out that in the near future the Target, if its successful growth continues as expected, could hire managers who will earn a gross salary exceeding such threshold. The Notifying Parties' Reply to RFI 3, dated 23 January 2023, Question 3.

15 Form CO, paragraph 69.

16 Form CO, Annex 12.

17 Form CO, paragraphs 85-89.

18 Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (2008/C 95/01).

19 Form CO, paragraph 64.

20 Turnover calculated in accordance with Article 5 of the Merger Regulation.

4. RELEVANT MARKETS

4.1. Activities of the Parties

(16) NeoGen[21] is engaged in the commercialization of FDPs and is also marginally active in the food supplements sector, over the counter ("OTC") pharmaceutical products, medical devices and cosmetics.

(17) Mediolanum operates in the pharmaceutical sector through its subsidiaries (i) Instituto Gentili S.r.l ("Istituto Gentili"), active in the commercialization of FDPs, (ii) Laboratoires Leurquin Mediolanum SA ("LLM"), active in the production and distribution of pharmaceutical products and food supplements in France, and (iii) Vamfarma S.r.l. ("Vamfarma"), acting as a CMO that manufactures FDPs on behalf of third-party pharmaceutical companies.

(18) The activities of the Parties give rise to horizontal overlaps in (i) the commercialization of FDPs and (ii) food supplements in Italy.[22] However, the Transaction does not give rise to any horizontally affected markets. As further explained in Section 4.2 below, one technically horizontal overlap would arise from the Parties' activities in the commercialization of FDPs at the ATC3 level,[23] class L03A ("*Immunostimolanting agents excluding interferons*") in Italy, where the Parties' combined market share would amount to *[70-80]%* in value (NeoGen: *[60-70]%*, Mediolanum: *[5-10]%*) and *[60-70]%* in volume (NeoGen: *[60-70]%*, Mediolanum: *[0-5]%*). In this class, NeoGen is active with the product Axil, used in the treatment of respiratory or urinary tract infections, while Mediolanum is present with the product Lonquex, which is used for the reduction of neutropenia as a possible complication of chemotherapy treatments. However, the products commercialized by NeoGen and Mediolanum belong to separate product markets, as further explained in section 4.2.1 below.

(19) The Transaction also gives rise to a series of vertically affected markets in relation to (i) Mediolanum's activities in the upstream market for CMO services (Table 1 below), and the (ii) the Target's activities in the downstream market for the commercialization of FDPs (Table 2 below).

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21 Besides NeoGen, the Ardian Group has a limited presence in the pharmaceutical sector through three of its portfolio companies: Sintetica S.A. ("Sintetica"), Biofarma S r.l. ("Biofarma"), Pranarom International S.A. ("Pranarom"). NBRPH does not control any company active in the pharmaceutical sector in Italy or elsewhere.

22 NeoGen has a limited portfolio of food supplements in Italy that do not give rise to any horizontally affected markets in relation to the activities of any of the Notifying Parties. The Commission has previously analysed food supplements in the context of consumer health products, on the basis of the International Consumer Health Classification ("ICH" classification) and with a national scope of the market. Based on this classification, the Notifying Parties submit that the Parties' market shares across all classes in Italy remain well below *20%* in terms of both volume and value. Form CO, paragraphs 160 *et seqq.* See Case COMP/M.6162 – *Pfizer / Ferrosan Consumer Healthcare Business*, decision of 9 June 2011, paragraph 11 (and the precedents cited therein).

23 See paragraph 21 of the present decision, for an explanation of the ATC level classification.

4.2. Finished Dose Pharmaceuticals

4.2.1. Product market definition

(20) FDPs are pharmaceutical products that have undergone all stages of production, including packaging in the final container and labelling. Production and sale of FDPs is one of the most common activities of pharmaceutical companies.

(21) To define the relevant product markets regarding FDPs, the Commission has previously used[24] the Anatomical Therapeutic Classification ("ATC") of the European Pharmaceutical Marketing Research Association. The first level (ATC 1) is the most general and the fourth level (ATC 4) the most detailed. More specifically, the Commission referred to the ATC3 level[25], where pharmaceuticals are grouped in terms of their therapeutic indications, *i.e.* their intended use, as the starting point for defining the relevant product market, since these groups of products generally have the same therapeutic indication and cannot be substituted by products belonging to other ATC 3 classes.

(22) However, the Commission has also recognised[26] that it may be appropriate, to carry out analyses at the narrower classification level ATC4[27], or possibly at the level of groups of molecules or individual molecules. Relevant factors to take into account include therapeutic (*e.g.* prescription only, or administration allowed only under medical supervision) or pharmacological criteria such as molecule class, formulation or mode of administration.

(23) The Notifying Parties submit that the product market definition can be left open because irrespective of the exact scope of the relevant product market, no competition concerns would arise. The Notifying Parties further submit that, even in the only FDP ATC3 level where the Parties' activities technically overlap horizontally (class L03A), NeoGen's Axil product and Mediolanum's Lonquex product (i) fall under different ATC4 classes, and (ii) are not substitutable.

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24 Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraphs 7-8; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraph 7. See also Case COMP/M.7559 – *Pfizer / Hospira*, decision of 4 August 2015; Case COMP/M.7480 – *Actavis / Allergan*, decision of 16 March 2015; Case COMP/M.6969 – *Valeant Pharmaceuticals International / Bausch&Lomb Holdings*, decision of 5 August 2013; Case COMP/M.6258 – *Teva / Cephalon*, decision of 13 October 2011; Case COMP/M.5778 – *Novartis / Alcon*, decision of 9 August 2010; Case COMP/M.5555 – *Novartis / EBEWE*, decision of 22 September 2009; Case COMP/M.5253 – *Sanofi-Aventis / Zentiva*, decision of 4 February 2009; Case COMP/M.5295 – *Teva / Barr Pharmaceuticals*, decision of 19 December 2008; Case COMP/M.4402 – *UBC / Schwarz Pharma*, decision of 21 November 2006; Case COMP/M.3751 – *Novartis / Hexal*, decision of 27 May 2005; Case COMP/M.1878 – *Pfizer / WarnerLambert*, decision of 22 May 2000; Case COMP/M.1846 – *GlaxoWellcome / SmithKline Beecham*, decision of 8 May 2000.

25 ATC3 level classification is narrower than ATC1 and ATC2 level classifications. At ATC1, drugs are divided into 16 anatomical main groups. At ATC2, drugs are divided at pharmacological or therapeutic groups.

26 Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraph 7; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraph 7. See also Case COMP/M.7559 – *Pfizer / Hospira*, decision of 4 August 2015; Case COMP/M.7480 – *Actavis / Allergan*, decision of 16 March 2015; Case COMP/M.5865 – *Teva / Ratiopharm*, decision of 3 August 2010; Case COMP/M.4314 – *Johnson & Johnson / Pfizer Consumer Healthcare*, decision of 11 December 2006; Case COMP/M.3354 – *Sanofi-Synthelabo / Aventis*, decision of 26 April 2004.

27 ATC4 level classification is typically based on mode of action or mode of administration of the drugs.

Therefore, according to the Notifying Parties, the Transaction does not give rise to any horizontal overlap among the Parties' activities in FDPs in Italy.[28]

(24) The Commission did not find any reason to depart from the approach analyzed in paragraphs 21-22 above for the purposes of this decision.

(25) According to the Notifying Parties,[29] ATC3 class L03A comprises *"Immunostimulating agents excluding interferons"* and is subdivided into two ATC4 categories: (i) L03A1, which includes colony-stimulating factors used to stimulate the formation of blood cells, in particular white blood cells, and (ii) L03A9, which includes all other immunostimulating agents. At ATC4 level, NeoGen's product Axil falls under the latter category, while Mediolanum's product Lonquex belongs to the former.

(26) The Commission notes that both products, namely Axil and Lonquex, differ in terms of pharmaceutical form, therapeutic indications, method of administration, distribution channel and cost. Lonquex is prescribed for the reduction of neutropenia,[30] which is a possible complication of chemotherapy treatments. It is a solution for injection and is mainly distributed through hospitals. The price for one dose of Lonquex is EUR 1 300. Axil, in turn, is prescribed for respiratory or urinary tract infections. It is sold in packets of sachets to be dissolved in water for swallowing. It is distributed via retail channels (*i.e.* pharmacies) and costs around EUR 30 for a package of 30 sachets.[31]

(27) During the Commission's pre-notification investigation, the main competitors of NeoGen and Mediolanum confirmed that Mediolanum's product Lonquex does not exert any competitive pressure on NeoGen's product Axil (or the respective competitors' products present on the market) and vice versa. As the main competitor of NeoGen's product Axil stated, "*Lonquex is not a competitor of Axil because Pidotimod is not a molecule in the treatment of oncological diseases*".[32] In the same vein, the main competitor of Mediolanum's product Lonquex explained that "*NeoGen's product Axil has a different therapeutic indication, mechanism of action, and is used in a different phase of treatment*" and "*cannot be used as a substitute for Amgen's product belonging to ATC4 level L03AA class*".[33]

(28) In light of the above and for the purpose of this decision, the Commission considers that NeoGen's product Axil and Mediolanum's product Lonquex belong to separate product markets. As far as the other FDPs the Target is active in and are relevant in the context of the present Transaction, *i.e.* in the context of vertically affected markets described in Table 2 below, are concerned, the exact product

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28 Form CO, paragraphs 133 *et seqq*.

29 Form CO, paragraph 219.

30 Low levels of neutrophils in the blood.

31 Form CO, paragraphs 151 *et seqq*.

32 Minutes of call with a competitor, dated 13 January 2023.

33 The competitor is referring to the World Health Organisation (WHO) classification of pharmaceutical products, which is very similar to EphMRA classification and can be considered as equivalent to ATC4 level L03A1 class for the purpose of this case. As stated in the Parties' reply to RFI 2 of 12 January 2023, Lonquex falls, in both systems, in the "Colony stimulating factors" category ("L3A1" in the EphMRA system and "L03AA" in the WHO system), while Axil is classified by both systems in the category "Other immunostimulants" (L3A9 "All other immunostimulating agents excluding interferons" in the EphMRA system and L03AX "Other immunostimulants" in the WHO system). Therefore, regardless of the classification system adopted, Axil and Lonquex fall in different ATC4 classes.

market definition can be left open, as the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA Agreement under any plausible product market definition (*i.e.* ATC3 or ATC4).

4.2.2. Geographic market definition

(29) In its past practice, the Commission defined the relevant geographic market for FDPs as national in scope due to the regulatory barriers, which result *inter alia* from the national reimbursement systems of the EU Member States.[34]

(30) In line with the Commission's practice, the Notifying Parties submit that the market for the commercialization of FDPs should be defined at the national level.[35]

(31) For the purpose of the present decision, the Commission considers that the geographic market for the commercialization of FDPs is national in scope.

4.3. Contract Development and Manufacturing Organisation services

4.3.1. Product market definition

(32) CDMO is an arrangement under which a manufacturer provides upstream manufacturing services of FDPs and active pharmaceutical ingredients ("APIs") under contract on behalf of third party pharmaceutical companies, which may or may not include packaging.[36]

(33) In the past, the Commission considered the existence of a market for the supply of CDMO services for APIs distinct from the market for the supply of contract manufacturing for FDPs.[37] With regard to the CDMO market for FDPs, further segmentations were considered on the basis of (i) the pharmaceutical form manufactured (*e.g.* solid, semi-solid, injectable); (ii) the conditions of manufacture (e.g. toxicity, sterile environment); (iii) the type of API used for its production; (iv) the delivery mechanism used (e.g. swallowing, intravenous, injection), and (v) between the supply of dosage formulation and development services (CDO) and of contract manufacturing services (CMO).[38]

(34) The Notifying Parties submit that the relevant product market should be defined as encompassing all CDMO services offered to pharmaceutical companies for FDPs,

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34 Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraph 41; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraphs 11-12. See also Case COMP/M.7480 – *Actavis / Allergan*, decision of 16 March 2015; Case COMP/M.6969 – *Valeant Pharmaceuticals International / Bausch&Lomb Holdings*, decision of 5 August 2013; Cases M.10247 – *CVC / COOPER*, para 41; M. 9461 – *AbbVie/Allergan*, para. 13; M.7919 – *Sanofi/Boehringer Ingelheim Consumer Healthcare Business*, paragraph 24; M.7645 – *Mylan/ Perrigo*, paragraph 23.

35 Form CO, paragraph 139.

36 Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraph 13; Case M.8541 – *Thermo Fisher Scientific / Patheon*, decision of 23 August 2017, paragraph 46.

37 Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraphs 150-152; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraphs 14-16; Case M.9315 – *Chr. Hansen / Lonza / JV*, decision of 16 July 2019, paragraph 17; Case M.8541 – *Thermo Fisher Scientific / Patheon*, decision of 23 August 2017, paragraphs 46-48; Case M.8362 – *Lonza Group / Capsugel*, decision of 21 April 2017, paragraphs 15-19.

38 ` Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraphs 150-152; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraphs 15-16; Case M.9315 – *Chr. Hansen / Lonza / JV*, decision of 16 July 2019, paragraphs 20-23.

without any further segmentation, given that irrespective of whether the market comprises both CMO and CDO or whether CDO should be considered separately, the Transaction does not raise any doubts as to its compatibility with the internal market.[39]

(35) The Commission considers that, for the purpose of the present decision, the exact product market definition for the supply of CDMO services can be left open since the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the functioning of the EEA Agreement irrespective of whether the market is defined as encompassing all CDMO services or is segmented by type of services.

4.3.2. Geographic market definition

(36) In previous decisions, the Commission has found the relevant geographic market for CDMO services to be worldwide or at least EEA-wide, as CDMO services are generally procured anywhere in the EEA, regardless of the EEA country where the pharmaceutical products are subsequently marketed, given the economics of the services under consideration, as well as the lack of any trade or other barriers.[40]

(37) The Notifying Parties submit that the relevant geographic market for CDMO services is EEA-wide, if not wider, in scope. The Notifying Parties further argue that even in the narrowest plausible geographic market definition, the Transaction would not give rise to serious doubts as to its compatibility with the internal market.[41]

(38) For the purpose of the present decision, the geographic market definition can be left open, since irrespective of whether the market for CDMO services and its plausible segmentations is EEA-wide or global in scope, the Transaction does not raise serious doubts as to its compatibility with the internal market or the EEA Agreement.

5. COMPETITIVE ASSESSMENT

(39) The market for the supply of CDMO services is upstream to the market for the commercialisation and supply of FDPs. Mediolanum provides services upstream through its subsidiary Vamfarma S.r.l. Mediolanum's market share is below *[0-5]%* in the EEA under any plausible product market definition, including CMO, CDO services and their potential sub-segments, as indicated in Table 1 below.[42]

39 Form CO, paragraphs 187 and 191.

40 Case M.10247 – *CVC / Cooper*, decision of 22 October 2021, paragraphs 154-157; Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraphs 17-18; Case M.9315 – *Chr. Hansen / Lonza / JV*, decision of 16 July 2019, paragraphs 24-27; Case M.8541 – *Thermo Fisher Scientific / Patheon*, decision of 23 August 2017, paragraphs 49-50; Case M.8362 – *Lonza Group / Capsugel*, decision of 21 April 2017, paragraph 21.

41 Form CO, paragraph 198.

42 Form CO, paragraphs 192-194.

Table 1: Mediolanum's market shares in the CDMO market in the EEA, 2021

Relevant Market Segment	Relevant Market Sub-segment	Mediolanum's market share in the EEA
CDMO for FDPs	-	Below *[0-5]%*
CDMO for FDPs segmented by their pharmaceutical form	Solid and powder	Below *[0-5]%*
	Semi-solid	Below *[0-5]%*
	Liquid	Below *[0-5]%*
	Injectables	No activities
	Sterile liquid pharmaceuticals	No activities
	Medicated confectionary pharmaceuticals	Below *[0-5]%*
CDMO for FDPs segmented by the conditions of manufacture	Toxicity	No activities
	Sterile environment	No activities
CDMO for FDPs segmented by the type of API used	Chemically-synthesized APIs	No activities
	Biopharmaceutical APIs	No activities
CDMO for FDPs segmented by the delivery mechanism used	Swallowing	No activities
	Inhalation	No activities
	Intravenous injection	No activities
CMO services (*i.e.* excluding the development aspect of the service)	Solid and powder	Below *[0-5]%*
	Semi-solid	Below *[0-5]%*
	Liquid	Below *[0-5]%*
	Sterile liquid pharmaceuticals	No activities
	Medicated confectionary pharmaceuticals	Below *[0-5]%*

Source: Form CO, paragraph 194.

(40) In the downstream market, and as further analysed above in paragraphs 20-31, the Target is active in several FDPs in Italy, with a market share that exceeds 30% in four ATC3 classes and in ten ATC4 classes, therefore giving rise to vertically affected markets. Table 2 below provides an overview of the affected FDPs downstream.

Table 2: NeoGen's market shares for FDPs at ATC3 and ATC4 level in Italy, 2021

ATC3 level			
Class	Description	Volume (units sold)	Value (Eur)
C04A	Celebral and peripheral vasotherapeutics	*[40-50]%*	*[50-60]%*
L03A	Immunostimolanting agents excluding interferons	*[60-70]%*	*[60-70]%*
N06C	Psycholeptics and psychoanaleptics combination	*[50-60]%*	*[60-70]%*
R03L	Anticholinergic in combination with B2-Agonist	*[30-40]%*	*[5-10]%*
ATC4 level			
C03A1	Potassium-sparing agents plain	*[30-40]%*	*[50-60]%*
C03A5	Potassium-sparing agents with thiazide and/or analogue combination	*[90-100]%*	*[50-60]%*
C04A1	Cerebral and peripheral vasotherapeutics excluding calcium antagonists with cerebral activity	*[60-70]%*	*[70-80]%*
C05A2	Topical anti-hemorrhoidal without corticosteroids	*[40-50]%*	*[40-50]%*
C10A9	All other cholesterol/trygliceride regulators	*[20-30]%*	*[30-40]%*
L03A9	All other immunostimolanting agents excluding interferons	*[70-80]%*	*[70-80]%*
R01A4	Nasal anti-infectives without corticosteroids	*[40-50]%*	*[30-40]%*
R03A2	All other immunostimolanting agents excluding interferons	*[80-90]%*	*[80-90]%*
R03A4	Short-acting B2-agonists, inhalant	*[20-30]%*	*[30-40]%*
R03L1	Short-acting anticholinergic in combination with shortacting B2-Agonists, inhalant	*[80-90]%*	*[80-90]%*

Source: Form CO, Tables 2 and 3.

(41) The Notifying Parties submit that they would have neither the ability nor the incentive to engage in any input or customer foreclosure because of their negligible market position upstream and their negligible share of total demand for CDMO services in the EEA downstream.[43]

[43] Form CO, paragraphs 195-196, and 262-263.

(42) According to the Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation, for input foreclosure to be a concern, the vertically integrated firm resulting from the merger must have a significant degree of market power in the upstream market.[44] The Commission considers that the Transaction does not raise concerns in relation to an input foreclosure theory of harm. Given (i) that Mediolanum's market share in the overall market for CDMO services for FDPs, as well as under all plausible sub-segmentations upstream, is below *[0-5]%*, and (ii) that the Target's demand for CDMO services represents less than *[0-5]%* in the EEA, input foreclosure appears unlikely.

(43) In addition, the Commission considers that the Transaction does not raise concerns in relation to a customer foreclosure theory of harm. Despite the fact that the Target's market shares are high on several downstream markets as set out in Table 2 above, those markets only account for a fraction of the overall EEA-wide demand for CDMO services. Indeed, the potential opportunity for the CDMO services linked to NeoGen's activities is low, given that NeoGen's demand vis-à-vis Mediolanum for such services would in any event be less than *[0-5]%* of the potential market for CDMO services for FDPs in the EEA. In particular, NeoGen's high market shares downstream will not give the Parties sufficient market power to harm rival upstream CDMO services providers. This is because the needs for CDMO services for FDPs are not differentiated according to the specific pathology covered by each specific FDP.[45] Therefore, CDMO services providers generally offer the same services for all FDPs. Consequently, this limited potential demand for CDMO services by NeoGen would not allow the Parties to foreclose their rival CDMO services providers upstream from accessing customers in the downstream markets for FDPs by withholding or reducing NeoGen's purchases (which are in any event limited). The results of the Commission's market outreach support this finding, as none of the contacted players raised any issue in relation to possible customer foreclosure.[46] On the basis of the above considerations, any customer foreclosure appears unlikely.

(44) In light of the above, the Commission concludes that the Transaction does not give rise to serious doubts as to its compatibility with the internal market or the EEA Agreement as a result of an input or customer foreclosure with regard to CDMO services for FDPs (upstream) and the commercialisation and supply of FDPs (downstream).

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44 Commission Guidelines on the assessment of non-horizontal mergers under the Merger Regulation (OJ C 265, 18.10.2008), paragraph 35.

45 In the same vein, see Case M.9995 – *Permira / Neuraxpharm*, decision of 4 December 2020, paragraph 36.

46 Minutes of call with a competitor, dated 13 January 2023; Minutes of call with a competitor, dated 24 January 2023.

6. CONCLUSION

(45) For the above reasons, the European Commission has decided not to oppose the notified operation and to declare it compatible with the internal market and with the EEA Agreement. This decision is adopted in application of Article 6(1)(b) of the Merger Regulation and Article 57 of the EEA Agreement.

For the Commission

(Signed)
Margrethe VESTAGER
Executive Vice-President