EUROPEAN COMMISSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 6.12.2024
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Subject: **Case M.11486 – NOVO HOLDINGS / NOVO NORDISK / CATALENT**
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]

Dear Sir or Madam,

(1) On 31 October 2024, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Novo Holdings A/S ("**Novo Holdings**") will acquire within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the whole of Catalent, Inc. ("**Catalent**"), by way of purchase of shares (the "**Transaction**"). Together Novo Holdings (including its subsidiaries such as Novo Nordisk A/S (hereafter "**Novo Nordisk**")) and Catalent are referred to as the "Parties".

[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').

1. THE PARTIES

(2) Novo Holdings is a Danish private limited liability company whose shares are 100% owned by Novo Nordisk Fonden (the "**Novo Nordisk Foundation**")[3]. Novo Holdings is a holding and investment company responsible for managing the assets of Novo Nordisk Foundation through strategic investments in the life sciences and related areas and through investments of a financial and venture capital nature in a broad portfolio of companies. Novo Holdings is the controlling shareholder of *inter alia* Novo Nordisk (companies controlled by Novo Holdings are referred to in this decision as "**Novo Holdings Controlled Portfolio Companies**").[4]

(3) Novo Nordisk is a publicly listed global healthcare company with a focus on developing treatments for metabolic disorders such as diabetes and obesity, and chronic diseases such as haemophilia and growth disorders. Novo Nordisk also holds a legacy portfolio of hormone replacement therapy treatments for menopause.[5] Novo Nordisk also has several pipeline products pursuing indications for *inter alia* diabetes, obesity, haemophilia, sickle cell disease, cardiovascular diseases, kidney disease, metabolic dysfunction-associated steatohepatitis ("**MASH**").[6] Novo Holdings holds 28.1% of the total share capital and controls 77.1% of the total voting rights in Novo Nordisk. Novo Holdings is the sole controlling shareholder of Novo Nordisk for the purposes of the Merger Regulation. The remaining share capital and voting rights are held by institutional and private investors.[7]

(4) Catalent is a publicly listed global contract development and manufacturing organisation ("**CDMO**") which provides third-party development and manufacturing solutions to companies in the pharmaceutical, biotech, and consumer health industries.[8] Catalent organises its activities into two operative segments:

(a) The Biologics segment, which deals with development and manufacturing of protein, mRNA, cell and gene therapy and vaccines, as well as formulation, development, and manufacturing of injectable dose forms for therapeutics including fill-finish manufacturing services for injectable products; and

(b) The Pharma and Consumer Health segment, which deals with oral and other solid dose form manufacturing, early-stage small molecule dose form development, and consumer health products, such as development and manufacturing of soft gelatine capsules ("**softgels**"), fast-dissolve tablets, traditional and advanced oral solid-dose pharmaceuticals, inhalers, and nasal delivery devices.

(5) Catalent's network of facilities spans over 50 sites located in Asia Pacific, Europe, Latin America, and North America.[9]

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3 The Novo Nordisk Foundation is an independent charitable foundation and is not controlled by any other entity (Form CO, paragraph 37).

4 Form CO, paragraphs 4, 13 and 217.

5 Form CO, paragraphs 30 and 41.

6 Form CO, paragraphs 5 and 30.

7 Form CO, paragraph 41.

8 Form CO, paragraph 6.

9 Form CO, paragraph 34.

2. THE CONCENTRATION

(6) On 5 February 2024, Novo Holdings and Catalent entered into an agreement whereby Novo Holdings will acquire all outstanding shares in Catalent for approximately EUR 15.4 billion.

(7) As a result of the Transaction, Novo Holdings will acquire sole control of Catalent within the meaning of Article 3(1)(b) of the Merger Regulation.

3. UNION DIMENSION

(8) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[10] (Novo Holdings: EUR [amount] million and Catalent: EUR 4 263 million). Each of them has a Union-wide turnover in excess of EUR 250 million (Novo Holdings: EUR [amount] million and Catalent: EUR [amount]), but neither of them achieves more than two-thirds of their aggregate Union-wide turnover within one and the same Member State. The notified operation therefore has a Union dimension.

4. OVERVIEW OF RELEVANT PRODUCTS AND MARKETS

4.1. Parties' activities

4.1.1. Novo Nordisk and Novo Holdings

(9) First, as regards Novo Nordisk, it is a global pharmaceutical company which focuses its activities on the treatment of serious chronic diseases, including metabolic diseases.[11]

(10) In the metabolic disease space, Novo Nordisk develops and commercialises a number of products indicated to treat, among others, type 1 and type 2 diabetes ("**T1D**" and "**T2D**" respectively), and obesity. These products are mostly administered to patients by way of periodic subcutaneous injections either by a medical practitioner or by the patients themselves.

(11) Specifically, Novo Nordisk commercialises incretin hormones responsible for the activation of GLP-1 receptors – a protein present in the human body - which regulate glycemic levels and have demonstrated significant success in promoting weight loss ("**GLP-1 receptor agonists**"). Novo Nordisk's products' liraglutide[12] and more recently semaglutide[13] are both GLP-1 receptor agonists that respectively require daily and weekly sub-cutaneous injections.

(12) In the past few years, the demand for semaglutide and other incretin-based T2D and obesity treatments has drastically increased, which does and will require a significant increase in capacity at all levels of the supply chain. This dramatic increase in demand does not appear to have been foreseen by Novo Nordisk in its

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

11 See also paragraph 3 above for a description of Novo Nordisk's activities more broadly.

12 Commercialised under the brand names Victoza and Saxenda for T2D and obesity indications respectively.

13 Commercialised under the brand names Ozempic and Wegovy for T2D and obesity indications respectively.

internal forecasting. Figure 1 illustrates the evolution of Novo Nordisk's long-term forecasts (i.e. its 10-year estimates) of demand for its semaglutide products over the years. This figure shows that following Novo Nordisk's initial demand estimates prepared during 2013-2019, over the last couple of years those forecasts progressively increased as the market potential for semaglutide became clearer. The fact that Novo Nordisk did not foresee the increase in demand, and thus its large capacity requirements, is illustrated by the significant difference in forecasted addressable patient population between 2024 ("LTF24 Aspiration") and 2022 ("LTF2022 Aspiration") for Novo Nordisk's semaglutide presented in Figure 1 below:

Figure 1: Novo Nordisk semaglutide demand forecast

[…]

Source: Annex 20 to the Form CO, slide 9

(13) As regards the Transaction rationale, [Novo Nordisk forecasts]. Overcoming these fill-finish capacity constraints is the main deal rationale and will allegedly allow Novo Nordisk to reach [amount] additional patients by 2030. The Transaction gives Novo Nordisk access to Catalent's existing high-volume fill-finish capacity in Brussels (Belgium), Anagni (Italy), and Bloomington (US) (the "**Carveout Sites**"), which Novo Nordisk intends over time to exclusively reserve to filling Novo Nordisk's injectable semaglutide products to help meet the growing demand. Additionally, [Novo Nordisk expectations]. The Notifying Party submits that acquiring capacity and expanding Catalent's facilities is faster than developing such capacity internally. It adds that even if Novo Nordisk has already contracted with Catalent for a large part of Catalent's capacity, the Transaction enables it to have access to the remainder and has the significant benefit of reducing the commercial risks that would come from relying on a third party CDMO for such a significant part of Novo Nordisk's business. Owning Catalent also gives Novo Nordisk greater flexibility to direct Catalent's expansion plans and strategy in a manner that best meets Novo Nordisk's needs.[14]

(14) In addition, Novo Nordisk is developing several pipeline products with the same indications as semaglutide and is looking to expand the indications for which semaglutide can be used.

(15) Similarly to most large pharmaceutical companies, Novo Nordisk holds product development and manufacturing capabilities in-house. In addition, and as is also common practice in the industry, it frequently contracts with CDMOs with respect to the development and the manufacturing of its medicines. Currently, Novo Nordisk manufactures most of the semaglutide active substance internally and uses the external manufacturing services of [Novo Nordisk's manufacturing strategy] to package these semaglutide products.[15] It also plans on [Novo Nordisk's manufacturing strategy] in the next few years.[16]

14 Form CO, paragraphs 63-71 and 201ff.

15 Annex 3 (00003.M11486-NNNHCTL) to the Form CO. Novo Nordisk also uses some external manufacturing and development services for some of its other products.

16 Form CO, paragraph 1301.

(16) The parent company of Novo Nordisk is Novo Holdings, which as noted above, is responsible for managing the assets of the Novo Nordisk Foundation through strategic investments in the life sciences and related areas and through investments of a financial and venture capital nature in a broad portfolio of companies. The portfolio companies controlled by Novo Holdings ("**Novo Holdings Controlled Portfolio Companies**") include companies that are active upstream and/or downstream of Catalent and companies with limited activities in the CDMO space, namely Altasciences, Bacthera (jointly controlled with Lonza), Ritedose and Xellia.[17]

(17) The Notifying Party submits that the acquisition of the sites other than the Carveout Sites ("**RemainCo Sites**") is in line with Novo Holdings' strategy of investing in established life science companies with strong long-term potential. It intends to operate Catalent's RemainCo Sites as an independent CDMO on a 'business as usual' basis. It submits that the RemainCo Sites will be operated by Novo Holdings in line with is approach to its wider portfolio, namely as an independent investment company on an independent, arm's length basis from its other portfolio companies, including Novo Nordisk.[18]

4.1.2. Catalent

(18) As a CDMO, Catalent acts as an outsourcing partner for pharmaceutical companies. In this context, it offers, on the one hand, research and development services when a product is at the clinical stage of development (referred to as "**CDO services**") and, on the other hand, product manufacturing services for products both at the clinical and commercial stages of their lifecycles (referred to as "**CMO services**").

(19) Catalent offers these development and manufacturing services for a wide range of molecules and processes, including small molecules and large molecules, whether synthetic or biological, and regarding both the active pharmaceutical substance ("**API**") and the finished drug product ("**FDP**").

(20) With respect to services provided for FDPs, Catalent offers manufacturing services referred to as "sterile fill-finish" services, which involves active pharmaceutical substance being filled and packaged into containers under sterile conditions. This typically includes compounding and mixing of the active pharmaceutical substance, filling, closing, sealing, sorting, inspecting, labelling, packaging, and quality control checks.

(21) More specifically, the sterile fill-finish technique involves processing and packaging a product into containers, followed by hermetic sealing. The process is designed to prevent viable microbial contamination of the drug product. The design of the manufacturing environment and equipment in place is an important aspect of the fill-finish process. For products administered in the injectable format, such as injectable semaglutide, fill-finish involves filling the active pharmaceutical substance into one of the following formats: (i) pre-filled syringes ("**PFS**"), which contain a single dose, and are often (but not necessarily) utilized in single-use auto-injector pens equipped with a built-in needle; (ii) cartridges, which contain multiple doses, and are inserted in durable auto-injector pens equipped with removable

17 Form CO, paragraphs 528 *et seq*.
18 Form CO, paragraphs 200 *et seq.*

needles; and (iii) vials, which may contain a single dose or multiple doses administered via a separate needle and syringe.

(22) Catalent possesses several facilities that offer sterile fill-finish manufacturing services including its sites in Bloomington (US), Brussels (Belgium), Limoges (France), and Anagni (Italy). These sites provide services to a number of customers, including both large and small pharmaceutical companies for products indicated to treat various diseases delivered via sub-cutaneous injections.

(23) Other FDPs services provided by Catalent include solid dose supply services, *i.e.* development and manufacturing services for solid dose form pharmaceuticals (most of which are intended for oral use), including formats such as softgels and orally dissolving tables ("**ODTs**").

(a) Catalent provides softgel development and manufacturing for prescription medicines as well as over-the-counter ("**OTC**") and consumer health softgels. For prescription medicines, softgel formats are used as a way of enhancing the bioavailability[19] of medicines and are therefore classified as a solubility enhancing technology. Catalent provides softgel manufacturing primarily for pharmaceuticals from its sites in Beinheim (France), Eberbach (Germany) and St. Petersburg (US).[20]

(b) ODT is a solid dose form that disintegrates or dissolves quickly in the mouth without the need for administration of water. Catalent offers process development and manufacturing ODT services based on its Zydis® technology out of its site in Swindon (UK). On a more limited and incidental basis, Catalent has in the past also manufactured ODTs out of its sites in Winchester (US) and Schorndorf (Germany). [21]

4.2. Market definitions

4.2.1. Overview of the vertical relationships

(24) The Transaction gives rise to several affected vertical links between the Parties:

(a) The supply of CMO FDP services for PFS (upstream) – the supply of (i) anti-obesity preparations excluding dietetics, and (ii) GLP-1 receptor agonists indicated for diabetes (downstream); and

(b) The supply of CMO FDP services for ODTs (upstream) – the supply of opioid use disorder ("**OUD**") treatments (downstream).

(25) The Transaction also gives rise to horizontally affected markets for the supply of CDO FDP services for solubility enhancing technologies and lipid-based drug delivery systems.

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19 Bioavailability refers to the extent to which a drug, once administered, enters into the circulatory system and can have the desired effect. For instance, when drugs are taken in oral form, various factors may influence the absorption of the drug substance into the blood stream, such as whether the drug is taken with or without food, the rate of gastric emptying, etc.

20 Form CO, paragraphs 455 and 457.

21 Form CO, paragraphs 460-462.

4.2.2. Product market upstream

(26) CDMOs are entities which offer CMO and CDO services to pharmaceutical companies. These services can consist in assisting with the development of a medicine (research, formulation, analytical services) referred to as CDO services or manufacturing a pre-determined product or substance for commercial or clinical trial use referred to as CMO services.

4.2.2.1. Contract Development services (CDO services)

(a) The Commission's past practice

(27) The Commission has previously analysed several transactions involving CDMO services, consistently distinguishing between the supply of CDMO services for APIs and those for FDPs. While it has also explored the possibility of separate markets for CMO and CDO services, it has ultimately left this question open.[22] However, no specific assessment of potential sub-segments within the CDO services market has been conducted.

(b) The Notifying Party's view

(28) The Notifying Party suggests that CDO services should be segmented in a manner consistent with CMO services, reflecting similar market dynamics.[23]

(c) Assessment

(29) Regardless of the precise product market definition, the Transaction does not give rise to any vertically affected links with respect to CDO services and only gives rise to a horizontally affected market under two plausible product market definitions, specifically the market for CDO FDP services for solubility enhancing technologies or (if a narrower market is defined) lipid-based drug delivery systems.[24] The precise product market definition for CDO services can be left open, as regardless of the definition adopted the Transaction does not raise serious doubts as to its compatibility with the internal market. The Commission will focus its assessment on the only plausible product market definitions that give rise to affected markets, i.e. CDO FDP services for solubility enhancing technologies or for lipid-based drug delivery systems.

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22 Case M.8541 – *Thermo Fisher Scientific/Patheon*, decision 23 August 2017; Case M.8362 – *Lonza Group/Capsugel*, decision 21 April 21 2017, Case M.10247 – *CVC/COOPER*, decision 22 October 2021, paragraph 150

23 Form CO, paragraphs 255-510.

24 The second plausible market definition, CDO FDP services for lipid-based drug delivery systems, is a narrower subset of the first, as it focuses specifically on lipid-based technologies within the broader category of solubility-enhancing technologies.

4.2.2.2. Contract Manufacturing services (CMO services)

(a) The Commission's past practice

(30) In its previous decisions, the Commission identified separate markets according to whether the product manufactured and supplied was an API or an FDP.[25] In *Chr. Hansen / Lonza / JV*, the Commission distinguished the services offered for those two types of products. Services at the API level involve the evaluation, characterisation, development of production and scaling processes in relation to the manufacturing of the actual molecule. Services at FDP level mostly pertain to the development of appropriate dosage formulation and large-scale manufacture of the final drug product. Additionally, from a supply-side perspective, manufacturing these two types of products does not involve the same equipment, know-how and expertise, as illustrated by the fact that several CDMO players are exclusively active either at the API level or at the FDP level.[26]

(31) At the FDP level, further segmentations were considered on the basis of the pharmaceutical form manufactured (e.g. injectables[27], semi-solid[28], liquids[29], solids[30])[31]. Although in the past the Commission ultimately left the market definition open, it has also found that, whilst certain core technologies in contract manufacturing are widely available and correspond to the most common pharmaceutical forms, certain other technologies are more specialized and cannot be substituted with the former from either the demand or supply side[32]. Consequently, the Commission in the past has concluded that FDP manufacturing services could be further segmented according to the manufactured pharmaceutical form, the delivery mechanism[33], and, in some cases, to the conditions of manufacture (e.g. the type of API used for its production, toxicity, sterile environment, etc)[34], even if it eventually left the market definition open.

(b) The Notifying Party's view

(32) In line with the Commission's past decisional practice, the Notifying Party submits[35] that contract manufacturing services should be segmented between: (i) services at API level, which includes clinical and commercial manufacture of APIs; and (ii) services at FDP level, which includes the clinical and commercial

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25 Case M.10997 - *NB / Ardian / Mediolanum / Neopharmed*, decision of 27 February 2023, paragraph 33; Case M.9995 – *Permira / Sestant / Kedrion / BPL*, decision of 5 August 2022, paragraph 32; 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.

26 Case M.9315 - *Chr. Hansen / Lonza / JV*, decision 16 July 2019, paragraph 17.

27 Liquid preparations that are inserted into or under the skin administered with a syringe or needle.

28 Preparations that are administered in the form of ointments, creams, pastes, or gels.

29 Non-injectable preparations including solutions or suspensions.

30 Tablets, capsules (including softgel capsules), powder and pills.

31 Case M.9995 - *Permira / Neuraxpharm*, decision 4 December 2020, paragraph 15; Case M.8385 - *Pillarstone/ Famar*, decision 3 May 2017, paragraph 20.

32 Case M. 5253 - *Sanofi-Aventis / Zentiva*, decision 4 February 2009, paragraph 188.

33 Case M.9315 - *Chr. Hansen / Lonza / JV*, decision 16 July 2019, paragraph 22

34 Case M.5953 - *Reckitt Benckiser/ Ssl*, decision 25 October 2010, paragraph 58-59; Case M.5253 - *Sanofi-Aventis / Zentiva*, decision 4 February 2009, paragraph 188.

35 Form CO, paragraphs 258 *et seq*.

manufacture of the finished drug product and incidental packaging as well as clinical trial logistics.

(33) The Notifying Party submits[36] that no further segmentation is warranted and that the Commission should not deviate from its past practice.

(c) Commission's Assessment

(34) In line with the Commission's past decisional practice and with the Notifying Party's submission, the vast majority of the respondents to the market investigation[37] agreed that services provided for the manufacture or development of APIs - sometimes also referred to as "drug substance" - and services provided for the manufacture or development of FDPs belong to separate product markets. Market participants further explained that: "*drug substance API and drug product* [are] *a very different business requiring different assets and different technologies*"[38] and that they: "*respectively address separate needs, in general do not involve the same equipment, and in general also require specific know-how and expertise*".[39]

(35) At the FDP level, the vast majority of respondents also agreed with the Commission's past practice of considering further segmenting the market based on the pharmaceutical form manufactured including solids, semi-solids, liquids and injectables. With respect to this segmentation, one market participant further explained that: "*The differentiation is highly relevant, as the infrastructure, equipment, quality system etc. are different for these subsegments. Often CDMOs are only offering some of the services.'*"[40]

(36) In light of the above, the Commission considers that the CMO FDP services market should be further segmented based on the manufactured pharmaceutical form, *i.e.* injectables, semi-solid, liquids and solids[41]. For the purposes of this decision, it will therefore assess the segmentation of CMO FDP services for injectables, and CMO FDP services for solids.[42]

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36 Form CO, paragraph 258.

37 Replies to question C.1 of the Questionnaire to CDMOs; Replies to question C.1 of the Questionnaire to CDMO customers.

38 Reply of one CDMO to question C.1.1 of the Questionnaire to CDMOs.

39 Reply of one CDMO customer to question C.1.1 of the Questionnaire to CDMO customers.

40 Reply of one CDMO to question C.2.1 of the Questionnaire to CDMO.

41 Further potential segmentations with respect, for example, to the production environment is not relevant for the purposes of this decision considering that the potential concerns identified and investigated by the Commission concerned Catalent's sterile fill finish services. In addition, a potential segmentation based on the type of API used is also not relevant for the purposes of this decision considering that the type of API filled does not have a measurable impact on the manufacturing process.

42 With respect to the other formats mentioned (semi-solids, liquids.), the Commission will not conduct a separate competitive assessment considering Catalent's low share in any plausible segment.

4.2.2.2.1. CMO FDP services for injectables

(a) The Commission's past practice

(37) As outlined above, the Commission has previously considered the possibility of segmenting the contract manufacturing services at FDP level market based the pharmaceutical form manufactured, including solid, semi-solid, injectable, and liquid formats[43].

(38) In *Novartis / EBEWE*, the Commission found that the vast majority of responding market participants considered that, with respect to a liquid injectable supplied in ampules, vials, and pre-filled syringes ("PFS"), dedicated production facilities and know-how were required for each format, but ultimately left open the question whether this would justify the delineation of a separate markets based on the format of the injectable product.[44]

(39) The Commission did not analyse these potential market segmentations further.

(b) The Notifying Party's view

(40) As mentioned above, the Notifying Party submitted that no further segmentation was needed beyond a segmentation between API and FDP services. It however acknowledged that there could be an additional segmentation of the injectable format, including: (i) PFS; (ii) cartridges; and (iii) vials.[45]

(41) With regard to demand-side substitutability between the various formats of injectables, the Notifying Party submits[46] that each format can be used for a given injectable product, and that the different formats are substitutable at each stage of the product development, as follows:

- In the early stages of product development, particularly during clinical trials, the choice of format is not crucial, and vials are commonly used, notably due to their low marginal per-dose cost.
- During later stages of product development, the choice of a format is typically made and feeds into the conditions for marketing authorization applications. Although each format offers different advantages to be assessed by pharmaceutical companies, the different formats are substitutable and serve the same end purpose (delivering a specified dose through an injection). This choice is not influenced by the type of product but comes down to the individual customer's strategy and preferences. While the PFS format is easily usable for patients leading to reduced medication errors, the vial format may allow for faster scaling[47].

43 Case M.9995 - *Permira / Neuraxpharm*, decision 4 December 2020, paragraph 15; Case M.8385 - *Pillarstone/ Famar*, decision 3 May 2017, paragraph 20; Case M.5953 - *Reckitt Benckiser/ Ssl*, decision 25 October 2010, paragraph 58-59.

44 Case M.5555 - *Novartis/ EBEWE*, decision 22 September 2009, paragraph

45 Form CO, paragraphs 323 *et seq*.

46 Form CO, paragraph 358 *et seq*.

47 Form CO, paragraph 361.

– At a later stage in the product life cycle, companies can still switch to other formats. However, adding or changing formats once a marketing authorization has been obtained requires significant resources and time to prepare and submit a new dossier to regulatory authorities.

(42) The Notifying Party also notes that pharmaceutical companies may choose to offer multiple presentations (i.e. formats) to differentiate themselves from competitors, to scale capacity or to supply new geographic markets.[48]

(43) With regard to supply-side substitutability, the Notifying Party submits[49] that few CDMOs offer manufacturing services in the cartridge format, resulting in most of the cartridge capacity being manufactured in-house. As regards product lines for vials and PFS, the Notifying Party argues that a majority of CDMOs offer production lines for both formats and can expand their production lines in either format. However, the Notifying Party notes that PFS and vials lines are not interchangeable, as a change in the product format would require the decommission of the previous line and the complete installation of a new one. [50]

(c) The Commission's assessment

(44) The PFS segment is the market segment underpinning the main transaction rationale. In addition, Catalent does not currently have any cartridge manufacturing capabilities and its market share with respect to vial manufacturing remain well below 30%. Hence, the Commission must determine, for the purposes of this market definition, whether it is possible to identify a PFS market segment distinct from market segments for vials and cartridges within the broader market for CMO FDP services for injectables. To do so, the Commission investigated the extent to which demand side and supply side switching is possible from vials or cartridges, on the one hand, to PFS on the other hand.

– *Supply side substitutability*

(45) On the supply-side, manufacturers submitted during the market investigation that injectables production lines designed to fill the vial injectable format[51], could only be used to produce vials and could not be used to fill PFSs, or could only be so used following significant adjustments and investments.[52] For example, one CDMO explained that adjusting a production line of vials to fill PFS: "*would be complex as the material flow are not the same for Vial and PFS. Vial operation typically are Wash / Dry / Sterilize / Fill / Cap / Seal. PFS work centres product flow, is quite different and for higher throughput; sterilized PFS Barrel are procured in tubs that are filled and assembled with plunger and needle. Here, instead of converting a Vial Filler to PFS Filler, if the need arose, a new PFS Line would be installed"*.[53]

48 Form CO, paragraph 361.
49 Form CO, paragraph 357.
50 Form CO, paragraph 363 *et seq*.
51 The Commission notes that there are lines designed specifically to fill multiple formats but those lines do not represent the majority of production lines.
52 Replies to question D.A.1 of the Questionnaire to CDMOs.
53 Reply of one CDMO to question D.A.3 of the Questionnaire to CDMOs.

(46) With respect to switching the injectable filling format from cartridge to PFS, most market participants submitted that it would only require some adjustments as there are similarities with respect to these two formats[54] with a market participant however explaining that: "*Although there are similarities in the technology and principles behind fill-finish processes for cartridges and PFS, specific differences mean that certain modifications are necessary. […] Overall, while it's entirely feasible to adapt the lines and equipment, it does require some investment and time to implement these changes effectively and ensure that the fill-finish process maintains its quality and compliance.*"[55]

– *Demand-side substitutability*

(47) In the course of the market investigation, the vast majority of customers of CMO services submitted that their needs with respect to injectables manufacturing would vary depending on whether a product is at the clinical stage or the commercial stage. For example, one CDMO customer detailed that: *"lead times, flexibility and volume requirements can all differ depending on the clinical and commercial stages. At the clinical stage, we require a CMO that can be flexible and that is able to produce small volumes at short notice, given that clinical supply tends to support clinical studies and clinical data. At the commercial stage, we require a CMO with plants that are well set up for scalability and larger volumes, and which has the requisite regulatory approval to supply commercially."* As such, the Commission looked at whether it was appropriate to define different markets for injectables at different stages of product development.

– *Substitutability at the clinical stage*

(48) On the demand-side, feedback from market participants was mixed. Indeed, CDMO customers were evenly split between finding the three formats to be substitutable and finding them not to be.[56] One CDMO customer explained that: "*the use of different formats may introduce additional complexity and risk to the drug development path*"[57] as all formats to be used in a clinical trial would require specific comparability assessments to ensure the appropriate dosage is used for each format. This would tend to highlight the limited substitutability of the formats.

(49) The Notifying Party has submitted that the exact format of the injectables is not crucial at the clinical stage of development. However, in light of the market feedback and the limited supply-side substitutability[58], the Commission cannot exclude that CMO FDP services for cartridges, PFS and vials are not substitutable at the clinical development stage of injectable products. In any case, the exact product market definition can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market whether CMO FDP services for vials, PFS and cartridges at the clinical stage of development are considered together or separated by format. For the purposes of this decision, on a conservative basis, the Commission will conduct its assessment on the narrowest plausible market segmentation which is CMO FDP services for PFS at the clinical stage.

54 Replies to question D.A.2 of the Questionnaire to CDMOs.
55 Reply of one CDMO to question D.A.3 of the Questionnaire to CDMOs.
56 Replies to question D.A.2 of the Questionnaire to CDMO customers.
57 Replies to question D.A.2.1 of the Questionnaire to CDMO customers.
58 See paragraph 45 above.

– *Substitutability at the commercial phase*

(50) With respect to customer needs at the commercial phase, demand-side substitutability can be split in two: (i) substitutability from a patient perspective and (ii) substitutability from the perspective of the pharmaceutical company.

(51) From a patient perspective which is relevant here to the extend it informs the pharmaceutical companies' format decisions and provides additional evidence regarding format substitutability, the majority of respondents to the market investigation considered that PFS were substitutable to cartridges to some extent and that PFS were substitutable to vials[59] to some extent. With respect to vials and PFS substitutability, one respondent nonetheless caveated that, while: "*from a clinical outcome perspective they can be substitutable, however the patient experience is significantly different. From the perspective of the end user (patient administration), taking into account e.g. delivery method and prices, the products are not substitutable*.[60]" Others further explained that: "*for a patient a vial cannot be used for self administration, unlike a PFS*"[61] whereas: "*For cartridges as long as the device is available it may substitute a PFS*"[62].

(52) In addition, a PFS can also be added to an auto-injector device with needle retraction mechanisms which differentiates it further from vials and cartridges and increases its attractiveness to patients.[63]

(53) Considering the difference in mode of administration between vials and PFS, it is likely that they are less substitutable than a PFS and a cartridge would be from a patient perspective as both PFS and cartridges are self-administrable (contrary to vials, which may require the assistance of a healthcare worker).[64]

(54) From the perspective of pharmaceutical companies, the market feedback was split with most of the respondents highlighting the need to obtain regulatory approval for each format separately as an argument against full substitutability.[65]

(55) Considering the limited supply-side substitutability, the Notifying Party's submission confirming that changing format once a marketing authorization has been obtained requires significant resources and time[66], which has been confirmed by the market investigation results on the demand-side, the Commission will, for the purposes of this Decision, consider that the market for CMO FDP services for injectables can be further segmented based on the exact format of the injectable.

(56) Accordingly, it will focus its assessment on the market for CMO FDP services for PFS, starting below with an assessment of whether this market should be further segmented.

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59 Replies to question D.A.3 of the Questionnaire to CDMO customers.
60 Reply of one CDMO customer to question D.A.3.3 of the Questionnaire to CDMO customers.
61 Reply of one CDMO customer to question D.A.3.3 of the Questionnaire to CDMO customers.
62 Reply of one CDMO customer to question D.A.3.3 of the Questionnaire to CDMO customers.
63 Form CO, paragraph 324; Minutes of call with CDMO dated May 23, 2024.
64 Form CO paragraph 1137.
65 Replies to question D.A.3 of the Questionnaire to CDMO customers
66 See paragraph 41.

4.2.2.2.1.1. CMO FDP services for PFS

(a) The Commission's past practice

(57) The Commission has not previously looked in detail at the CMO FDP services for PFS market and its further potential segmentations including based on the stage of the product or the speed of the manufacturing processes.

(b) The Notifying Party's views

(58) The Notifying Party submits[67] with regard to demand-side substitutability, that pharmaceutical companies' primary focus is to fulfil patient demand for their product, and various factors such as production speed, output, and cost all influence the manufacturer selection process. Accordingly, CMO providers are often selected based on availability of capacity, combined with factors such as profile and approach to managing risks, performance, track record, and cost.

(59) In contrast, CDMO customers very rarely request to use a specific speed line, as they can use both high-speed and medium-speed lines to satisfy high volume requirements at a similar price per unit. [68] The Notifying Party submit that this lack of clear advantage to using high-speed lines for most customers demonstrates the substitutability of high-speed lines and lower-speed lines for customers, and, as such, it would not be appropriate to further segment the hypothetical market for PFS contract manufacturing based on the speed of the production line.

(60) With regard to supply-side substitutability, the Notifying Party submit[69] that most manufacturers offer both low-, medium-, and high-scale fill-finish PFS lines and provide the same fill-finish PFS services from any production line. They are therefore able to fulfil orders of different magnitude.

(61) In the Notifying Party's view, depending on the actual or perceived demand, any manufacturer can invest in a high-scale fill-finish line, as the technology, know-how, and expertise required do not differ substantially between lines of different scales. The process of ordering and installing a new line, regulatory approval, and commercial manufacturing requirements are the same regardless of the line's scale. In addition, the cost and time needed for a manufacturer to install a high-scale line versus a lower-scale line are similar.

(c) The Commission's assessment

(62) As mentioned previously[70], the majority of the responding CDMO customers submitted during the market investigation that their needs with respect to injectables manufacturing services varied depending on whether the product was at the clinical or the commercial phase mostly with respect to the volumes required.

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67 Form CO, paragraphs 387 *et seq*.

68 Form CO, paragraph 393 *et seq*. From the Parties' perspective, a "low-speed" line refers to filling lines that manufacture 15 to 100 units per minute in batches of 1,000 to 50,000 units. A "medium-speed" line refers to filling lines that manufacture 100 to 300 units per minute in batches of 30,000 to 200,000 units. A "high-speed" line refers to filling lines that manufacture 300 to 1,000 units per minute in batches of 100,000 or more - see Form CO, Footnote 293.

69 Form CO, paragraphs 408 *et seq*.

70 See paragraph 47.

(63) At the clinical stage of development, customers do not require large volumes of products to be manufactured as said products will be used on a small subset of the potential addressable patient population in the context of clinical trials. As regards CDMOs, these smaller volume requirements at the clinical stage mean that CDMOs serving clinical stage customers would typically use production lines that prioritise flexibility (i.e. quick and efficient change-overs between products) rather than lines capable of producing a high volume of products at speed[71], further indicating that catering to these customers requires specific equipment on the supply-side including low or medium speed filling lines.

(64) At the commercial stage (i.e. once the product is marketed), pharmaceutical companies have differing volume requirements based, among others, on the size of the patient population (e.g. small population for rare diseases and large population for vaccines such as the flu vaccine), the cost and rarity of the API, the frequency of administration of the product (daily, weekly, etc.), [72] and the number of other available treatments for the same indication. There are therefore indications that CMO FDP services for PFS at the commercial level can be split further based on whether the volume of product required is low-to-medium or high.

(65) In the course of the pre-notification outreach, several market participants highlighted that commercialised products requiring to be manufactured on a large scale, such as the GLP-1 receptor agonists indicated to treat T2D and obesity, required the use of PFS production lines of a certain speed in order to produce the high volumes required,.[73] One market participant further explained that a line designed to manufacture a high number of units is: "*characterized by multiple pinheads"*, and as such, "*designed to produce large quantities quickly, such as millions or billions of […] PFS*".[74] These high-speed lines usually result in higher wastage, but the percentage of lost product is minimal compared to the total output. Conversely, low-speed lines are used for products which require a much smaller number of units to be produced: "*They prioritize minimizing wastage due to the high value and smaller batch sizes of these products. As a result, these lines operate at lower speeds with fewer pinheads to reduce product loss."*[75]This would include clinical stage products which would not be manufactured in high volume and therefore mostly require low to medium speed lines.

(66) The results of the market investigation tend to support a market segmentation based on capability to manufacture very high-volume commercialised products in PFS, for which line speed is a key determinant. The majority of CDMO customers submitted that they would only consider using one or more high-speed lines for a product that would require a large number of units.[76]

(67) Indeed, the majority of both responding CDMOs and CDMO customers submitted that, for a product which requires a large number of units to be produced, a single or multiple high-speed lines would be appropriate to use as the most cost/effective

71 Minutes of a call with a CDMO dated June 19, 2024.

72 Minutes of a call with a CDMO dated May 23, 2024.

73 Minutes of a call with a CDMO dated June 19, 2024; Minutes of a call with a pharmaceutical company dated June 11, 2024.

74 Minutes of a call with a CDMO dated May 23, 2024.

75 Minutes of a call with a CDMO dated May 23, 2024.

76 Replies to question D.A.5 of the Questionnaire to CDMO customers.

option.[77] One market participant further highlighted that, for some products, using a single or several high-speed lines is the better option to guarantee the stability of the product.[78]

(68) On the other hand, low or medium speed lines are more likely to be used for products requiring a small volume of units to be produced, either at the commercial or clinical stages as explained above.

(69) From the supply-side, the Commission's market outreach further highlighted that not every CDMO owns high-speed lines catering to large-scale production.[79] With respect to the supply of these production lines, market participants have further highlighted that the price of a high-speed line is typically double the price of a low or medium-speed line[80].Based on the above, the Commission considers it is likely that production lines of different speed are not on the same market as they address different needs (clinical phase products, low-to-medium volume commercialised products, and high-volume commercialised products) and require different equipment of dissimilar prices.

(70) With respect to the exact definition of what constitutes a "high-speed" line, a "medium-speed" line, a "low-speed" line, Table 1 shows the feedback of the market investigation pointed towards the below split on average[81].

Table 1 - High-speed vs medium speed vs low speed PFS lines

Line Category	Minimum speed expressed as units per minute
High Speed	393
Medium Speed	159
Low Speed	61

(71) In light of the above, the Commission considers that, for a line to be considered "high-speed", it should produce above 300 units per minutes, while, below that and until 100 units per minutes, the line is likely to be considered medium-speed, and below 100 units per minutes low-speed.[82] The exact minimum speed for a line to be considered "high-speed" can however be left open as no competition concerns arise under any plausible speed segmentation.

(72) In any case, the Commission considers that the exact product market definition can be left open since the Transaction does not raise serious doubts as to its compatibility with the internal market under any plausible segmentation relating to speed of the line.

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77 Replies to question D.A.5 of the Questionnaire to CDMOs; Replies to question D.A.5 of the Questionnaire to CDMO customers.

78 Reply to question D.A.5.1 of the Questionnaire to CDMO customers.

79 Replies of CDMOs to the Commission market reconstruction exercise; Minutes of a call with a CDMO dated May 23, 2024; Minutes of a call with a CDMO dated June 19, 2024

80 Minutes of a call with an equipment manufacturer dated July 31, 2024.

81 Replies to question D.A.4 of the Questionnaire to CDMO customers; Replies to question D.A.4 of the Questionnaire to CDMOs.

82 This is in line with the Notifying Party's submissions – see footnote 68 above.

4.2.2.2.1.2. Conclusion

(73) In light of the above, the Commission will conduct its assessment of the market for CMO FDP services for PFS,[83] leaving the precise market definition open as to whether clinical and commercial supply form part of the same market, and to what extent a potential market segment for commercial supply can be segmented based onthe speed of the production line.

4.2.2.2.2. CMO FDP services for solid dose format

(a) The Commission's past practice

(74) As previously described, the Commission has in the past considered further segmentation of the market for FDP services based on the pharmaceutical form manufactured (e.g. solid, semi-solid, injectable).

(75) Specifically in relation to solid format, the Commission has previously considered whether the market of solid oral dose delivery mechanisms should be further sub-segmented into different dosage delivery mechanisms (i.e., tablet or capsule) and the different types of these dosages (e.g., soft gelatine, hard gelatine). However, the Commission has in the past left the exact market definition open.[84]

(b) The Notifying Party's view

(76) As mentioned above, the Notifying Party submitted that no further segmentation was needed beyond a segmentation between API and FDP services. However, it noted that, should the Commission consider it appropriate to further segment the CDMO FDP services market, it should consider FDP services for all solid forms given the interchangeability between the various possible formats.[85]

(77) Should the Commission consider narrower sub-segments, the Notifying Party suggests that FDP services for solid forms could be further segmented by technologies, namely: (i) solubility-enhancing technologies, which comprises of lipid-based drug delivery systems ("**LBDDs**") (including softgels), spray-drying dispersion and hot melt extrusion; on the one hand, and (ii) non-solubility-enhancing technologies such as ODTs, on the other hand. According to the Notifying Party there is no plausible basis to go beyond such segmentation.[86]

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83 For completeness, the Commission also considered whether this market could be further segmented based on the possibility for the line to receive regulatory approval from the EMA to supply the EU. However, according to the guidelines of the EMA, there is no specific technological restrictions regarding the type of line which it can approve as long as it complies with the EMA standards. During the market investigation, the majority of responding CDMOs submitted that their sites had already received EMA approval with only a handful of sites not having yet received EMA approval. The Commission therefore does not consider it appropriate to further segment the market for CMO FDP services for PFS based on the technology used on the line and on whether it is approvable by the EMA.

84 Case M.6231 – *KKR / Capsugel*, decision of 26 July 2011, paragraphs 11-12 and 19 *et seq.*; Case M.8362 – *Lonza Group / Capsugel*, decision of 21 April 2017, paragraphs 36-41; Case M.8385 – *Pillarstone / Famar*, decision of 3 May 2017, paragraphs 20-22 (2017), Case M.9315 – *Chr. Hansen / Lonza / JV*, decision of 16 July 2019, paragraphs 28-31.

85 Form CO, paragraphs 470 *et seq.*

86 Form CO, paragraph 476 *et seq.*

(c) The Commission's Assessment

(78) The results of the Commission's market investigation generally confirmed a segmentation between solubility enhancing technologies and non-solubility enhancing technologies for CDMO FDP services for solid forms. The majority of both CDMOs and CDMO customers indicated that FDP services for solid forms with solubility-enhancing technologies are not substitutable with non-solubility-enhancing technologies. Market participants further explained that: "*processes, required technology and know-how differ significantly*"[87] between these two technologies and that: *"[s]olid forms based on solubility enhancing technologies enable the development of drugs which contain a drug substance which would otherwise not be bioavailable enough in the human body to unfold the intended effect*".[88]

(79) The Commission also investigated potential further segmentations for the solubility-enhancing technology segment: (i) based on the type of solubility-enhancing technology (i.e., LBDDs, hot melt extrusion, spray-dried dispersion) and (ii) further downstream, and specifically for the LBBD segment, based on the format of LBDDs (softgels versus liquid-filled hard capsules, "**LFHCs**"). As regards the non-solubility-enhancing technology segment the Commission investigated the substitutability of ODTs versus other oral solid dose forms such as conventional tablets, effervescent tablets, chewable tablets, and capsules. The results of the Commission's market investigation were inconclusive regarding whether these narrower segments constitute plausible markets.[89]

(80) In light of the above, the Commission concludes that solubility-enhancing technologies constitute a plausible market within the CDMO FDP services for solid dose formats. The Commission further considers that this market can be further segmented based on the type of solubility-enhancing technology, but leaves the market open, since no serious doubts arise under any plausible market definition in relation to solubility-enhancing technologies – the narrowest relevant plausible affected market in this case being that for LBDDs. At the same time, and for the purposes of this Decision, the Commission will focus its assessment on the narrowest plausible affected market in the non-solubility-enhancing technologies segment, specifically the market for CMO FDP services for ODTs, leaving the exact product market definition open, as the Transaction does not raise serious doubts about its compatibility with the internal market.

4.2.3. Geographic market upstream

(a) The Commission's past practice

(81) In its previous decisions, the Commission has found the relevant geographic market for contract manufacturing services to be worldwide or at least EEA-wide[90]. This is based on the fact that CMO services are procured across the EEA, or even worldwide regardless of the country where the pharmaceutical products are

87 Reply of one CDMO customer to question E.A.1 of the Questionnaire to CDMO customers.

88 Reply of one CDMO to question E.A.1 of the Questionnaire to CDMOs.

89 Responses to questions E.A.1 and F.A.1 of the Questionnaire to CDMO customers; and responses to questions E.A.1 and F.A.1 of the Questionnaire to CDMOs.

90 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.

subsequently marketed.[91] This was found to be irrespective of the need for a facility to require EU certification standards. [92]

(b) The Notifying Party's view

(82) The Notifying Party submits[93] that CDMOs operate and supply their services to customers globally. CDMO customers do not display preferences for national or regional suppliers as long as CDMOs can fulfil procurement and regulatory requirements, and hence CDMO customers procure their services on a global scale. In addition, a system for mutual recognition of national and international inspections regarding the manufacture of a product has been established and there are no significant trade barriers or transportation costs that could limit competition in countries where manufacturers do not have production facilities. Finally, the prices of the services are comparable in most regions.

(c) Commission's assessment

(83) Overall, the majority of responding CDMO customers submitted that they procured CDMO services from facilities located worldwide.[94] However, this can depend on the exact product manufactured.

(84) In the course of the Commission's investigation, a number of market participants have raised concerns regarding the viability of using the manufacturing services of facilities located in China. [95] In addition, several manufacturers[96], including Novo Nordisk[97], have adopted a "China for China" strategic approach which limits their Chinese site production to the domestic Chinese market. In fact, the majority of responding CDMOs submitted that they do not supply the European market from their facilities located in China.[98]

(85) In any case, the exact geographic market definition can be left open as the Transaction does not raise serious doubts as to the compatibility with the internal market regardless of the geographic market definition (whether EEA, global, or global excluding China).

4.2.4. *Product market downstream*

(a) The Commission's past practice and general approach to product market definition in pharmaceutical cases.

(86) In the past[99], the Commission noted that medicines may be subdivided into therapeutic classes by reference to the "Anatomical Therapeutic Classification" (ATC), devised by the European Pharmaceutical Marketing Research Association

91 Case M.5953 – *Reckitt Benckiser / SSL*, decision 25 October 2010, paragraph 66

92 Case M.5253 - *Sanofi-Aventis / Zentiva*, decision of 4 February 2009, paragraph 191; Case M.6613 - *Watson / Actavis*, decision of 5 October 2012, paragraph 124.

93 Form CO, paragraph 511 *et seq.*

94 Replies to question C.3 of the Questionnaire to CDMO customers.

95 Minutes of Call with CDMO customer dated October 4, 2024; Minutes of Call with CDMO customer dated May 16, 2024.

96 EC RFI 4 Q.21.006

97 Form CO Section 5.4.104.

98 Replies to question C.4 of the Questionnaire to CDMOs.

99 See for example Case M.8889 - *Teva / PGT OTC Assets*; Case M.7919 - *Sanofi/Boehringer Ingelheim Consumer healthcare Business*; Case M.6969 - *Valeant Pharmaceuticals International/Bausch & Lomb Holdings*; Case M.5778 - *Novartis/Alcon*; and Case M.5865 - *Teva/Ratiopharm*

(EphMRA) and maintained by EphMRA and IQVIA (formerly known as IMS Health). [100]

(87) The ATC system is a hierarchical and coded four-level system which classifies medicinal products by class according to their indication, therapeutic use, composition, and mode of action. In the first and broadest level (ATC1), medicinal products are divided into the 16 anatomical main groups. The second level (ATC2) is either a pharmacological or therapeutic group. The third level (ATC3) further groups medicinal products by their specific therapeutic indications. Finally, the ATC4 level is the most detailed one (not available for all ATC3) and refers, for instance, to the therapeutic or – more frequently – to the pharmacological criteria such as molecule class, formulation or mode of action (e.g. some ATC3 classes are differentiated into topical and systemic depending on their way of action). Medicinal products are classified according to the ATC system in the MIDAS IQVIA (formerly IMS Midas) database. In its past practice, the Commission has referred to the third level (ATC3) as the starting point for defining the relevant product market. However, it may be appropriate to carry out analyses at other levels, or across classes, if specific circumstances indicate that the ATC3 level is not the most appropriate for the purposes of market definition. In this case, the ATC4 level has been frequently considered as a possible alternative market definition or, where appropriate, the Commission has also considered competition at the more detailed, molecule level. [101]

(b) The Commission's past practice

– *Diabetes*

(88) There are multiple treatments available to treat the various types of diabetes (e.g. insulins or GLP-1 receptor agonists).

(89) The Commission has not previously looked specifically at GLP-1 receptor agonists indicated for the treatment of diabetes, or any product in the relevant ATC 3 class of such products (i.e. A10S). ATC 3 class A10S (GLP-1 agonist antidiabetics) includes GLP-1 receptor antidiabetics and dual GIP/GLP-1 agonist antidiabetics.

– *Anti-obesity preparations*

(90) Anti-obesity preparations are categorized in ATC3 class A8A (anti-obesity preparations, excluding dietetics). This ATC3 class covers products indicated to treat obesity, acting either centrally or peripherally and including molecules such as *orlistat*[102] or *sibutramina*[103]. In the past, the Commission has considered that the

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100 The EphMRA ATC classification, whilst very similar to the ATC classification maintained by the World Health Organization (WHO), is not exactly the same as the latter. The WHO classification uses similar categories but is based on active ingredients and serves a scientific, rather than commercial, purpose. Thus, a given active ingredient is classified in only one place in the WHO classification, whereas products based on it may be classified in more than one class of the IQVIA (formerly IMS) classification, depending on formulation and approved use in a given country.

101 See for example Case M.5253 - *Sanofi-Aventis / Zentiva*, decision of 4 February 2009, paragraph 15-18; Case M.4007 - *Reckitt Benckiser/Boots Healthcare*, decision 6 January 2006, paragraph 9-15; Case M.3751 - *Novartis / Hexal*, decision of 27 May 2005, paragraph 2-3; Case M.3544 - *Bayer Healthcare / Roche (OTC Business)*, decision of 19 November 2004, paragraph 12.

102 A pancreatic lipase inhibitor used as an anti-obesity drug to be used in combination with reduced-calorie diet and increased physical activity.

market for anti-obesity preparations should be defined at the ATC3 level of A8A[104]. More recently however, in *Teva/Allergan Generics* and *Teva / PGT OTC Assets*, the Commission also considered a narrower relevant market segment within the ATC 3 class on the basis of the molecule used for the anti-obesity preparation (i.e. including only *orlistat*-based products), but ultimately left open the question.[105]

– *Opioid Use Disorder*

(91) The Commission has not, to date, carried out an assessment of opioid dependency treatments.

(c) The Notifying Party's views

– *Diabetes*

(92) The Notifying Party proposes to assess the Transaction based on the relevant ATC3 classifications for GLP-1 agonist antidiabetics i.e. A10S.

– *Obesity*

(93) The Notifying Party proposes to assess the Transaction based on the relevant ATC3 classification of obesity preparations excluding dietetics i.e. A8A.

– *Opioid Use Disorder*

(94) The Notifying Party classifies opioid group dependency drugs in ATC 3 class N7F and submits that the precise definition of the relevant product market can be left open since the Transaction does not lead to competition concerns under any plausible market definition involving treatments of Opioid Use Disorder.[106]

(d) The Commission's assessment

– *Diabetes*

(95) In light of its past approach regarding pharmaceutical products, and considering the Parties' submission and the overall market feedback, the Commission considers the relevant market to be the market for GLP-1 receptor agonists (ATC class A10S) indicated for the treatment of diabetes.[107]

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103 An appetite suppressant withdrawn from the U.S. market in October 2010. It worked as a serotonin–norepinephrine reuptake inhibitor (SNRI) and was used together with diet and exercise to treat obesity that may be related to diabetes, high cholesterol, or high blood pressure.

104 Case M.457 - *La Roche/Syntex*, decision 12 June 1994, paragraph 35.

105 Case M.8889 - *Teva / PGT OTC Assets*, decision 29 June 2018, paragraph 214-215; Case M.7746 - *Teva / Allergan Generics*, decision 10 March 2016, paragraph 127-128.

106 Form CO, paragraph 887.

107 For completeness, the Commission investigated whether there could be a potential split between older generation (daily) GLP-1 receptor agonists and new generation (weekly) GLP-1 receptor agonists. The market feedback received mostly pointed towards the fact that the older generation of GLP-1 receptor agonists likely still exercised competitive constraints over the new generation but only to a limited extent. In any case, the specific market definition can be left open as the Transaction does not raise serious doubts as to the compatibility with the internal market regardless of the market definition.

– *Obesity*

(96) In light of its past approach in the obesity sphere and more generally when it comes to pharmaceutical products, considering the Parties' submission and the overall market feedback, the Commission considers the relevant market to be the market for anti-obesity preparation excluding dietetics (ATC class A8A). Whether further segmentation based on the type of molecule used in the obesity preparation (GLP-1 receptor agonist or other) is appropriate can be left open as the Transaction does not raise serious doubts as to the compatibility with the internal market regardless of the product market definition.[108]

– *Opioid Use Disorder*

(97) In light of the above, for the purposes of the decision the Commission will assess the narrowest plausible market, specifically the market for the supply of opioid use disorder treatments (ATC3 class N7F), leaving the exact market definition open, since no serious doubts arise under any plausible market definition in relation to Opioid Use Disorder treatments.

4.2.5. Geographic market downstream

(a) The Commission's past practice

(98) The Commission has previously consistently defined the geographic markets for finished pharmaceutical products as being national in scope.[109] This conclusion has been reached because of: (i) varying regulatory controls for pharmaceutical products; (ii) perceived differences in price setting and purchasing patterns/reimbursement by Member States; (iii) differences in national clinical guidelines, medical views and patient preferences; (iv) differences in brand, pack size and distribution system; and (v) because competition between pharmaceutical companies generally takes place at national level.[110]

(99) However, more recently, the Commission has also acknowledged a trend towards standardization at the EEA level.[111]

(b) The Notifying Party's views

(100) The Notifying Party did not provide a specific assessment of the geographical market beyond the Commission's past practice. It later provided its assessment both at the EEA and the national levels.

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108 For completeness, the Commission investigated whether there could be a potential split between older generation (daily) GLP-1 receptor agonists and new generation (weekly) GLP-1 receptor agonists. The market feedback received mostly pointed towards the fact that the older generation of GLP-1 receptor agonists likely still exercised competitive constraints over the new generation but only to a limited extent. In any case, the specific market definition can be left open as the Transaction does not raise serious doubts as to the compatibility with the internal market regardless of the market definition.

109 See for example Case M.8889 - *Teva / PGT OTC Assets*, decision 29 June 2018, paragraph 29-31; Case M.7746 - *Teva / Allergan Generics*, decision 10 March 2016, paragraph 127-128; Case M.7813 - *Sanofi / Google / DMI JV*, decision 23 February 2016, paragraph 24; M.7559 – *Pfizer / Hospira*, decision 4 August 2015, paragraph 30-31.

110 Case M.8675 - *CVC/Teva's Women's Health Business*, decision 20 December 2017, paragraph 20; Case M.6705 - *Procter&Gamble/Teva Pharmaceuticals OTC II*, decision 9 November 2012, paragraph 11.

111 Case M.7276 – *GSK/Novartis Vaccines Business (excl. Influenza)/Novartis Consumer Health Business*.

(c) The Commission's assessment

(101) In light of the above, the Commission will consider both national markets and the EEA as potential geographic markets to conduct its assessment of the GLP-1 receptor agonist market and the obesity preparations excluding dietetics, leaving the precise market definition open as the Transaction does not raise serious doubts as to the compatibility with the internal market regardless of the precise definition.

5. COMPETITIVE ASSESSMENT

5.1. Legal framework

5.1.1. Horizontal mergers

(102) A merger can entail horizontal effects. In this respect, the Commission Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "Horizontal Merger Guidelines") [112] distinguish between two main ways in which mergers between actual or potential competitors on the same relevant market may significantly impede effective competition, namely (a) by eliminating important competitive constraints on one or more firms, which consequently would have increased market power, without resorting to coordinated behaviour (non-coordinated effects); and (b) by changing the nature of competition in such a way that firms that previously were not coordinating their behaviour are now significantly more likely to coordinate and raise prices or otherwise harm effective competition. A merger may also make coordination easier, more stable or more effective for firms that were coordinating prior to the merger (coordinated effects).[113]

5.1.2. Non-horizontal mergers

(103) In addition, a merger can entail non-horizontal effects when it involves companies operating at different levels of the same supply chain or in closely related markets. Pursuant to the Commission Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings (the "**Non-Horizontal Merger Guidelines**"),[114] non-horizontal mergers do not entail the loss of direct competition between merging firms in the same relevant market and provide scope for efficiencies. However, there are circumstances in which non-horizontal mergers may significantly impede effective competition. This is in particular the case if they give rise to foreclosure.[115]

(104) Vertical mergers involve companies operating at different levels of the supply chain, for example, when a manufacturer of a certain product merges with one of its distributors.

(105) In assessing potential vertical effects of a merger, the Commission analyses whether a merger results in foreclosure so that actual or potential rivals' access to supplies or markets is hampered or eliminated as a result of the merger, thereby reducing these companies' ability and/or incentive to compete. Such foreclosure

112 OJ C 31, 5.2.2004, p. 5.
113 Horizontal Merger Guidelines, paragraph 22.
114 OJ C 265, 18.10.2008, p. 6.
115 Non-Horizontal Merger Guidelines, paragraph 18.

may discourage the entry or expansion of rivals or encourage their exit. Foreclosure thus can be found even if the foreclosed rivals are not forced to exit the market: it is sufficient that the rivals are disadvantaged and consequently led to compete less effectively. Such foreclosure is regarded as anti-competitive where the merging companies — and, possibly, some of their competitors as well — are as a result able to profitably increase the price charged to consumers.

(106) The Non-Horizontal Merger Guidelines distinguish between two forms of foreclosure.[116] The first is where the merger is likely to raise the costs of downstream rivals by restricting their access to an important input (input foreclosure). The second is where the merger is likely to foreclose upstream rivals by restricting their access to a sufficient customer base (customer foreclosure).

(107) In assessing both types of foreclosure, the Commission applies the ability, incentive, effects framework. This implies the assessment of three cumulative conditions, i.e. whether (1) the merged entity would have the ability to engage in foreclosure, (2) it would have the incentive to do so, and (3) what would be the overall impact on effective competition in the affected markets.

(108) Finally, as acknowledged in the Non-Horizontal Guidelines, the merged entity may gain access to commercially sensitive information regarding the upstream or downstream activities of rivals. For instance, by becoming the supplier of a downstream competitor, a company may obtain critical information, which allows it to price less aggressively in the downstream market to the detriment of consumers. Such acquisition of commercially sensitive information may also put competitors at a competitive disadvantage, thereby dissuading them from entering or expanding in the market.[117]

5.2. Overview of affected markets

(109) The Transaction gives rise to various vertically affected markets as well as one horizontally affected market.

(110) The Transaction also results in horizontal overlaps and vertical relationships for a number of other markets. However, none of these overlaps or relationships give rise to affected markets within the meaning of recital 25(g) Annex I to Regulation (EU) 2023/914.[118] Therefore, these overlaps and relationships will not be further discussed in this decision.[119]

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116 Non-Horizontal Merger Guidelines, paragraph 30.

117 Non-Horizontal Merger Guidelines, paragraph 78.

118 Commission Implementing Regulation (EU) 2023/914 of 20 April 2023 implementing Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings and repealing Commission Regulation (EC) No 802/2004, OJ L 119, 5.5.2023, p. 22.

119 One market participant has raised concerns in relation to gene therapy. The Commission does not consider the Transaction to raise risk of significant impediment to effective competition in the internal market in relation to Catalent's activities in gene therapy. *First*, Catalent's EEA-wide and global market shares in gene therapy (and its various plausible segments) do not exceed 30% and post-Transaction Catalent will continue to compete with various CDMOs currently providing gene therapy services such as for example Fujifilm Diosynth Biotechnologies, Lonza, Recipharm and Thermo Fisher. *Second*, Novo Holdings Controlled Portfolio Companies' (including Novo Nordisk) current activities in the gene therapy space are limited – only Novo Nordisk has two pre-clinical projects developed for the treatment of haemophilia, [Novo Nordisk's development strategy]. *Third*, Catalent is not currently providing gene therapy services to any products marketed or developed for haemophilia. (Form CO, paragraphs 276 *et seq.* and response to RFI 15).

5.2.1. Horizontal overlap

(111) The Transaction gives rise to a horizontal overlap between Catalent and one of Novo Holdings' portfolio companies, Altasciences, which provides CDMO services for LBDDs, which are a solubility enhancing technology. Depending on whether a broader or narrower market definition is adopted, this overlap results in a horizontally affected market for the supply of (i) CDO FDP services for solubility enhancing technologies, where the Notifying Party estimates the Parties' combined market shares to be just over [20-30]% worldwide,[120] or, (ii) CDO FDP services for LBDDs, where the Notifying Party estimates the Parties' combined market shares to be below [50-60]% worldwide.[121]

(112) The Commission considers this horizontal overlap unlikely to give rise to serious doubts as to the compatibility of the Transaction with the internal market, for the following reasons.

(113) First, regardless of the precise market definition, the increment from Altasciences is minimal (less than [0-5]% under any plausible market definition). This is all the more so in the EEA, where Altasciences [information about sales in the EEA].

(114) Second, Catalent's and Altasciences' activities are differentiated given that they are active in different segments of LBDDs, namely LFHCs for Altasciences and softgels for Catalent, with the result that there is no overlap in these potential narrower market segments.[122]

(115) Third, Altasciences is primarily a CRO focused on providing clinical and analytical services to small- to medium-sized customers at the early stage of clinical development and its CDO services for LBDDs are not a focus and represent an ancillary part of its business. In view of its focus, Altasciences' offering lacks the scale to compete with established CDMO players such as Catalent.[123]

(116) Fourth, Altasciences and Catalent do not appear to be close competitors in practice. Several respondents to the Commission's market investigation confirmed that they do not consider Catalent's offering in LBDDs to be closely competing with Altasciences' offering in LBDDs.[124] This is also supported by the fact that Catalent's opportunity tracking database, which tracks *inter alia* sales prospects lost to its rivals, […].[125]

(117) In view of the foregoing, the Transaction is unlikely to give rise to serious doubts as to its compatibility with the internal market as a result of horizontal effects in either of the plausible markets for CDO FDP services for solubility enhancing technologies, or for CDO FDP services for LBDD.

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120 The Notifying Party estimates Catalent's market share to be [20-30]% worldwide and in the EEA and Altasciences market share to be less than [0-5]%. Form CO, Tables 8 and 9.

121 The Notifying Party estimates Catalent's market share to be [40-50]% worldwide and in the EEA and Altasciences market share to be [0-5]% or less. Form CO, Tables 8 and 9.

122 Form CO, paragraphs 546ff.

123 Form CO, paragraph 538.

124 Responses to question E.B.3 of the Questionnaire to CDMO customers and responses to question E.B.3 of the Questionnaire to CDMOs.

125 Form CO, paragraph 539.

5.2.2. Vertical relationships

(118) The Transaction gives rise to several vertically affected markets:

(a) The supply of CMO FDP services for PFS (upstream) – the supply of (i) anti-obesity preparations excluding dietetics, and (ii) GLP-1 receptor agonists indicated for diabetes (downstream); and

(b) The supply of CMO FDP services for ODTs (upstream) – the supply of opioid use disorder ("**OUD**") treatments (downstream)

(119) A number of complaints were raised by market participants to the Commission with regard to the Transaction. Notably[126]:

(a) Market participants raised input foreclosure concerns whereby the Parties would stop or deteriorate the provision of CMO FDP services for PFS to customers of Catalent, both to (potential) rivals of the merged entity for the supply of (i) anti-obesity preparations excluding dietetics, and (ii) of GLP-1 receptor agonists indicated for diabetes, and (iii) to other companies active with regard to the supply of injectable FDPs. The Commission addresses these complaints in Section 5.3.1.[127]

(b) Some market participants raised a concern that the merged entity may gain access to commercially sensitive information of its downstream rivals, putting them at competitive disadvantage. The Commission addresses these complaints in Section 5.4.[128]

5.3. Assessment of the supply of CMO FDP services for PFS (upstream) – supply of (i) anti-obesity preparations excluding dietetics, and (ii) GLP-1 receptor agonists indicated for diabetes (downstream)

(120) A vertically affected market arises as a result of Catalent's provision of CMO FDP services for PFS (upstream) and Novo Nordisk's supply of (i) anti-obesity preparations excluding dietetics, and (ii) GLP-1 receptor agonists indicated for diabetes (for the purposes of this Decision, together "**the supply of obesity and**

126 In the course of its market investigation, a limited number of market participants raised concerns about Catalent being one of the few CDMOs capable of offering a variety of CDMO services across the full life cycle of a product and across therapeutic indications and product presentation (so called "end-to-end" services). However, the overall market feedback shows that different CDMO services are frequently sourced separately from different CDMO and the majority of respondents to the market investigation submitted that it was entirely possible, and common, to source these services from separate CDMOs (See responses to question G.2 of the Questionnaires) Finally, several CDMOs have been identified by market participants as capable of providing a broad range of CDMO services, including for example Fujifilm Diosynth Biotechnologies, Lonza, Recipharm, Samsung Biologics, Siegfried, Thermo Fisher and Vetter (See responses to question G.1 of the Questionnaires). Considering the above, the Commission considers that: (i) there is no separate market for end-to-end CDMO services; and (ii) even if such a market were to be identified, it is not likely that the Transaction would result in significant impediment to effective competition in relation to end-to-end CDMO services. The Decision will therefore not further discuss end-to-end CDMO services in this decision.

127 For the purposes of this Decision, the Commission will focus its assessment on the competitors per (i) and (ii), noting that the same conclusions regarding the inability to foreclose apply to market participants per (iii).

128 Non-confidential Minutes of a call with a CDMO customer, held on 29 April 2024, paragraphs 24-28. See also replies to questions H.1 to H.5 of the Questionnaires to CDMOs and CDMO customers, and questions I.1, I.3 and I.4 of the Questionnaire to CDMO customers.

diabetes products") [129] (downstream). The Commission will first review whether post-Transaction, the Parties will have the ability and the incentive to engage in input foreclosure, and whether this strategy will have an impact on competition (Section 5.3.1). Second, the Commission will assess potential customer foreclosure concerns (Section 5.3.2).

5.3.1. Input foreclosure

5.3.1.1. Market and capacity shares

(121) For the market upstream, Table to Table show the Notifying Party's estimates for Catalent's market shares on the market for the supply of CMO FDP services for PFS (upstream) for each of 2023, 2022 and 2021.

Table 2 - Market shares for the supply of CMO FDP services for PFS – 2023

2023	Supply of CMO FDP services for PFS (upstream)	
	Global	EEA
Value	[0-5]%	[0-5]%
Volume	[0-5]%	[0-5]%

Source: M.11486 - Novo Holdings - Novo Nordisk - Catalent - Annex Q3 RFI 11 – Confidential, contained in Annex 00011.M11486-NNNHCTL to the Form CO; and Annex 00057.M11486-NNNHCTL to the Form CO.

Table 3 - Market shares for the supply of CMO FDP services for PFS – 2022

2022	Supply of CMO FDP services for PFS (upstream)	
	Global	EEA
Value	[0-5]%	[0-5]%
Volume	[0-5]%	[0-5]%

Source: M.11486 - Novo Holdings - Novo Nordisk - Catalent - Annex Q3 RFI 11 – Confidential, contained in Annex 00011.M11486-NNNHCTL to the Form CO; and Annex 00057.M11486-NNNHCTL to the Form CO.

Table 4 - Market shares for the supply of CMO FDP services for PFS – 2021

2021	Supply of CMO FDP services for PFS (upstream)	
	Global	EEA
Value	[0-5]%	[0-5]%
Volume	[0-5]%	[0-5]%

Source: M.11486 - Novo Holdings - Novo Nordisk - Catalent - Annex Q3 RFI 11 – Confidential, contained in Annex 00011.M11486-NNNHCTL to the Form CO; and Annex 00057.M11486-NNNHCTL to the Form CO.

(122) The Notifying Party also provided its estimate of shares in terms of fill-finish capacity. Catalent holds an estimated [10-20]% in PFS (globally).[130]

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129 Given the competitive dynamics for both indications, the assessment will cover both together. Novo Nordisk develops products for other indications such as MASH or Alzheimer's disease by relying on GLP-1 receptor agonists (including a semaglutide product in Phase III for MASH, per Table 32 of the Form CO). The Commission's conclusion in relation to a potential foreclosure strategy against manufacturers of products in those other indications is the same as for obesity and diabetes products.

130 Form CO, paragraph 1220 (capacity shares based on total capacity, taking into account capacity of CDMOs in Europe (including Switzerland and the UK) and the U.S., per Form CO, fn. 956).

(123) In addition to the Parties' own estimates, the Commission conducted a market reconstruction during pre-notification to establish Catalent's share of capacity for CMO FDP services for PFS. The market reconstruction had a high response rate (94%), covered 70% of the supply of CMO FDP services for PFS based on the Parties' estimates[131] and included players with a meaningful role in the competitive dynamics on the market for CMO FDP services for PFS based on a review of the Parties' internal documents and feedback received in pre-notification calls with market participants. Table and Table show the results of the Commission's market reconstruction regarding Catalent, for all lines and high-speed lines[132] separately:

Table 5 - Catalent's capacity shares for all lines

High speed lines	Total capacity		Committed capacity		Spare capacity	
	Global (ex-China)	EEA	Global (ex-China)	EEA	Global (ex-China)	EEA
2024	[10-20%]	[0-10%]	[10-20%]	[10-20%]	[0-10%]	[0-10%]
2025	[10-20%]	[10-20%]	[20-30%]	[20-30%]	[0-10%]	[0-10%]
2026	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
2027	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]

Source: data provided by several CDMOs including Catalent.

Table 6 - Catalent's capacity shares for high-speed lines

High speed lines	Total capacity		Committed capacity		Spare capacity	
	Global (ex-China)	EEA	Global (ex-China)	EEA	Global (ex-China)	EEA
2024	[10-20%]	[0-10%]	[20-30%]	[10-20%]	[0-10%]	[0-10%]
2025	[10-20%]	[10-20%]	[20-30%]	[20-30%]	[0-10%]	[0-10%]
2026	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]	[10-20%]
2027	[10-20%]	[10-20%]	[20-30%]	[20-30%]	[10-20%]	[10-20%]

Source: data provided by several CDMOs including Catalent.

(124) For the downstream market, Table to Table below provide market shares for the supply of obesity and diabetes products (downstream) based on value and volume for years 2023, 2022 and 2021, split between obesity and diabetes.[133]

(125) With respect to these market shares, the Commission notes that the Parties also provided market share estimates per Member State and at the ATC4 level for diabetes. The Commission's assessment does not change as a result of these data, or of the segmentation per level or geographic scope. This is because the assessment concerns a strategy in which the merged entity would foreclose access to Catalent's CMO FDP services for PFS, which is at least an EEA-wide or global market (potentially excluding China). Accordingly, the merged entity's ability to foreclose would not vary by Member State, as a customer in a given Member State

131 Notably based on the capacity share data submitted with the Briefing Paper of 10 April 2024.

132 For the purposes of the market reconstruction, high-speed lines were defined as lines with a speed of 300 units and above. The Commission notes, however, that should lines with a speed of 400 units and above be used as a reference, the shares would not materially differ.

133 Annex 00056.M11486-NNNHCTL to the Form CO.

could turn to CDMOs across the EEA or worldwide. Additionally, Catalent's ability to target a foreclosure strategy at particular Member States would be hampered by the fact that it typically ships PFS to the warehouse/facility specified by the customer, but customers decide where to market the products and may re-ship them to other destinations – Catalent is not informed of the final destination of the product in the ordinary course of business.[134]

Table 7 - Novo Nordisk's market shares on the supply of obesity and diabetes products – 2023

2023	EEA	
	Obesity	Diabetes
Value	[>90]%	[60-70]%
Volume	[70-80]%	[60-70]%

Source: Data submitted by the Parties based on IQVIA MIDAS data and included in the Form CO

Table 8 - Novo Nordisk's market shares on the supply of obesity and diabetes products – 2022

2022	EEA	
	Obesity	Diabetes
Value	[80-90]%	[50-60]%
Volume	[50-60]%	[50-60]%

Source: Data submitted by the Parties based on IQVIA MIDAS data and included in the Form CO

Table 9 - Novo Nordisk's market shares on the supply of obesity and diabetes products – 2021

2021	EEA	
	Obesity	Diabetes
Value	[60-70]%	[50-60]%
Volume	[30-40]%	[50-60]%

Source: Data submitted by the Parties based on IQVIA MIDAS data and included in the Form CO

5.3.1.2. The Notifying Party's views

(126) As regards the ability of the merged entity to engage in a foreclosure strategy, the Notifying Party argues that[135]:

(a) Catalent's share on the market of CMO services for FDP injectables is limited.[136] For instance, the Notifying Party submitted Catalent's share on the segment of CMO FDP services for PFS, showing it is only [0-5]% globally and in the EEA, by value.[137] On that specific segment, Catalent faces competition from a wide range of competitors including Vetter (globally around [10-20]%), Thermo Fisher (globally around [10-20]%), Simtra

134 Response to RFI 2, question 15.
135 Form CO, paragraphs 1219-1220.
136 Form CO, paragraph 1219.
137 Annex 00057.M11486-NNNHCTL.

(globally around [0-5]%), Pfizer CentreOne (globally around [0-5]%), and Recipharm (globally around [0-5]%).[138]

(b) There is significant available capacity in the market to serve Catalent's customers in the event of a hypothetical foreclosure strategy, and there is significant planned capacity coming to market during the period when rivals may be looking to launch and scale up. In addition to third party CDMO capacity for fill-finish services, market participants can also rely on in-house capacity.[139]

(c) Catalent only supplies limited volumes of fill-finish services for obesity and diabetes products to its customers. The volumes that Catalent supplies to the customers in question are not decisive for their ability to compete with marketed products or bring pipeline products to market in a timely manner. In particular, Novo Nordisk's competitors are not major customers of Catalent.[140] The limited volumes in question can therefore easily be placed with third-party suppliers.[141] For example, the Parties referred to Pfizer CenterOne, Aspen, INCOG, Simtra as CDMOs with (future) capacity on lines for 100 million PFS units or more.

(d) Regarding lines for high-volume products specifically, the Parties submitted similar observations explaining that there is available capacity. Notably, the Parties referred to various announcements made by CDMOs for the set-up of new high-speed lines in the coming years, as well as Novo Nordisk's own experience with CDMOs.[142]

(127) As regards to the incentive of the Parties to engage in a foreclosure strategy, the Notifying Party argued notably that:[143]

(a) For the customers using PFS lines, refusing or downgrading services supplied to customers for a specific downstream product could lead to significant broader losses for Catalent due to the potential damage to overall customer relationships.[144]

(b) Novo Nordisk does not plan to use the capacity currently contracted at Catalent's sites for manufacturing in the short term (even though its intention is eventually to use that capacity for its internal needs).

(c) The likelihood of any recoupment downstream is low and uncertain.

(d) Since customers can switch CDMO suppliers, and since there is more than sufficient capacity in the market to accommodate these customers' volumes, a hypothetical input foreclosure strategy is in any event unlikely to be successful in raising these rivals' costs to the benefit of Novo Nordisk downstream.

(128) As regards the impact of a potential foreclosure strategy would have on the market, the Notifying Party argued notably that:[145]

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138 Annex 00057.M11486-NNNHCTL, data provided for 2023.
139 Form CO, paragraph 1220.
140 Form CO, paragraph 1221-1245.
141 Form CO, paragraphs 1246-1253.
142 Form CO, paragraphs 1297-1308.
143 Form CO, paragraphs1314-1326.
144 Form CO, paragraphs 1211 and 1315.
145 Form CO, paragraphs 1327 and 1333.

(a) Catalent holds only a modest share of fill-finish capacity for PFS services, and is not the main supplier or, in the case of the pipeline products, currently contracted to service obesity and diabetes products beyond (early-stage) clinical trials.

(b) There is ample available capacity on the market, and CDMOs are currently expanding so that customers can move to source such other capacity.

(c) Many of the products at Catalent's sites are backed by large and established pharmaceutical companies who will have sufficient internal capacity to continue to develop and bring these products to market, and be able to secure external capacity, should they be successful. None of these products rely on Catalent. As regards other smaller biotech companies, any such company that shows promise based on trial readouts will be able to raise funds, or may be acquired by, or partner with larger companies, as seen with several recent compounds, and therefore will also have the resources to secure external manufacturing capacity as and when needed.

5.3.1.3. The Commission's assessment

(129) First, as mentioned above, market participants raised input foreclosure concerns where Catalent would stop supplying them with CMO FDP services for PFS (total foreclosure) or would deteriorate the quality of the CMO FDP services for PFS provided to them (partial foreclosure)[146]. The Commission will cover the total and partial foreclosure concerns together given that, in this case, the same considerations generally apply to both concerns. Where applicable, the Commission will identify those considerations that are specific to either total or partial foreclosure.

(130) Second, several market participants have raised concerns that post-Transaction, there would be a lack of capacity or of credible alternative CDMOs for products during all development/production phases, in particular in relation to high-volume commercialised products.[147] The assessment will therefore take into account, where applicable, considerations specific to: (i) clinical phase products[148]; (ii) low-to-medium volume commercialised products; and (iii) high-volume commercialised products.

(131) Third, the Commission typically considers markets for the supply of pharmaceutical products as national. For the purposes of this Decision however, given that the same considerations generally apply across the EEA per the comments in paragraph (125) and that the market for the supply of CMO FDP services for PFS is at-least EEA wide, if not global (potentially excluding China), the Commission will assess the vertical link at hand at EEA level for the supply of obesity and diabetes products (downstream market).

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146 For instance, some respondents have shared concerns that Catalent, going forward, would deteriorate the quality of its services, e.g. by deprioritising products of other competitors in favour of Novo Nordisk's own products or by reducing the quantities supplied (for instance, minutes of 11 June 2024 with a CDMO customer, paragraph 23, or minutes of 3 May 2024 with a CDMO customer).

147 Please see for instance, minutes of 24 June 2024 with a CDMO customer, minutes of 3 May 2024 with a CDMO customer; minutes and presentation of 29 April 2024 with a CDMO customer and, feedback received during the market investigation, responses to question I.1. of the Questionnaire sent to CDMO customers.

148 Note that products at the clinical phase typically do not require to be produced at high-volume given the number of participants in clinical trials.

5.3.1.3.1. Ability

(132) The Commission considers that the merged entity is unlikely to have the ability to engage in a successful total or partial input foreclosure strategy for the following reasons.

(133) *First*, per the shares listed above in Table and Table , the Commission notes that Catalent's share does not exceed 30% in any of the years considered, for CMO FDP services for PFS regardless of the line-speed segmentation, both at the EEA-wide and global level. Indeed, in a majority of segments, the capacity shares are below 20%.

(134) *Second*, the market investigation confirmed that there are several credible, good quality and sizeable alternatives to Catalent for CMO FDP services for PFS (including Thermo Fisher, Vetter, Pfizer CentreOne). Other CDMOs such as Rovi, INCOG or Corden Pharma were also mentioned by CDMOs and CDMO customers, although market participants considered they were generally of lower quality and technical capabilities than Thermo Fisher, Vetter and Pfizer CenterOne.[149] The fact that Novo Nordisk has signed agreements with, *inter alia*, [Novo Nordisk's manufacturing strategy], illustrates the fact that these other CDMOs can also provide their services for PFS products.[150]

(135) As regards capacity for clinical phase products (*i.e.* products likely requiring low to medium speed production lines), a majority of respondents considered that there will remain sufficient choice of credible CDMOs with available capacity for CMO FDP services for PFS.[151] For instance, a CDMO stated that: "*the CDMO manufacturing space is fragmented and very competitive. Many companies provide services from preclinical through Phase III, and CDMOs are not highly specialized*". Similar feedback was provided by CDMO customers: "*plenty of small scale CDMOs are available for low volume demand required at clinical stage*".

(136) As regards capacity for low-to-medium volume commercialised products (*i.e.* products likely requiring low to medium speed production lines), a majority of respondents confirmed that there will remain sufficient choice of credible CDMOs with available capacity for CMO FDP services for PFS.[152] For example, respondents stated that: "*there are many CDMO´s facilities with medium and low speed lines.*" and "*for medium to low volumes we anticipate that there will be enough choice of CDMO's with sufficient capacity*".

(137) As regards capacity for high-volume commercialised products (*i.e.* products likely requiring high speed production lines), the Commission notes the following:

149 The Commission notes that while some respondents, who use CMO FDP services for PFS, have argued that a key parameter of competition to choose CDMOs is the fact that they can offer a "full-service", the market investigation shows that such a parameter, as regards CMO FDP services for PFS, is the least relevant for CDMO customers (please see footnote 126).

150 Form CO, paragraph 1301.

151 Please see response to question D.B.A.6. of the Questionnaire sent to CDMOs, and to question D.B.10 of the Questionnaire sent to CDMO customers.

152 Response to question D.B.A.7. of the Questionnaire sent to CDMOs, and to question D.B.11. of the Questionnaire sent to CDMO customers.

(a) The majority of Catalent's current fill-finish capacity at the Carveout Sites is already committed to Novo Nordisk under agreements that predate the Transaction, and therefore not available to third party customers.[153]

(b) The Parties would individually not invest in new PFS capacity absent the Transaction in addition to what they already planned. Rather, in such a case, Novo Nordisk would have approached alternative CDMOs for their PFS capacity in addition to the already contracted capacity at Catalent.[154]

(c) There is sufficient capacity on the market to meet demand for CMO FDP services for PFS. As shown in the market investigation, a majority of competitors believe that there is either enough or plenty of capacity to meet the future demand for PFS services for high volume products. CDMO customers seemed to be more cautious in providing such feedback, even though half of CDMO customers agreed with this conclusion.[155]

(d) Catalent's share of spare capacity (*i.e.* PFS capacity free for CMO customers to purchase) is below 5% at global and EEA levels in 2024 and 2025, and in any event below 20% both at global and EEA levels in the coming years.

(e) There are alternative CDMOs that offer CMO FDP services for PFS. Even though, based on the market participants' submissions, capacity for such high-volume products is more constrained than the two other segments mentioned above, a majority of respondents still considered that there will be sufficient choice of credible CDMOs with available capacity for CMO FDP services for PFS.[156] For example, market participants listed Vetter, Corden Pharma, Grand River, Pfizer CenterOne, ThermoFisher, Rovi, Aspen as CDMOs that could credibly supply CMO FDP services for PFS for high-volume commercial products.

(f) Capacity on the market will likely increase in the coming years as Catalent's rivals have announced major expansions. During the market investigation, market participants acknowledged that CDMOs are currently investing in building new high-speed PFS lines, which could cater for the demand of high-volume products. For example, several CDMOs such as Aspen, Simtra, and Rovi have announced major investments in the manufacturing sector.[157]

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153 Form CO, paragraph 1336.

154 Response to RFI 16 of 25 November 2024. The Notifying Party submitted that absent the Transaction, Novo Nordisk would have invested in new production lines, primarily for filling cartridges, which it is now likewise investing in as part of the Transaction.

155 Some respondents argued that the Transaction would lead to an increase of price for CMO FDP services for PFS, or a decrease in innovation and quality on the market, notably due to a reduction of CDMOs being active on the market (see for example, responses to question I.2. of the Questionnaire sent to CDMO customers). The Commission notes in that regard that the market reconstruction exercise has shown that there is sufficient capacity and that CDMOs are investing to launch new lines – including for high-volume products – in the coming years, hence increasing the supply of CMO FDP services for PFS. As a result, there will remain a number of credible CDMOs on the market that will continue to compete e.g. on price, innovation and quality. Therefore, the Commission considers that the Transaction is unlikely to lead to an increase of price for CMO FDP services for PFS or a decrease in innovation and quality on the market.

156 Response to question D.B.A.8. of the Questionnaire sent to CDMOs, and to question D.B.12. of the Questionnaire sent to CDMO customers. Available capacity for high-volume products could for example be used by entrants (e.g. CDMO customers that are currently developing new GLP-1 type drugs including generics).

157 Form CO, paragraph 1308 and Catalent High-Scale Paper paragraph 61, contained in Annex 00028.M11486-NNNHCTL of the Form CO. This is in addition to other announced investments such as those of Vetter and Thermo Fisher, as mentioned in Form CO, paragraph 1118.

The market reconstruction also confirmed that new lines are being built and will be running in the coming years, many of which would be appropriate for high-volume products.

(138) *Third*, customers of CMO FDP services for PFS can switch their contract manufacturer.

(a) In many instances, customers have multiple CDMOs qualified for CMO FDP services for PFS for their respective products, often in addition to in-house capabilities.[158] In such cases, switching can happen without significant delays provided that the alternative CDMO has spare capacity. In this case for example, this is shown, first, in the market reconstruction that indicated several CDMOs had spare capacity available for CDMO customers; and, second, in the fact that some customers of Catalent have already switched or are in the process of undertaking a technology transfer away from Catalent.[159]

(b) Adding a new supplier or a new line is accomplished by completing a technology transfer. Technology transfers can take 6 to 12 months for products which are at the clinical stage of development and 6 to 18 months for commercialised products. Respondents to the market investigation detailed that the specific timeline for a given product depends on its characteristics and on the experience level of the CDMO involved. If the CDMO needs to procure and install additional equipment this would also extend the timeline.[160]

(c) The cost for switching between CDMOs for CMO FDP services for PFS is generally in the range of EUR 1-7 million. This also varies based on the complexity of the product, the stage of its development (with transfer being less costly for products at the clinical stage) and the number of doses/formulations being switched.[161] This number should also be read in light of the downstream revenues that the pharmaceutical products are expected to generate, and therefore the likely low proportion of the cost of switching represents in the overall investment. For instance, Novo Nordisk's sales in 2023 in the EEA amounted to several billions of euros for obesity and diabetes products.[162]

(d) On balance, while the Commission acknowledges that switching might take time and requires some investment, it remains a viable option for customers of CMO FDP services for PFS. Respondents to the market investigation have also highlighted this fact, with one clinical stage manufacturing CDMO

158 As shown for example in M.11486 - Novo Holdings - Novo Nordisk - Catalent - Annex Q. 12 EC RFI 13, contained in Annex 00013.M11486-NNNHCTL to the Form CO.

159 As illustrated in feedback received in relation to question I.1. of the Questionnaire sent to CDMO customers, and in Annex Q. 12 EC RFI 13 within Annex 00013.M11486-NNNHCTL of the Form CO, which lists several customers of Catalent who will continue production in-house and / or at another CDMO.

160 See response to question D.B.A.12. and D.B.A.13. of the Questionnaire sent to CDMOs, and to question D.B.14. and D.B.15. of the Questionnaire sent to CDMO customers. The Parties submit that Catalent's CDMO customers that use CMO FDP services for PFS will be able to maintain production at the relevant facilities for the coming years allowing for sufficient time to switch.

161 Response to question D.B.A.14. of the Questionnaire sent to CDMOs, and to question D.B.16. of the Questionnaire sent to CDMO customers. The Parties submit in that regard that customers that currently have a Phase III pipeline in the PFS format at Catalent sites have the possibility to receive monetary compensation up to a certain cap, to facilitate such process.

162 Annex 00056.M11486-NNNHCTL to the Form CO.

customer for example replying that: "*it will have enough time to secure the needed capacity*".[163]

(139) Therefore, Catalent is unlikely to have significant market power in the supply of CMO FDP services for PFS in the EEA or worldwide, and the merged entity would not have the ability to engage in an input foreclosure strategy, in particular as its market shares are limited, a number of credible rival sources of supply will remain and have spare capacity, and customers can switch to alternative CDMOs.

5.3.1.3.2. Incentive

(140) The Commission's investigation indicated several reasons why the merged entity is likely to have an incentive to stop providing CMO FDP services for PFS to Catalent's customers at the Carveout Sites[164] or to worsen the terms or conditions on which these services are provided to customers of the Carveout Sites.[165] This would be with a view to prioritising Novo Nordisk's needs for CMO FDP services for PFS in these sites so that it can meet the significant and growing demand for its obesity and diabetes products. Accordingly, the merged entity may have an incentive to stop or reduce supplies to actual and potential competitors for obesity and diabetes products (or indeed customers of the Carveout Sites more generally), to focus its supplies on Novo Nordisk instead.

(141) First, it is clear from the Transaction rationale that the merged entity intends to use the capacity in Catalent's Carveout sites to exclusively meet Novo Nordisk's demand for PFS. The Notifying Party explains that: "*Novo Nordisk expects demand for its GLP-1 RA semaglutide products to continue growing… [Novo Nordisk's manufacturing capacity]…the Transaction will allow Novo Nordisk to internalize fill-finish activities at the Carveout Sites*".[166] While the Notifying Party submits that Novo Nordisk would initially keep Catalent's CMO business separate from Novo Nordisk's internal demand, and honour all existing PFS contracts, it acknowledges that there would be a "gradual phase-out" of offering CMO services at the Carveout Sites to third parties.[167] This is also clear from Novo Nordisk's internal documents, which demonstrate its expectation that capacity at the Carveout Sites would over time be exclusively reserved to Novo Nordisk to help meet growing demand.[168] In addition to the benefits of internalising Novo Nordisk's

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163 Response to question I.1. of the Questionnaire sent to CDMO customers.

164 As explained in paragraph (13) above, the Transaction rationale for Novo Nordisk is to acquire the Carveout Sites so that it can access its PFS capacity and expansion potential, with a view to ultimately reserving that capacity exclusively for Novo Nordisk's obesity and diabetes products. The assessment of incentives therefore focuses on the Carveout sites. By contrast, as explained in paragraph (17) above, Novo Holdings intends to continue to operate the RemainCo sites as a CDMO on a business as usual basis. The merged entity's incentives regarding the RemainCo sites are assessed in paragraph (144) below.

165 To the extent that partial foreclosure strategies would aim to prioritise the provision of CMO FDP services for PFS to Novo Nordisk with a view to maximising its output, or would aim to encourage customers to switch to another CDMO to free up capacity for Novo Nordisk at the Carveout Sites, the Commission considers that similar considerations apply to these strategies and total foreclosure in assessing the merged entity's incentive to foreclose in this case.

166 Form CO, paragraphs 67 and 69.

167 Form CO, paragraph 201. During the process of the Commission's investigation, the Parties informed the Commission that they have entered into revised contracts with a number of Catalent's customers which provide certain guarantees regarding minimum volume commitments, extended contract durations and prioritisation protocols.

168 For instance, Annex 00001 to the Form CO, Documents 4c-7 (slide 9), 4c-26 (slide 10), 4c-22 (slide 39).

sourcing of PFS within the merged entity, the Commission notes that the merged entity would have higher incentives to potentially foreclose PFS customers that rely on Catalent for their obesity and diabetes products (compared with customers that procure services from Catalent for other products), to the extent that Novo Nordisk's obesity and diabetes products may benefit from reduced competitive pressure from those customers.

(142) Second, the market investigation suggests that the risk of contractual liability is unlikely to be a sufficient deterrent for the merged entity from engaging in input foreclosure. The Notifying Party submitted that Novo Nordisk would not have the incentive to foreclose, as any failure to honour its existing contracts with customers, for example by ceasing or disrupting supplies, is likely to expose Novo Nordisk to the risk of contractual claims or litigation.[169] However, the majority of customers responding to the investigation indicated that their contract with Catalent for CMO FDP services for PFS does not bind Catalent to meet all of their needs.[170] Customers generally considered that penalty clauses for a failure to supply or for substandard performance, to the extent their contract contained such clauses, were unlikely to be sufficient to prevent the merged entity from prioritising Novo Nordisk's demand in the Carveout Sites.[171] Customers therefore considered that the risk of contractual liability is unlikely to discourage prioritising Novo Nordisk's demand, in particular as some customers' contracts with Catalent only relate to low volumes and so imply a modest liability risk (compared with the significant profits the merged entity might earn from Novo Nordisk's obesity and diabetes products).[172]

(143) Third, the market investigation suggested that the risk of reputational damage is unlikely to be a sufficient deterrent for Novo Nordisk should it decide to engage in input foreclosure. The majority of customers considered that reputational considerations would not prevent the merged entity from prioritising Novo Nordisk in the Carveout Sites. Nevertheless, a number of customers pointed out that reputation is important in the pharmaceutical industry and so may deter the merged entity from creating a situation where patients' needs are unmet.[173]

(144) For completeness, it appears unlikely that the merged entity would have an incentive to foreclose customers at the RemainCo sites which will be operated by Novo Holdings. This is because the RemainCo sites do not offer CMO FDP services for PFS, with the exception of the site in Limoges which offers clinical stage CDMO services, and has a limited capacity with a single smaller scale (lower speed) line that is at present primarily focused on clinical stage CMO services, as opposed to commercial stage CMO services. Having access to capacity on this line would therefore be unlikely to contribute meaningfully to Novo Nordisk's high scale production needs, as also reflected by the fact that the line will be acquired by Novo Holdings with a view to operating it as a CDMO offering services to third parties on an arm's length basis, rather than Novo Nordisk with a view to vertically integrating it.[174] Only one customer relies on this line for clinical development services for PFS for GLP-1 products, and this customer is still at an early stage of

169 Form CO, paragraph 1319.
170 Response to questions D.B.18-19 of the Questionnaire sent to CDMO customers.
171 Response to questions D.B.20-21 of the Questionnaire sent to CDMO customers.
172 Response to question D.B.22 of the Questionnaire sent to CDMO customers.
173 Response to question D.B.23 of the Questionnaire sent to CDMO customers.
174 Form CO, paragraph 1337.

clinical trials (meaning switching is feasible, see paragraph (138) above), and intends to work with other CDMOs for the commercial stage.[175] Accordingly, it is unlikely that the merged entity would have the ability or the incentive to foreclose this customer in the RemainCo Sites given that the strategy would be unlikely to succeed.

(145) In light of the foregoing, it cannot be excluded that the merged entity would have the incentive to prioritise Novo Nordisk's demand in the Carveout Sites over demand from actual or potential competitors for obesity and diabetes products, or indeed demand from existing Catalent PFS customers more generally. Nevertheless, it is not necessary for the Commission to conclude on the presence or not of an incentive to foreclose, as the merged entity would lack the ability to engage in a foreclosure strategy (for the reasons outlined in Section 5.3.1.3.1) and such a strategy, even if attempted, would be unlikely to have a significant detrimental effect (for the reasons outlined in Section 5.3.1.3.3).

5.3.1.3.3. Effect

(146) The Commission considers that a total or partial input foreclosure strategy would be unlikely to have a significant detrimental effect on companies developing or marketing obesity and diabetes products (or indeed Catalent's customers more broadly) for the following reasons.

(147) First, as explained in Section 5.3.1.3.1, post-Transaction, customers will be able to turn to a number of credible CDMOs with sufficient capacity for CMO FDP services for PFS. These CDMOs are capable of meeting demand for both lower and high-volume products. Customers will therefore be able to avoid or mitigate the impact of any attempted foreclosure strategy through switching and some customers have already begun this process in response to the Transaction.[176] Additionally, the majority of customers responding to the investigation already have multiple CDMOs qualified to manufacture some or all of their products, meaning that they may be able to quickly increase their purchases from those other suppliers to cover (at least an increased proportion of their demand) without having to engage in a full technology transfer and qualification process.[177]

(148) Second, customers responding to the market investigation also indicated that alternative counterstrategies would be available, such as increasing in-house supply of PFS or even considering supplying products in alternative forms (e.g. cartridges rather than PFS).[178] Such strategies could enable them to mitigate the impact of any attempted foreclosure strategy, though this would depend on the extent to which internal spare capacity is available and on the time needed to change product forms (which may be time consuming, depending on the extent to which regulatory approval is already obtained for the form and for the production line).

(149) Third, the market investigation indicated that customers generally only depend on Catalent to a limited extent. For the vast majority of customers, Catalent currently represents less than 10% of their supplies of PFS, and this is expected to remain

175 Form CO, footnote 124 and paragraphs 1243-1245.
176 As described in paragraph (138).
177 Response to question D.B.26 of the Questionnaire sent to CDMO customers.
178 Response to question D.B.27 of the Questionnaire sent to CDMO customers.

broadly similar over the next three years.[179] This is also linked to the fact that the majority of Catalent's capacity for PFS is dedicated to or reserved for Novo Nordisk as a result of contracts agreed independently from and prior to the Transaction.[180]

(150) As regards commercial manufacturing (for both low-medium and high-volume products) more specifically, some competitors for obesity and diabetes products have contracts in place with Catalent and may have hoped to rely on Catalent to meet their needs in future.[181] However, pre-Transaction, rival obesity and diabetes product manufacturers only rely on Catalent to a limited degree. There is only one marketed obesity and diabetes product for which Catalent provides CMO FDP services for PFS, and Catalent accounts for a small portion of those volumes.[182] Catalent has not manufactured any commercial PFS batches of obesity and diabetes products for that customer as they have yet to complete technology transfer and receive regulatory approval for the line. Novo Nordisk is the only company that commercialises obesity and diabetes products based on the supply of CMO FDP services for PFS from Catalent.[183]

(151) At the clinical stage, Catalent provides CMO FDP services for PFS for some obesity and diabetes products that are in clinical trials.[184] As explained in paragraph (138) above, the time and cost for switching at the clinical stage is surmountable, in particular in the context of the cost and timeline of the development of pharmaceutical products generally. Customers and CDMOs responding to the market investigation consider that customers can generally continue to work with their existing CDMO while undertaking a technology transfer to another supplier and note that it is standard industry practice for CDMOs to support this process. They also point out that it is possible (and standard practice) for pharmaceutical companies to build up sufficient inventory to cover their needs during the process of a technology transfer as a way to ensure the continuity of supply (indeed, at the clinical stage the level of reserves will be significantly lower than at the commercial stage).[185] Finally, none of the competitors who currently receive CMO FDP services for PFS for their obesity and diabetes products at the clinical stage have contracted with Catalent to provide CMO FDP services for these products at the commercial stage.[186]

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179 Response to questions D.B.24-25 of the Questionnaire sent to CDMO customers.

180 The Notifying Party explains that six of Catalent's eight high scale PFS lines are already fully or partially contracted by Novo Nordisk. Form CO, paragraphs 1309-1312.

181 Please note that this assessment would not change regardless of the speed of the line.

182 The Notifying Party estimates that Catalent's CMO FDP services for PFS only account for around [10-20]% of the total volumes of this product marketed in 2023 (Form CO, paragraph 1332).

183 Catalent's paper on the available capacity for high-scale fill finish PFS lines, paragraphs 51-52.

184 Please see the explanation on the line speed in the clinical phase, paragraph 63.

185 Response to question D.B.A.15.1 of the Questionnaire sent to CDMOs and question D.B.A.15.1 of the Questionnaire sent to CDMO customers. For instance, one customer explains: "*[m]ost companies will start the process to another CMDO when they have sufficient inventory to meet clinical demand for the period where the tech transfer takes place in the clinical phase. To avoid interruption to market supply in the commercial phase a company would continue dual sourcing while transferring technology until the receiving CDMO is ready to manufacture*". Another noted that "*[i]t is a standard in the industry to create a bridge stock to cover this transfer period, or to continue delivering product until the new CDMO is approved*". During the process of the Commission's investigation, the Parties informed the Commission that they have entered into revised contracts with a number of Catalent's customers which provide certain guarantees regarding the duration of supply, minimum supply volumes and a last time buy right that would enable customers to stockpile products.

186 Catalent's paper on the available capacity for high-scale fill finish PFS lines, paragraph 53.

(152) Fourth, some market participants suggested that the Transaction may lead to higher prices for CMO FDP services for PFS (charged by other suppliers), because removing Catalent as a source of supply significantly reduces the availability of spare PFS capacity for third parties. The Commission considers that to be unlikely. While demand is increasing for CMO FDP services, the Commission's market reconstruction confirmed that CDMOs are rapidly expanding capacity to meet this growing demand. Moreover, Catalent currently represents a modest share of supply both in terms of sales and spare capacity ([20-30]% or less in 2024). Already pre-Transaction, Catalent only has limited spare PFS capacity that is available to new customers due to its prior contracts with Novo Nordisk.[187] Following the Transaction, Catalent will not be able to meet all of Novo Nordisk's demand, so Novo Nordisk will also procure CMO FDP services for PFS from other CDMOs (see paragraph (164)). Likewise, absent the Transaction, Novo Nordisk would try to turn to Catalent or alternative CDMOs to try to meet its demand for PFS (as well as undertaking internal capacity expansions for cartridges in particular, which would take time).[188] The Notifying Party estimates that Novo Nordisk would need to procure capacity for [amount] of PFS in order to meet existing demand in the short-term absent the Transaction.[189] Therefore, with or without the Transaction, Novo Nordisk would seek to purchase (or internalise for itself) significant amounts of PFS capacity (either with Catalent or other CDMOs) to meet its demand. This increase in demand could impact the terms on which or ease with which customers can procure capacity, but this would occur independently of the Transaction. In light of these elements, the Transaction is unlikely to have a material impact on prices for CMO FDP services for PFS.

(153) Therefore, any attempted foreclosure strategy would be unlikely to have a significant detrimental impact on PFS customers in the EEA or worldwide, in particular due to Catalent's limited upstream position and the availability of alternatives to Catalent, and the relatively limited extent to which competitors for obesity and diabetes products rely on Catalent.

5.3.1.3.4. Conclusion

(154) In light of the foregoing, given the merged entity would be unlikely to have the ability to engage in an input foreclosure strategy and the limited effect such a strategy would have, the Commission concludes that the Transaction is unlikely to give rise to serious doubts as to its compatibility with the internal market as a result of non-horizontal effects in the form of input foreclosure of CMO FDP services for PFS in the EEA or worldwide.[190]

187 Form CO, paragraphs 1309-1312.

188 Document NN 4c-18, slides 12, 15, 17 in Annex 1 (00001) to the Form CO, and paragraph 1.10 of the response to RFI 16.

189 Paragraph 1.10 of the response to RFI 16.

190 With respect to CMO FDP services for vials, the Commission notes that some market participants, customers of CMO FDP services for vials, have voiced their concerns in relation to insufficient capacity on the market should they have to switch to alternative CDMOs (response to question I.1. of the Questionnaire to CDMO customers). In addition to the observations that the Commission makes in relation to PFS (Section 5.3.1.3), the Commission notes that, first, per the Notifying Party' submission, Catalent's share in vials is around [10-20]% both at global and EEA levels in 2023 (as shown in Annex 00057.M11486-NNNHCTL to the Form CO); and, second, there is plenty of capacity and alternatives present on the market including Thermo Fisher, Recipharm, Simtra, Pfizer CenterOne (Form CO, Table 49). For these reasons, the Commission does not consider it likely that the Parties would be able to engage in foreclosure strategies in relation to vials customers.

5.3.2. Customer foreclosure

5.3.2.1. The Notifying Party's views

(155) The Notifying Party submits that the Transaction would not give rise to a risk of customer foreclosure as a result of the vertical link between Catalent's CMO FDP services for PFS (upstream) and Novo Nordisk's obesity and diabetes products (downstream).

(156) As regards ability, the Notifying Party submits that even if Novo Nordisk may have a market share in excess of 30% in the downstream supply of obesity and diabetes products, Novo Nordisk represents only a low share of all purchases of CMO FDP services for PFS. It notes that demand for PFS is continuing to grow so rival CDMOs will continue to have a sufficient base of customers following the Transaction.[191]

(157) As regards incentive, the Notifying Party submits that Novo Nordisk intends to continue to contract with CDMOs for PFS services in view of its increasing demand and the desire to diversify its supply base.[192]

(158) As regards effect, the Notifying Party submits that even in a hypothetical scenario where Novo Nordisk were to switch all of its PFS demand to Catalent, this would not have a material impact on third party CDMOs, as the volumes Novo Nordisk currently procures from third party CDMOs is limited in comparison with the rising demand for CMO FDP services for PFS.[193]

5.3.2.2. The Commission's assessment

5.3.2.2.1. Ability

(159) The Commission considers that the merged entity is unlikely to have the ability to engage in a successful customer foreclosure strategy for the following reasons.

(160) First, even if Novo Nordisk may be a significant supplier of obesity and diabetes products, it represents a small proportion of downstream demand for CMO for services for PFS, which are provided for a broad range of different pharmaceutical products. The Notifying Party estimates that the merged entity would represent only around [0-5]% of demand for CMO FDP services for PFS by value worldwide, and only [0-5]% at EEA level.[194] The market investigation confirmed that, at present, Novo Nordisk represents a small proportion of demand of PFS (<10%) for virtually all CDMOs responding to the investigation.[195] Such a finding is consistent not only with Novo Nordisk representing only a small proportion of downstream demand for CMO for services for PFS , but also with Novo Nordisk's pre-Transaction procurement strategy, whereby Catalent is the main CDMO that Novo Nordisk relies on for the supply of CMO FDP services for PFS for obesity

191 Form CO, paragraphs 1580ff.
192 Form CO, paragraph 1590.
193 Form CO, paragraphs 1592ff.
194 Annex 6.XI.A (00053) to the Form CO.
195 Response to question D.B.B.1 of the Questionnaire sent to CDMOs. The market investigation did not provide any reason to consider that the assessment of the merged entity's ability to foreclose would vary with respect to CMO FDP services for PFS at the clinical stage compared with at the commercial stage.

and diabetes products and Nordisk's purchases from other CDMOs are more limited.[196]

(161) Second, the market investigation confirmed that demand for CMO FDP services for PFS is expected to increase in the coming years and that a number of customers plan to increase their purchases of PFS from CDMOs.[197] The vast majority of CDMOs responding to the market investigation indicated that in their view they will have a sufficient base of customers to turn to, such that even if Novo Nordisk were to switch its PFS demand entirely to Catalent this would not affect their competitiveness.[198] CDMOs indicated that they typically try to avoid concentrating risk by depending on a single customer, and that even if the loss of a customer may have a negative impact on revenues this would be expected to only be temporary.[199]

(162) Therefore, Novo Nordisk is unlikely to be a sufficiently important customer of CMO FDP services for PFS in the EEA or worldwide to have the ability to foreclose CDMOs, in particular as its share of purchases is limited and CDMOs will have access to a sufficient base of other customers.

5.3.2.2.2. Incentive

(163) The Commission considers that the merged entity is unlikely to have the incentive to engage in a customer foreclosure strategy for the following reasons.

(164) First, a customer foreclosure strategy would be inconsistent with Novo Nordisk's strategy of maximising the (internal and external) capacity available to meet its needs. Novo Nordisk's need for CMO FDP services for PFS is growing in the context of high and increasing demand for its obesity and diabetes products. Even with the Transaction, […] will be greater than the capacity it currently has or can bring online internally and with Catalent in this period.[200] In order to meet this demand, Novo Nordisk is therefore unlikely to rely exclusively on Catalent to the detriment of its commercialisation strategy for obesity and diabetes products. This is demonstrated by the fact that, since the Transaction was agreed, Novo Nordisk has contracted with several other CDMOs (such as [CDMOs]) to supply CMO FDP services for PFS.[201]

(165) Second, the merged entity's upstream operations would not benefit from an attempted foreclosure strategy. The rationale for the Transaction is that the merged entity intends to use the capacity in Catalent's Carveout Sites to exclusively meet Novo Nordisk's demand for PFS (see paragraph 141). The Catalent Carveout Sites would therefore no longer be active as a supplier of CMO FDP services for PFS, and so would not benefit from higher prices in the upstream market. To the contrary, it would be beneficial for Novo Nordisk if prices in the upstream market were lower, as it will continue to procure CMO FDP services for PFS given that its

196 Form CO, paragraph 198.

197 Response to question D.B.2 of the Questionnaire sent to customers of CDMOs.

198 Response to question D.B.B.2 of the Questionnaire sent to CDMOs. For completeness, the very few CMOs that indicated that they may not have access to a sufficient customer base following such a strategy also indicated that Novo Nordisk represents less than 10% of their sales, so it appears unlikely that they would be materially affected.

199 Response to question D.B.B.2 of the Questionnaire sent to CDMOs.

200 Response to RFI 2 question 31.

201 Form CO, paragraph 1301 and paragraph 1.5 of the reply to RFI 16.

demand outstrips internal capacity even with the Transaction. Therefore, the merged entity would not have any incentive to foreclose upstream rivals in order to increase its prices and profits upstream, as it will no longer be active in that market.

(166) Third, the merged entity's downstream operations would not benefit from an attempted foreclosure strategy. This is because a customer foreclosure strategy is unlikely to successfully foreclose rival CDMOs in light of the limited share of purchases that it represents and the availability of a sufficient alternative customer base (as described in paragraph 160). The merged entity is therefore unlikely to engage in a customer foreclosure strategy to the detriment of its own sourcing needs, given that it would be unlikely to result in any gains upstream or downstream (i.e. given that CDMOs will continue to be competitive, downstream customers' competitiveness would not be affected by such a strategy either).

(167) In light of the foregoing, it is unlikely that the merged entity would have the incentive to attempt to foreclose rival providers of CMO FDP services for PFS, in particular due to Novo Nordisk's ongoing need for services from these suppliers and the fact that such a strategy would be unlikely to succeed.

5.3.2.2.3. Effect

(168) The Commission considers that upstream suppliers are unlikely to face any significant impact even if the merged entity were to internalise all of its purchases of CMO FDP services for PFS with Catalent. As outlined in Sections 5.3.2.2.1 and 5.3.2.2.2 above, pre-Transaction Novo Nordisk already procures most of its needs for CMO FDP services for PFS from Catalent, so its purchases from other CDMOs represent a small proportion of those CDMOs' supply, and an even smaller proportion of the overall market for CMO FDP services for PFS. Further, these other CDMOs that supply Novo Nordisk have a diverse customer base, meaning that if Novo Nordisk were to switch its demand entirely to Catalent this would not affect their competitiveness.[202] Therefore, any attempted foreclosure strategy would have a limited impact on the upstream market of CMO FDP services for PFS in the EEA or worldwide and so would be unlikely to have a significant detrimental impact on downstream customers of these services.

5.3.2.2.4. Conclusion

(169) In light of the foregoing, given the merged entity is unlikely to have the ability or incentive to engage in a customer foreclosure strategy or have significant adverse effects should such a strategy be adopted, the Commission concludes that the Transaction is unlikely to give rise to serious doubts as to its compatibility with the internal market as a result of non-horizontal effects in the form of customer foreclosure of CMO FDP services for PFS in the EEA or worldwide.

[202] Response to question D.B.B.2 of the Questionnaire sent to CDMOs. For completeness, the very few CMOs that indicated that they may not have access to a sufficient customer base following such a strategy also indicated that Novo Nordisk represents less than 10% of their sales (and in fact they confirmed that they do not sell CMO FDP services for PFS to Novo Nordisk), so it appears unlikely that they would be materially affected by a foreclosure strategy.

5.4. Commercially sensitive information: CDMO services (upstream) – pharmaceutical companies (downstream)

(170) Some market participants raised concerns relating to the merged entity gaining access to their commercially sensitive information thereby putting them at competitive disadvantage.[203] For example, the merged entity may use the information to its own benefit, *e.g.* to develop new competing products, delay rivals' product development, adjust its pricing or commercial strategy in response to rivals' plans, *etc*.

5.4.1. The Notifying Party's views

(171) The Notifying Party submits that the existing safeguards in place by Catalent, coupled with the additional measures and policies that will be implemented post-Transaction, and the broader corporate structure within Novo Holdings, provide sufficient guarantees against any potential spill-over of commercially sensitive information relating to customers.[204] The Notifying Party further submits that neither Novo Holdings nor Novo Nordisk has an incentive to use customers' commercially sensitive information to their disadvantage.[205] Lastly, according to the Notifying Party, in any event, the impact of such a strategy would not be meaningful in the downstream markets.[206]

5.4.2. The Commission's assessment

5.4.2.1. Type of commercially sensitive information available to Catalent in the ordinary course of business

(172) In its ordinary course of business, Catalent often receives commercially sensitive information related to its customers' projects. Catalent's current confidentiality policy distinguishes four types of confidential information that it receives from customers: (i) business related information (strategic plans, customer names, production data, and distribution data); (ii) IP (inventions, technical know-how, trade secrets); (iii) financial (budgets, pricing, sales and cost data); and (iv) internal information (email, memoranda, intranet content, and employee lists).[207]

(173) The type of commercially sensitive information available to Catalent depends on the type of service provided. For instance, sites performing fill-finish operations will not need to have access to the same type of information as a site working on API operations. Of most relevance to this assessment, the commercially sensitive information the merged entity will likely have relates to: (i) dates for expected initial product approval and/or launch; (ii) estimated dates for launches in other markets; (iii) product format/formulation changes; (iv) surges in production volumes (potentially suggesting increased demand or new sources of demand); and (v) and regulatory/supply chain/manufacturing disruptions.[208]

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203 Non-confidential Minutes of a call with a CDMO customer, held on 29 April 2024, paragraphs 24-28. See also replies to questions H.1 to H.5 of the Questionnaires to CDMOs and CDMO customers, and questions I.1, I.3 and I.4 of the Questionnaire to CDMO customers.

204 Form CO, paragraphs 1597 *et seqq*.

205 Form CO, paragraphs 1679-1682.

206 Form CO, paragraphs 1683-1686.

207 Form CO, paragraph 1601.

208 Form CO, paragraph 1602.

5.4.2.2. Ability to use the commercially sensitive information available to Catalent to put rival pharmaceutical companies at a competitive disadvantage.

(174) The evidence in the Commission's file does not enable the Commission to conclude whether the merged entity will have the ability post-Transaction to put rival pharmaceutical companies at a competitive disadvantage by using the confidential information described above.

(175) *First*, the merged entity has in place mechanisms to restrict the use of such data for purposes other than the ones intended in the ordinary course of business as a CDMO supplier, which are in line with industry practice. The evidence available to the Commission indicates that the merged entity will likely continue to adhere to such mechanisms. The implication underlying such mechanisms is that, while CMDOs may have the ability to access and/or use commercially sensitive information, they typically lack the incentive to do so, as will be discussed in section 5.4.2.3 below.

(176) In particular, as per the industry standard for CDMO providers, Catalent has a strict confidentiality / ethical wall policy in place, aimed at ensuring the protection of commercially sensitive information of its customers. This policy covers: (i) periodic compliance training and corporate policies in place to ensure awareness of obligations; (ii) access to confidential documents is limited to a need-to-know basis; (iii) strict prohibition against sharing confidential information of any customer with another customer or individuals within Catalent who are not permitted to have access to it under the relevant agreement governing use of such information; (iv) procedures for segregation of similar projects, including facilities and equipment to the extent possible; (v) additional team specific controls to prevent disclosure across customers of confidential information; and (vi) non-disclosure obligations for personnel with access to information across several similar projects.[209]

(177) The existence of strict confidentiality policies in the industry has been widely confirmed by the Commission's market investigation. For example, as a competitor noted: "*industry standard confidentiality agreements would prevent parties from using such confidential information to their own benefit without breaching their respective confidentiality obligations*".[210] When asked about the ability of the merged entity to use such commercially sensitive information post-Transaction to its own benefit, several market participants explained that, while theoretically possible, the relevant firewalls (and contractual obligations, as discussed further below) would probably not allow for such a practice to be established.[211]

(178) For example, CDMO competitors noted the following:

(a) "*Novo Nordisk may be able to obtain more detailed information on the exact status of the pipeline of activities than it otherwise might have. However, Catalent, as any CDMO, should have procedures in place that would create Chinese Walls inside the company that prevent information about one customer program leaking to other customers. If these continue to be respected this risk should be small*";

209 Form CO, paragraphs 1604-1616, 1644, 1664 and 1665.

210 Reply to question H.4 of the Questionnaire to CDMOs.

211 Replies to questions H.2, H.4 and H.5 of the Questionnaire to CDMOs and the Questionnaire to CDMO customers.

(b) "*I believe that Catalent does have access to such information, however I do not know if it would be commercially beneficial to Novo Nordisk. Further, I would expect that Novo Nordisk would respect Catalent's client's confidential information*";

(c) "*Novo & Catalent would need to implement a firewall program to prevent comingling of IP in either direction or risk losing business as customers have numerous CDMO options*";[212] and

(d) "[i]*n the context of* [the competitor*], contractual firewalls would prevent internal leakage of confidential information outside of the specific purpose for which it was provided. We would expect the same to be true of Catalent / Novo. We see no risk of Novo Nordisk or Catalent acting in this way*".[213]

(179) Similar considerations were also made by CDMO customers:

(a) "[the risk] *may exist* […] *if no sufficient firewalls are established*";

(b) "*They could potentially access such information, but they would likely not be allowed to make use of it. We do not believe that this is a big concern that exceeds that of key employees switching jobs which can happen between any two companies. Also, apart from demand forecasts (which could be used to increase knowledge around our sales forecast), there is limited proprietary information in this segment of the value chain that can be leveraged by competition*";[214] and

(c) "*There is always a risk of leakage. Companies often work on firewalls modalities to avoid leakage of information between businesses*".[215]

(180) The Commission also takes note of the fact that Novo Holdings is putting in place additional ring-fencing measures applying to Catalent. On the one hand, Novo Holdings has formalised a specific governance protocol[216], including *inter alia* that no third-party commercially sensitive information can be shared within the Novo Holdings Controlled Portfolio Companies, and that suitable arrangements will be put in place, such as separate IT access levels.[217] On the other hand, Novo Nordisk itself has communicated to relevant customers the additional confidentiality protocols put in place to ensure that their confidential information is fully protected and not shared within Novo Nordisk beyond what is strictly required to service customers within ringfenced teams.[218] During the Commission's market investigation, a responding customer specifically commented on these additional measures when asked about the ability of the merged entity to use customers' commercially sensitive information post-Transaction, by noting that: "[g]*iven the committments made most recently by Novo not to use commercially sensitive*

212 Replies to question H.2 of the Questionnaire to CDMOs.

213 Reply to question H.4 of the Questionnaire to CDMOs.

214 Replies to question H.2 of the Questionnaire to CDMO customers.

215 Reply to question H.4 of the Questionnaire to CDMO customers.

216 Form CO, Annexes 6.XIII.D.(a) and 6.XIII.D.(b).

217 Form CO, paragraph 1646.

218 Specifically, commercial operations and decisions about capacity allocations on the lines servicing third-party customers at the three sites will be managed by a new, internal, ringfenced Global Customer Operations business area, operating under distinct management, independently of other internal Novo Nordisk functions, and protected by strict information firewalls. A distinct and ringfenced Quality function with responsibility for reviewing, validating and releasing products from the relevant sites will be in place (The Notifying Party's response to RFI 14).

information received in its (future) CDMO area i.e. having firewalled its organization we consider this unlikely".[219]

(181) *Second*, and even though the applicable legal framework does not in itself eliminate the risk that the merged entity can access Catalent's customers' confidential information in a way to impede effective competition,[220] the Commission notes that, in addition to the already existing and new confidentiality protocols adopted by the merged entity, there appear to be certain enhanced legal limitations on the use of such commercially sensitive information by the merged entity post-Transaction. These would derive from both existing legislations, for example for IP law, and specific contractual obligations vis-à-vis customers, which typically include confidentiality agreements and legal liability in case of breach of said agreements.

(182) During the Commission's market investigation, the legal obstacles to the use of the confidential information that the merged entity has access to was widely raised by market participants, who, while acknowledging that the merged entity's ability to access such information post-Transaction would be theoretically possible, nevertheless noted that contractual obligations and confidentiality agreements in place would likely not allow for such a strategy to take place.[221] For example, one CDMO competitor explained that:

(a) "[e]*ven if theoretically* [they]*could access, in practice this is covered by confidentiality obligation / prevented through contractual arrangements. In practice, a lot of pharma companies offer excess capacity to other pharm, as part-time CDMO*",[222] while another noted that:

(b) "*CMO contracts typically contain strong confidentiality clauses which prohibit the CMO provider from disclosing to third parties sensitive information relating to the products manufactured for the laboratory in question and non-use of such information for a purpose other than the object of the agreement between the parties*".[223]

(183) CDMO customers also made similar considerations:

(a) "*While this could be hypothetically possible, we are aware that manufacturing agreements typically have provisions restricting confidentiality and use of confidential/sensitive information and we would expect parties to comply with these provisions*";[224] and

(b) "*Existing contractual language preserves a certain degree of protection and risk of losing customers in a competitive space acts as a further disincentive*".[225]

(184) *Third*, the overall results of the Commission's market investigation with regard to the merged entity's ability post-Transaction to access and use third-party customers' commercially sensitive information to its own benefit appear

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219 Reply to question H.4 of the Questionnaire to CDMO customers.

220 See for example Case M.9660 – *Google / Fitbit*, decision of 17 December 2020, recital 412.

221 Replies to questions H.2, H.4 and H.5 of the Questionnaire to CDMOs and the Questionnaire to CDMO customers.

222 Reply to question H.2 of the Questionnaire to CDMOs.

223 Reply to question H.4 of the Questionnaire to CDMOs.

224 Reply to question H.2 of the Questionnaire to CDMO customers.

225 Reply to question H.4 of the Questionnaire to CDMO customers.

inconclusive. While the majority of CDMO competitors considers there is no such ability, the results are mixed on the side of customers.[226] However, most respondents – both competitors and customers – were unaware of such strategies having been implemented in the past by other pharmaceutical companies which also serve as CDMO providers, considered it unlikely or were simply not concerned. In fact, in response to the question, several market participants reiterated that the industry is typically characterised by strict firewalls and contractual obligations / confidentiality agreements that would serve as a counter-balance to any such theoretical ability on the side of the merged entity.[227]

5.4.2.3. Incentive to use the commercially sensitive information available to Catalent to put rival pharmaceutical companies at a competitive disadvantage.

(185) The Commission considers that the merged entity would not have the incentive to use the commercially sensitive information available to Catalent in the ordinary course of business to put rival pharmaceutical companies at a competitive disadvantage.

(186) *First*, the Commission's market investigation confirmed that the merged entity would have no such incentive post-Transaction, mainly due to concerns over substantial reputation damage and/or significantly high litigation risks.[228]

(187) For instance, competitors noted the following:

(a) "*The risk is too high in terms of consequences and damages*";

(b) "*It would have a very negative impact on the company's reputation and might trigger litigation if it happened. It would impact the company's ability to operate and collaborate and the company will most likely establish procedure and safeguards to ensure this will not be possible*"; and

(c) "*Novo/ catalent could access to sensitive information of rivals but if Novo and Catalent use such sensitive information to its own benefit it would certainly be sued for damages by the owner of the technology, KH and sensitive information.* […] *We cannot believe that such big international companies would take such risk and act in such an unethical way*".[229]

(188) Customers also made similar considerations explaining that the risk is too high to render such strategy likely:

(a) "*risk of reputational damage/litigation makes this unrealistic*";

(b) "*While Novo may have the capability through the transaction to access additional information that they otherwise did not have, it is unlikely that they would do so considering the legality, good operating principles, and the potential for reputational damage. Other pharmaceutical companies have successfully navigated the course to have an embedded CDMO model in their business. There is no obvious reason that Novo would not be able to adopt a similar separation of business services*"; and

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226 Replies to question H.2 of the Questionnaire to CDMOs and the Questionnaire to CDMO customers.

227 Replies to question H.5 of the Questionnaire to CDMOs and the Questionnaire to CDMO customers.

228 Replies to questions H.3 and H.4 of the Questionnaire to CDMOs and the Questionnaire to CDMO customers.

229 Replies to question H.4 of the Questionnaire to CDMOs.

(c) "*The risk of loss of integrity and reputation is too great. It would destroy their business*".[230]

(189) Some market participants explained that they consider that the Notifying Party's incentive would rather be the opposite, *i.e.* to enhance confidentiality protection rather than mistreat it:

(a) "*Typically the CDMO has Chinese Walls in place to prevent leakage of confidential information, internally and externally in order to prevent the exposure to claims and concerns, Novo Nordisk is likely to be motivated to strengthen these, rather than weaken these*";

(b) "*Novo and Catalent are long-standing businesses with strong reputations in the market place. Any sharing of commercially sensitive information would be very detrimental to both businesses and would result in considerable damage to reputation, loss of business/market share and potential litigation. It is therefore highly unlikely that this would happen, and we would expect both parties to put in place firewalls to ensure that this is the case. We expect that Catalent's customers will seek reassurance as to the adequacy of these firewalls as a condition of doing business with the company*";[231] and

(c) "*Although workers at the merged entity might have an incentive to use commercially sensitive information of rival pharmaceutical companies to the merged entity's own benefit, we would expect that the merged entity's values of respect and ethics along with the potential risk of reputational damage and/or litigation would cause the merged entity to put in place controls to segregate and limit access to such commercially sensitive information and otherwise train and guide its workers to not access or otherwise use such information*".[232]

(190) In addition, market participants responding to the Commission's market investigation further explained that the potential benefits of pursuing such strategy would be unlikely to outweigh the damages caused. For example, one competitor mentioned that: "*the reputational (and legal) damage of Novo Holdings exchanging sensitive and/or confidential information between affiliates would greatly overweight the advantage they would get from such behavior. It would make no sense and to our knowledge it has proven not to be the strategy of other similar companies having similar situations*", while another one explained that "[t]*hey will lose trust vis-à-vis other companies and damage their CDMO business*".[233] In the same vein, a customer noted that: "*the reputational damage of this kind of misappropriation would be substantial were it to be discovered, especially as compared to the advantage that Novo could gain from such actions*", while another one mentioned that "[b]*enefit vs. risk would be too high, and knowing Novo Nordisk as a high integrity company, we find this unlikely to happen*".[234]

230 Replies to question H.4 of the Questionnaire to CDMO customers.
231 Replies to question H.4 of the Questionnaire to CDMOs.
232 Reply to question H.4 of the Questionnaire to CDMO customers.
233 Replies to question H.4 of the Questionnaire to CDMOs.
234 Replies to question H.4 of the Questionnaire to CDMO customers.

(191) *Second*, the Commission notes that the vertical integration between a CDMO provider and a pharmaceutical company is not unprecedented in the market. In fact, approx. 20% of the CDMO competitors responding to the Commission's market investigation are also active downstream in the pharmaceutical market. The majority of these vertically integrated players provide services to pharmaceutical companies with potentially competing products to their own.[235] In the same vein, approx. 40% of responding customers contract with CDMO provider(s) which are also active in the supply of pharmaceutical products. Some of them explain that their CDMO provider does have competing products to their own, while some have simply not considered the possibility, *e.g.* one explains that it: "*wouldn't eliminate a CDMO solely due to them being a pharmaceutical company*".[236]

(192) Similar observations were made during the Commission's pre-notification investigation. One CDMO provider vertically integrated downstream explained to the Commission that a: "*common concern among* [its] *clients regards IP protection. To this end,* [the CDMO provider] *has implemented procedures to safeguard its clients' and its own IP, including firewalls and password protection systems. Indeed, IP protection is important also from* [the CDMO provider's] *perspective as clients could come across documentation regarding manufacturing processes that are not offered in the public sphere and are considered business secrets to* [its pharmaceutical business]. *This could happen, for instance, in the context of quality, environmental and safety audit checks which clients can perform pursuant to the terms contained in their manufacturing contracts. However,* [the CDMO provider's] *success in guaranteeing IP protection is demonstrated by the fact that over its almost 50-year lifespan, the company has never been challenged on IP or trade secret violations*".[237] In the same vein, a pharmaceutical company explained that it does work with a CDMO provider which is also a direct competitor downstream. The customer: "*fairly evaluates CDMO providers that are also its competitors downstream, though it may sometimes take this fact into consideration for its ultimate manufacturing decision*". The customer has never experienced any data-related issue and: "*considers the reputational risk to be too significant for a CDMO provider to engage in such misuse of data*".[238]

(193) The Commission therefore observes that it is a commercial decision made by customers whether to take a CDMO's activities as a downstream supplier of pharmaceutical products into account when selecting a supplier, making it unlikely for any vertically integrated CDMO provider to have the incentives to pursue a strategy whereby it would use the commercially sensitive information of its customers to its own benefit.

5.4.2.4. Effect on competition

(194) The Commission considers that, even if the merged entity were to access and use Catalent's customers' commercially sensitive information to put rival pharmaceutical companies at a competitive disadvantage, such strategy would be unlikely to significantly impede effective competition.

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235 Replies to question H.1 of the Questionnaire to CDMOs.

236 Replies to question H.1 of the Questionnaire to CDMO customers.

237 Non-confidential Minutes of a call with a CDMO, held on 6 May 2024, paragraph 10.

238 Non-confidential Minutes of a call with a CDMO customer, held on 16 May 2024, paragraphs 12 and 24.

(195) *First*, most customers responding to the Commission's market investigation did not express concerns with regard to any impact of such a strategy.[239] On the contrary, several customers reiterated either that there is no concern due to the limitations explained above or that any such strategy would not affect them due to the nature of the information available to Catalent or because there is no direct competition between their products and the products of the Notifying Party.[240]

(196) *Second*, it results from the Notifying Party's analysis with regard to vertical relationships that Catalent does not serve many customers with products potentially competing with Novo Holdings' products.

5.4.2.5. Conclusion

(197) On the basis of the above considerations, the Commission concludes that the Transaction does not raise serious doubts as to its compatibility with the internal market as a result of access and use of the commercially sensitive information available to Catalent in the ordinary course of business.

5.5. Assessment of the supply of CMO FDP services for ODTs (upstream) – Supply of opioid use disorder ("OUD") treatments (downstream)

(198) The Transaction gives rise to a vertically affected market between Catalent's upstream activities in the supply of CMO FDP services for ODTs, in which it has market shares exceeding 30%, and the downstream activities of Orexo, a Novo Holdings Controlled Portfolio Company, in the treatment of OUD under ATC 3 class N7F with its ODT-based product, Zubsolv.[241] The Parties' shares are provided in the tables below.

Table 10 - Catalent's market shares in the supply of CMO FDP services for ODTs (upstream)

2023	Global	EEA
Value	[60-70]%	[40-50]%
Volume	[10-20]%	[20-30]%

Source: Form CO, Annex 8.1.2.(b) (00057.M11486-NNNHCTL) and Annex 11 (00011.M11486-NNNHCTL)

Table 11 - Accord Healthcare's market share in the supply of OUD treatments (ATC 3 class N7F) (downstream)

2023	EEA
Value	[0-5]%
Volume	[0-5]%

Source: RFI 5, Annex 5, Q2 and Form CO, Annex 23, paragraph 7

239 Replies to questions I.1-I.4 of the Questionnaire to CDMO customers.

240 Replies to questions H.2-H.5 and I.1-I.4 of the Questionnaire to CDMO customers.

241 Orexo is not currently procuring ODT services from Catalent. However, Catalent provides ODT services to […], both of which are being developed for Opioid Use Disorder and could potentially compete with Zubsolv, Orexo's product, in the market for opioid dependence treatments as they target the same therapeutic indication. Form CO, paragraphs 890, 896 and RFI 5, Q35, Table 30.

(199) The Transaction does not give rise to customer foreclosure concerns in relation to ODTs given that Orexo's purchasing shares for CMO FDP services for ODTs are marginal ([0-5]% in the EEA and [0-5]% globally).[242] Therefore, potential customer foreclosure is not addressed further in this decision.

5.5.1. Input foreclosure

5.5.1.1. The Notifying Party's views

(200) According to the Notifying Party, the Transaction will not result in any risk of input foreclosure in light of the following considerations.

(201) *First*, the Notifying Party submits that the merged entity would not have the ability to foreclose downstream pharmaceutical companies as: (i) most pharmaceutical companies manufacture ODTs in-house; (ii) ODTs compete with other solid forms[243]; (iii) Catalent's value share overstates its competitive importance; and (iv) existing contracts protect customers.[244]

(202) *Second*, the Notifying Party submits that the merged entity would not have the incentive to foreclose access to Catalent's ODT offering as: (i) Catalent provides ODT services from Catalent RemainCo sites, which Novo Holdings will operate independently; (ii) Novo Holdings merely has a minority stake of 27.78% in Orexo, making any foreclosure strategy unlikely; (iii) Orexo only receives limited revenues from Zubsolv royalties and [information on supply agreement] in the EEA; and (iv) Zubsolv has an insignificant downstream market position, limiting any potential gains.[245]

(203) *Finally*, the Notifying Party submits that competitors remain both in the upstream market for the provision of manufacturing services for ODTs and in the downstream market for OUD treatments (ATC 3 class N7F).[246]

5.5.1.2. The Commission's assessment

(204) Based on the market investigation, the Commission does not consider that the Transaction would result in input foreclosure of Catalent's offering in ODT services as the merged entity is unlikely to have the ability to engage in an input foreclosure strategy regarding Catalent's offering in ODT services:

(a) *First*, while only a limited number of the CDMO customers who have responded to the Commission's market investigation have in-house capabilities, the majority of both CDMO customers and CDMOs consider that there will continue to be sufficient alternatives for sourcing development and manufacturing services for ODTs.[247] Market participants explain that:

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242 Form CO, Annex 6.XI.A (00053.M11486-NNNHCTL).

243 In the broader market for CMO FDP services for solid forms Catalent's market shares remain below 30% namely (Globally: value share: [10-20]%, volume share: [5-10]%, EEA-wide: value share: [10-20]%, volume share: [5-10]%).

244 Form CO, Annex 23 (00023.M11486-NNNHCTL), paragraphs 37-44.

245 Form CO, Annex 23 (00023.M11486-NNNHCTL), paragraphs 45-52.

246 Form CO, Annex 23 (00023.M11486-NNNHCTL), paragraphs 53-55.

247 Responses to question F.B.1 of the Questionnaire to CDMO customers; and responses to question F.B.1 of the Questionnaire to CDMOs.

"[t]he space is highly competitive"[248] and that: "*customers would have sufficient alternatives from third-party CDMO players*".[249]

(b) *Second*, the majority of CDMO customers who have expressed an opinion in the market investigation also consider it feasible to switch between two ODT service providers both for marketed products and products in development. Such views were also shared by the vast majority of the CDMOs.[250]

(c) *Third*, the Commission takes note of the fact that OUD treatments, classified under ATC 3 class N7F, are available in multiple formats, including loosely compressed tablets, conventional tablets, and capsules, which all exert competitive constraint on ODTs.[251]

(205) The merged entity would also be unlikely to have the incentive to engage in an input foreclosure strategy:

(a) *First*, Orexo's Zubsolv has a negligible share of the relevant market of OUD treatments in ATC3 class N7F ([0-5]% EEA-wide), and as a result an ODT input foreclosure strategy would be highly unlikely to be profitable;

(b) *Second*, this unlikelihood is compounded by the fact that Orexo does not market Zubsolv itself in the EEA but only receives limited revenues from royalties and [information on supply agreement] through its exclusive license and supply agreement with Accord Healthcare, running until [information on supply agreement].[252]

(206) As regards the likely impact of an input foreclosure strategy, the market feedback also indicates that companies currently sourcing ODT services from Catalent generally consider their current contractual relationships to sufficiently secure supply also post-Transaction, and no concerns have been raised in relation to Catalent's ODT activities.

(207) Therefore, taking into account the market investigation results and other available evidence, the Commission considers that the Transaction does not raise serious doubts as to its compatibility with the internal market as a result of the described vertical relationship.

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248 Reply of one CDMO customer to question F.B.1 of the Questionnaire to CDMO customers.

249 Reply of one CDMO customer to question F.B.1 of the Questionnaire to CDMO customers.

250 Responses to question F.B.2 of the Questionnaire to CDMO customers; and responses to question F.B.2 of the Questionnaire to CDMOs.

251 Form CO, Annex 23 (00023.M11486-NNNHCTL), table 1.

252 For reference, in 2023, Orexo received SEK [amount] million (approximately EUR [amount] million) in royalties. Moreover, Orexo does not [information on supply agreement]. Please see Form CO, paragraph 895 and footnote 678.

6. CONCLUSION

(208) 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)
Teresa RIBERA
Executive Vice-President