Anticipated acquisition by Cochlear Limited of the hearing implants division of Demant A/S

Decision on relevant merger situation and substantial lessening of competition

ME/6999/22

The CMA's decision on reference under section 33(1) of the Enterprise Act 2002 given on 6 December 2022. Full text of the decision published on 20 January 2023.

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges at the request of the parties for reasons of commercial confidentiality.

SUMMARY

1. Cochlear Limited (**Cochlear**) has agreed to acquire the hearing implant division (**Oticon Medical**) of Demant A/S (**Demant)** (the **Merger**). Cochlear and Demant are together referred to as the **Parties**, and for statements relating to the future, Cochlear and Oticon Medical are referred to as the **Merged Entity**.

2. After examining a range of evidence, the Competition and Markets Authority (**CMA**) believes that the Merger, if carried into effect, will result in the creation of a relevant merger situation, and meets the threshold for reference to an in-depth phase 2 investigation, giving rise to a realistic prospect of a substantial lessening of competition (**SLC**).

3. The CMA is therefore considering whether to accept undertakings under section 73 of the Enterprise Act 2002 (the **Act**). The Parties have until 13 December 2022 to offer an undertaking to the CMA that might be accepted by the CMA. If no such undertaking is offered, then the CMA will refer the Merger pursuant to sections 33(1) and 34ZA(2) of the Act.

Competitive overlap

4. The Parties overlap in the supply of cochlear implants (**CI**) and bone conduction solutions (**BCS**) (together, **hearing implants**) in the UK, which are devices that are surgically implanted in patients with hearing loss to improve their ability to hear.

5. The CMA found that CI and BCS products serve distinct clinical patient needs. Therefore, these devices are not alternatives for each other. Further, the CMA found that other hearing solutions, such as hearing aids, are not good alternatives for hearing implants. Hearing implants are typically prescribed after hearing aids have been tried and failed, they typically seek to correct more serious hearing loss than hearing aids, cost significantly more than hearing aids, and, unlike hearing aids, require surgery. The CMA has assessed the impact of the Merger on the basis of the supply of (i) BCS and, separately (ii) CI, in the UK.

Demant's strategic plans

6. Demant submitted that absent the Merger it would have exited its hearing implants business, maintaining only some limited activities to support existing implants. As such, Demant submitted that absent the Merger it would not be competing against Cochlear in the supply of BCS or CI and, as a result, the Merger cannot result in any loss of competition. Demant told the CMA that it agreed to the Merger in order to ensure that its patients would have the best lifelong technical and functional support.

7. Following the agreement of the Merger, Demant has publicly stated it is exiting the hearing implants business. Based on the evidence, the CMA believes strategic exit was one of a number of options considered by Demant, and that it decided to try to sell Oticon Medical in the first instance. The CMA does not consider that the evidence shows that Demant decided that Oticon Medical would have exited had it not agreed to sell the business to Cochlear. Moreover, the CMA also considers it would be commercially irrational for Demant to discontinue the entire hearing implant business given parts of the business were generating profits and worth almost £100 million without at least fully exploring other options.

Bone conduction solutions

8. BCS devices can be categorised as passive BCS or active BCS. Passive BCS use an external transducer (ie outside of the skin) whereas active BCS use an implanted transducer, to transmit the necessary vibrations to the inner ear. BCS have traditionally been passive, although the Parties submitted that active BCS is becoming more frequently used. Non-surgical BCS, which are typically attached to a headband or a patient's skin, are also available primarily for children who are not old enough for surgery or for adults with fluctuating degrees of hearing loss.

9. The CMA considered competition across the different types of BCS currently in the market – in particular active and passive BCS – and whether the fact that Oticon Medical does not currently have an active BCS means that Oticon Medical is a weaker competitive constraint than the shares of supply suggest. Oticon Medical is

currently the leading supplier of passive BCS, with Cochlear the only other option for patients and clinics. The CMA found that while there is likely to be a shift from passive to active BCS in the future, the extent and speed of such a shift is unclear, and there will still be demand for passive BCS products in the foreseeable future. Further, the CMA also considers, based on the available evidence, that Oticon Medical could become a strong competitor in the supply of active BCS in the future.

10. The CMA found the Merged Entity would have a combined share of [90-100]% in the supply of BCS in the UK, and the Merger would result in the elimination of the strongest competitor. The CMA considered that the one remaining competitor, Med-El, would not impose a sufficient constraint on the Merged Entity, considering its low share of supply and because it only supplies an active BCS product. As such, the CMA believes that there is a realistic prospect that the Merger would result in significant competition concerns in the supply of BCS in the UK, which could result in reduced innovation, quality and service, and higher prices.

Cochlear implants

11. The CMA found that the supply of CIs in the UK is highly concentrated, with the Merged Entity having a combined share of approximately [70-80]%, with an increment of [0-5]%. The CMA examined the evidence carefully given Cochlear's substantial presence, however, the CMA found that Oticon Medical's low share of supply was consistent with its weak strength as a competitor both currently and going forward.

12. The CMA found that competition in the supply of CI is primarily based on product innovation, followed by other factors such as price. Oticon Medical was seen as a weaker constraint relative to other existing providers. There is limited evidence to suggest that it currently is or would in the future impose a material constraint on Cochlear. The CMA believes that there will remain two competitors to constrain the Merged Entity in CI in the UK post-Merger who would provide a much greater constraint on Cochlear in comparison to Oticon Medical.

13. The CMA believes that Oticon Medical's ability to compete with Cochlear going forward may be impacted by its recent CI product recall. This is because Oticon Medical was a newer entrant in the supply of CIs in the UK, and the CMA considers that the recall would be a setback in Oticon Medical's future growth prospects as a less established supplier.

14. As such, the CMA believes that the Merger does not result in a realistic prospect of an SLC in relation to the supply of CI in the UK.

Countervailing factors

15. The CMA believes that barriers to entry and expansion for the supply of BCS and CI in the UK are high, given the regulatory costs of entry and the significant resources

and time required to develop suitable products. As such, the CMA found that entry into BCS was unlikely in the foreseeable future.

16. The CMA also found that purchasers of CIs and BCSs, which are primarily the NHS and clinics, were unlikely to have buyer power, given the lack of alternative suppliers.

17. The CMA therefore believes that the Merger gives rise to a realistic prospect of a SLC in the supply of BCS in the UK, as a result of horizontal unilateral effects.

ASSESSMENT

PARTIES

18. Cochlear is a public company listed on the Australian Securities Exchange and headquartered in Sydney.[1] Cochlear manufactures and supplies hearing devices globally, which treat a range of types of hearing loss, with a particular focus on CI and BCS.[2] In the UK, Cochlear's CI products include the Nucleus range, and its BCS products include the Osia 2, Baha Connect, Baha Attract and a softband non-surgical device. Cochlear's turnover in the financial year 2021 was approximately £878 million worldwide, of which approximately **[✂]** was generated in the UK.[3]

19. Demant is a global hearing healthcare and technology group headquartered in Denmark and listed on the Copenhagen Stock Exchange.[4] Demant develops, manufactures and supplies hearing implants (both CI and BCS) through Oticon Medical.[5] Demant also develops and supplies hearing aids, operates clinics providing hearing care solutions, and supplies hearing diagnostic products and audio solutions for enterprise, gaming and air traffic control.[6]

20. Oticon Medical's CI products include the Neuro Zti implant, the Neuro and Neuro 2 sound processors, and its BCS products include the Ponto range, Ponto 5 Mini, and the non-surgical Ponto 5 Softband. Oticon Medical's turnover in the financial year 2021 was approximately **[✂]** worldwide, of which approximately **[✂]** was generated in the UK.[7]

TRANSACTION

21. Cochlear and Demant entered into a Put Option Agreement and agreed the form of the Asset Sale and Purchase Agreement on 27 April 2022, which was finalised on 25 May 2022.[8] Cochlear, upon completion of the Merger, would acquire 100% of the shares of Oticon Medical's legal entities, which are:

    (a) Oticon Medical AB, a Swedish private limited liability company;

    (b) Oticon Medical Maroc, a Moroccan limited liability company;

[1] FMN, paragraph 45.
[2] FMN, paragraph 45.
[3] FMN, paragraph 46.
[4] FMN, paragraph 48.
[5] FMN, paragraph 49.
[6] FMN, paragraph 49.
[7] FMN, paragraph 53.
[8] FMN, paragraph 55.

(c) Oticon Medical, LLC, a US limited liability company incorporated in New Jersey;

(d) Neurelec S.A.S, a French simplified joint-stock corporation; and

(e) Oticon Medical A/S, a Danish private limited company.[9]

22. The Merger consideration is DKK 850,000,000 (a little under £100 million).[10]

23. The Parties informed the CMA that the Merger is also the subject of review by competition authorities in Australia and Spain. The Australian authority published its Statement of Issues in relation to the Merger on 1 December 2022. The Spanish authority subsequently requested the referral of the Merger to the European Commission.[11]

24. Cochlear submitted that its strategic rationale for the Merger is to gain increased scale to invest in hearing implants technology and clinical trials, which would improve awareness of and access to hearing implants, provide patients with clinical solutions better suited to their needs, and provide long-term support to Oticon Medical's CI and BCS patients, in order to avoid detriment to these patients and reputational damage to the industry.[12]

25. Cochlear's internal documents broadly support this rationale. One internal document notes that the Merger rationale for BCS is that increased scale would enable more investment in implant technology, clinical evidence and clinical and patient awareness.[13] For CI, the same document advises that the rationale is that Cochlear would adapt its sound processor to support Oticon Medical's patients throughout their lives, and that this is important for the industry's credibility.[14]

PROCEDURE

26. The Merger was considered at a Case Review Meeting.[15]

JURISDICTION

27. The CMA believes that the Merger constitutes arrangements in progress or contemplation for the purposes of the Act.[16]

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[9] FMN, paragraph 56; Cochlear will also acquire certain other assets, including the relevant intellectual property and the transfer of current employees employed within the above entities. FMN, paragraph 56(b).
[10] FMN, paragraph 58.
[11] FMN, paragraph 59.
[12] FMN, paragraph 62.
[13] Annex 024 to the FMN - **[✂]** – 21 February 2022, page 3.
[14] Annex 024 to the FMN - **[✂]** – 21 February 2022, page 3.
[15] See Mergers: Guidance on the CMA's jurisdiction and procedure (CMA2revised), December 2020, from page 46.
[16] Section 33(1)(a) of the Act.

28. Each of Cochlear and Oticon Medical is an enterprise.[17] As a result of the Merger, these enterprises will cease to be distinct.

29. The Parties overlap in the supply of BCS devices in the UK, with a combined share of supply, when measured by either value or volume, of approximately [90-100]% (with an increment of approximately [20-30]% based on volume, and an increment of approximately [40-50]% based on NHS year 2021 revenue). Accordingly, the CMA believes that the share of supply test in section 23 of the Act is met.

30. The CMA therefore believes that it is or may be the case that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation.

31. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 12 October 2022 and the statutory 40 working day deadline for a decision is therefore 6 December 2022.

INDUSTRY BACKGROUND

32. The hearing solutions sector constitutes a range of treatments designed to reduce the impact of hearing loss on individuals, which include hearing aids, hearing implants, assistive listening devices and reconstructive surgery.[18] The Parties overlap in the supply of two types of hearing implants, CI and BCS, in the UK.[19]

33. The Parties primarily supply CI and BCS products at the wholesale level, with sales to the NHS accounting for **[✂]**% of the Parties' sales, with the remaining sales made to private hospitals.[20] As such, the NHS procurement process is important for understanding the nature of competition in the supply of these products.

Hearing implants

34. CI and BCS devices address different patient needs. As explained below, the clinical choice of whether to opt for a CI or BCS will depend, in part, on where the patient's hearing loss emanates from (eg the inner ear or outer ear) and the severity of hearing loss. Therefore, the devices are not interchangeable.

Cochlear Implants

35. CIs are electronic devices designed to replace a patient's damaged inner ear or cochlea. Unlike hearing aids, which amplify sounds, CIs bypass the functions of the

[17] An enterprise is defined under section 129(1) of the Act as the activities, or part of the activities, of a business. A business includes a professional practice and any other undertaking which is carried on for gain or reward, or which supplies goods or services otherwise than free of charge.
[18] FMN, paragraph 134.
[19] FMN, paragraph 128.
[20] FMN, paragraphs 203 and 260.

middle and inner-ear structures and stimulate auditory nerves directly.[21] CIs consist of an external processor which contains a microphone to pick up sound, a sound processor to convert those sounds into electrical signals, and an internal implant which sends signals to the inner ear.[22]

36. CIs are typically used for patients experiencing severe or total hearing loss.[23] CIs are classified as 'Class III' medical devices in the UK, [24] and the surgery typically requires a general anaesthetic.

Bone Conduction Solutions

37. BCS rely on the stimulation of bones in the patient's skull to bypass damaged outer or middle ear structures.[25] This is achieved through an external sound processor which converts sounds into vibrations that are sent through the skull to the inner ear.[26] BCS products can be subcategorised into:[27]

    (a) *Passive BCS:* These rely on vibrations created by an **external** transducer which are transmitted to an internal implant before travelling to the inner ear.[28] Passive BCS devices generally use an abutment which penetrates the skin to hold the sound processor in place.[29] Passive BCS products are usually categorised as Class II medical devices in the UK, and the surgery typically involves a 10-20 minute procedure under local anaesthetic.[30]

    (b) *Active BCS:* These use an **internal** implant or transducer to create the necessary vibrations to stimulate bones in the inner ear to produce sound. These devices do not require an abutment and leave the skin intact.[31] Similar to a CI, active BCS devices are classified as Class III devices in the UK and typically require a general anaesthetic during surgery.[32]

    (c) *Non-Surgical BCS*: These are typically used for children who are too young for surgery, patients who cannot have surgery or patients who want to sample BCS before adopting a surgical solution.[33] These devices typically use a headband to hold an external sound processor in place which will generate vibrations through the skin to the skull without an implant.[34]

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[21] FMN, paragraph 140.
[22] FMN, paragraph 141.
[23] FMN, paragraph 142(a).
[24] FMN, paragraph 263; In the UK, medical devices are classified into four risk levels (I, IIa, IIb and III), with Class III devices being the highest risk. See Chapter 2: Classification - GOV.UK for further information.
[25] FMN, paragraph 146.
[26] FMN, paragraph 146.
[27] FMN, paragraph 147
[28] FMN, paragraph 147.
[29] FMN, paragraph 147.
[30] FMN, paragraphs 3 and 263.
[31] FMN, paragraph 148.
[32] FMN, paragraph 29; Third party responses to the CMA's questionnaire.
[33] FMN, paragraph 186.
[34] FMN, paragraph 155.

38. BCSs are suitable for patients with mild, moderate, moderately severe, or severe hearing loss.[35]

NHS Procurement Supply Chain

39. In the UK, almost all CI and BCS devices are supplied to NHS hospitals. To supply either CI or BCS to NHS hospital trusts for use in their audiology clinics, suppliers have to first go through a process to be listed on an NHS framework agreement, which they can do by meeting the necessary pricing and quality conditions set by the framework.[36] Each UK nation is responsible for maintaining its own procurement frameworks for CI and BCS.[37]

40. There are some differences in how CI and BCS devices are purchased. In the case of England, for CI products, pricing is generally determined between the manufacturer and clinic via NHS Supply Chain based on a pre-agreed framework price, and the hospital trust bears the cost of each device.[38] For BCS products, once products are added to the framework, the Parties submitted that individual clinics cannot negotiate prices further with suppliers.[39] The CMA understands that because BCS products are part of the Specialised Service Devices Program, the costs of BCS products are not borne by the clinic but by NHS England.[40]

41. The CMA understands that decisions on which specific products are purchased occur at the clinic level based on clinical need and in consultation with the patient.[41]

Patients' route to an implant

42. When determining patient eligibility for CI, clinics take the National Institute for Health and Care Excellence (NICE) guidelines into account.[42] For BCS, the clinical commissioning guidance for bone conduction hearing implants determines patient eligibility.[43] In practice, clinic evidence indicates that non-price factors, such as the reliability and suitability of the product to address a patient's needs, are a key concern of clinics when determining patient eligibility.[44]

43. Potential candidates for CI or BCS will be referred to an NHS clinic, with a multidisciplinary team determining the most suitable product for the patient.[45] Clinics

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[35] FMN, paragraph 146.
[36] FMN, paragraph 233; Note of a call with a third party; The CMA refers to 'clinics' to mean the relevant audiology department or clinic within an NHS hospital.
[37] FMN, paragraph 230.
[38] FMN, paragraph 255(a) and 284(a); Third party response to the CMA's request for information.
[39] FMN, paragraph 284(c).
[40] Third party response to the CMA's request for information.
[41] Notes of calls with third parties.
[42] FMN, paragraph 234; NICE, Cochlear implants for children and adults with severe to profound deafness, 7 March 2019.
[43] NHS England, Clinical Commissioning Policy: Bone conducting hearing implants (BCHIs) for hearing loss (all ages), 13 July 2016.
[44] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[45] FMN, paragraph 143; Notes of calls with third parties.

will discuss with potential patients the appropriate brand of implant, taking into consideration cost, reliability, and support.[46] The CMA understands that typically a surgeon will have the final decision of which product is chosen, taking into consideration the aforementioned factors and patient preferences.[47]

COUNTERFACTUAL

44. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For anticipated mergers the CMA generally adopts the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[48]

45. The Parties submitted that the counterfactual to the Merger is that Demant would have inevitably exited the hearing implants segment, while maintaining some limited activities (in-house or outsourced) in order to provide continued support to its installed base of patients,[49] and that there would not have been an alternative purchaser for Oticon Medical.[50]

46. The exit from a market of one of the merger firms might be because of financial failure or because of a change in the firm's corporate strategy.[51] As set out in the CMA's Merger Assessment Guidelines, for the CMA to accept an exiting firm counterfactual at Phase 1, it must believe, based on compelling evidence, that it is inevitable that, absent the Merger:

    (a) the firm is likely to have exited (through failure or otherwise) (**limb 1**); and, if so

    (b) there would not have been an alternative, less anti-competitive purchaser for the firm or its assets to the acquirer in question (**limb 2**).[52]

47. The CMA has considered whether Demant would have discontinued its hearing implants business for strategic reasons.[53] In reaching its view, the CMA has considered a range of factors, including Demant's board decisions, its public

[46] FMN, paragraph 219(b), paragraph 235; Notes of calls with third parties; Responses to the CMA's questionnaire.
[47] FMN, paragraph 237; Notes of calls with third parties.
[48] Merger Assessment Guidelines (**CMA129**), March 2021, from paragraph 3.12.
[49] The CMA notes the Parties originally submitted that absent the Merger, Oticon Medical's patients 'would not be supported in respect of product repairs, product updates/sound processor upgrades and aftercare'. DMN, 1 June 2022, paragraph 10. This original submission appears to be at odds with the FMN.
[50] FMN, paragraphs 8 and 117.
[51] CMA129, paragraph 3.22
[52] CMA129 paragraphs 3.21 to 3.23.
[53] See paragraph 3.29 of CMA129.

announcements, its internal documents and projections regarding its CI and BCS businesses performance, and the sales process for Oticon Medical.

Limb 1 – Oticon Medical is likely to exit the market absent the merger

The Parties' submissions

48. Broadly, the Parties submitted Demant would inevitably have exited the hearing implants segment for strategic reasons absent the Merger because:

(a) **Oticon Medical was loss-making:** Oticon Medical's hearing implants business had incurred persistent financial losses, including a loss of around £**[✂]** in 2021 as a result of the Neuro Zti CI recall.[54] These losses were exacerbated by the COVID-19 pandemic, and Demant considered that it is unlikely to **[✂]** in the foreseeable future.[55] The CI business's losses are also compounded by Oticon Medical's lack of scale, **[✂]**, given it is a newer and smaller supplier.[56]

(b) **Significant investment is required to develop new products and be competitive, which Demant considers unfeasible:** Oticon Medical could not deliver products with additional quality, cost or price benefits compared to its competition, and its products lagged behind its competitors on many performance metrics.[57] Oticon Medical's pipeline active BCS device, **Sentio**, **[✂]**; **[✂]**.[58] Demant submitted that active BCS patients would require lifelong support, which it is not prepared to commit to, and as such it considers Sentio a stranded product.[59] In the absence of supplying an active BCS product, Oticon Medical would be unable to maintain its passive BCS revenue streams as the market shifted towards active BCS solutions.[60] Demant determined that for Oticon Medical to be sustainable, **[✂]**, which was not feasible.[61]

(c) **Oticon Medical's BCS and CI businesses are interdependent and subsidised by Demant:** Demant submitted that the BCS business' profitability is overstated and if Oticon Medical only exited the CI business, this would have a negative effect on the BCS business. This would be because (a) Demant's pipeline active BCS product, Sentio, as a Class III device, would require Oticon Medical to maintain know-how and a suitable facility; the relevant facility is currently shared with its CI business;[62] and (b) as Oticon Medical's BCS

[54] FMN, paragraph 9. Oticon Medical discovered an issue with its Neuro Zti CI in October 2021, which resulted in it launching a voluntary field corrective action of approximately 4000 Neuro Zti devices in October 2021. FMN, paragraph 216.
[55] FMN, paragraph 61.
[56] FMN, paragraph 9.
[57] Parties' response to CMA's issues letter, 15 November 2022 (**issues letter response**), paragraph 7.6.
[58] FMN, paragraph 9; Issues letter response, paragraphs 7.6 and 7.8.
[59] Issues letter response, paragraph 7.8.
[60] FMN, paragraph 9.
[61] FMN, paragraph 10.
[62] FMN, paragraph 123 and 125.

business shares costs with its CI business and Demant, the BCS business would be **[✂]**.[63] Demant submitted it shares its resources and staff with the CI and BCS businesses and does not currently allocate these costs to the hearing implants businesses.[64]

49. Demant submitted that in August 2021, Demant's board discussed whether to exit hearing implants as some members of the board considered it was unrealistic for Oticon Medical to achieve its goals within a reasonable timeframe and without disproportionate levels of investment.[65] Demant advised the CMA that while a decision was not made at that time, following the CI product recall in October 2021, the discussion arose again and this ultimately led Demant's board of directors to make a decision in late 2021 to discontinue the hearing implants business.[66] This timeline is discussed further below.

50. Demant submitted that it reviewed its options, and in order to ensure the best lifelong support for its patients, it considered:

    (a) a sale to an existing provider of hearing implants with a buyer commitment to support Oticon Medical's patient base; or

    (b) a controlled withdrawal from the hearing implants business with a service arrangement with a third-party provider supporting Oticon Medical's patient base.[67]

51. The Parties submitted that the designation and announcement of Oticon Medical as a 'discontinued operation,' Demant's communications with its customers, and other external and internal communications, together amounts to a public commitment to either sell Oticon Medical or otherwise discontinue its business and demonstrates a clear intention of exiting the market in the absence of the Merger.[68]

CMA's assessment

52. As stated above, to accept an exiting firm argument at Phase 1, the CMA requires compelling evidence that exit was inevitable and, in the case of a strategic exit, needs to be satisfied that the exit is unrelated to the merger.[69] That exit is one of a number of plausible options, including continuing the business for a period, or even the most likely option, would not meet the Phase 1 standard for inevitable exit.

[63] FMN, paragraph 123; Issues letter response, paragraph 7.9.
[64] FMN, paragraph 124; Meeting between Demant and the CMA, 29 September 2022.
[65] RFI4 response, page 2.
[66] Response to the CMA's request for information dated 16 September 2022 (**RFI4 response**), page 2.
[67] RFI4 response, page 2.
[68] RFI4 response, page 6.
[69] CMA129, paragraphs 3.23 and 3.29.

53. The CMA will usually attach greater weight to evidence that has not been prepared in contemplation of the merger.[70] The Parties signed the Put Option Agreement and publicly announced the Merger on 27 April 2022. The CMA believes that the evidence submitted by Demant was either (a) produced prior to the Merger and does not evidence a decision by Demant to exit, or (b) demonstrates a decision by Demant to exit but was produced in contemplation of or after the Merger was announced. The evidence and the timing of the evidence is set out below.

Pre-Merger announcement evidence

54. The CMA considered Demant board documents from 19 August 2019 to 10 March 2022 and reviewed copies of notices and minutes produced between 1 June 2021 and 30 June 2022. In its review, the CMA found that Demant's board minutes and Christmas letter from December 2021, and board minutes from February and March 2022, discussed the challenges faced by the CI business, and that it was considering the future strategy and opportunities for the hearing implants business overall.[71] These documents record that the management had reached out to **[✂]** to discuss Oticon Medical and subsequently had agreed a term sheet with Cochlear.[72] One board document, from only two months before the Put Option Agreement, noted that if Demant failed to sell Oticon Medical, it would have an obligation to continue its activities in the sector, and that the failure to sell the business would require it to '**[✂]**'.[73] This document does not indicate that Demant had taken a decision to exit irrespective of the Merger.

55. Demant submitted that the language used in the board documents, when read with an English-language lens, may appear vague, but told the CMA that there were clear directions to find a solution for patients in the event of an exit.[74]

56. Demant also provided a document, produced in November 2022 for the purpose of the CMA's investigation, with further descriptions of board and chairmanship meetings held prior to the announcement of the Merger, which were not included in the meeting records and were based on board member recollection.[75] Demant submitted that these discussions included evaluation of the long-term impact of the recall on the hearing implants business, the need to discontinue the business area while safeguarding patients, possible costings of winding down the business and the timing of when to announce the business as a 'discontinued operation'.[76]

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[70] CMA129, paragraph 3.24.
[71] See **[✂]** 7 December 2021; Annex 113 to the FMN - **[✂]**, page 2; **[✂]** 7 February 2022, page 6; **[✂]** 10 March 2022, page 3.
[72] See **[✂]** 7 December 2021; Annex 113 to the FMN - **[✂]**, page 2; **[✂]** 7 February 2022, page 6; **[✂]** 10 March 2022, page 3.
[73] **[✂]** 7 February 2022, page 6.
[74] Issues letter response, paragraph 7.12.
[75] Issues letter response, Annex A.
[76] Issues letter response, Annex A, page 3.

57. The CMA does not accept that language differences account for the lack of clear evidence of a decision to exit being taken. Instead, the CMA believes that the board meeting documentation and further descriptions provided show that Demant was considering the future options for Oticon Medical and chose first to try to sell the business. Other options considered in the months prior to the Merger seem to include continuing to operate,[77] at one point **[✂]**,[78] or winding down.[79] However, the evidence makes clear that (at least some of) the Board considered that simply winding down was not an option,[80] and so in order to exit they would need to safeguard their existing patients by having the hearing implants business taken over through a sale or other arrangement.[81]

58. The CMA therefore believes that statements that Demant was looking at the viability of Oticon Medical and clarifying possible strategic possibilities, or considering whether to announce Demant as a discontinued operation, do not constitute compelling evidence that Demant would inevitably have exited its hearing implants business absent the Merger. The CMA considers that this evidence indicates that Demant was willing, indeed keen, to divest the Oticon Medical business. It did find Cochlear as a willing buyer (the steps it took to do this, and to find other possible buyers, are discussed in the section on limb 2 of the CMA's counterfactual assessment), but this does not answer the counterfactual question of what would have happened to Oticon Medical absent the sale to Cochlear.

Evidence produced in contemplation of the Merger or post-Merger announcement

59. The CMA considered the internal and external documents created by Demant and Oticon Medical which discuss Demant's decision to discontinue its hearing implants business. Based on the timing of the creation of these documents, the CMA considers they were prepared in contemplation of or after the Merger announcement. Therefore, the CMA takes a cautious approach to placing evidential weight on these documents.

60. Demant provided documents which were created in April 2022 and which discuss Demant's exit.[82] The CMA considers that, given the contents and timing of these documents, they were created in contemplation of the Merger, as they were created

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[77] Evidenced by Demant internal documents which show that in late 2021 and early 2022 it was still discussing ongoing product development and the future of the CI and BCS businesses. For example, the March 2022 Demant board notice mentions that Demant is continuing to develop its **[✂]**, and a December 2021 CI Recovery Plan discusses opening new accounts in existing markets across **[✂]**. See Annex DMT-V1-0013825 to the FMN – **[✂]**– 11 January 2022; Annex DMT V1 0013066 to the FMN – **[✂]** – 20-21 December 2021 and Annex DMT-V1-0007263 to the FMN – **[✂]** – 27 October 2021.
[78] Issues letter response, Annex A, page 2.
[79] Issues letter response, Annex A, page 5.
[80] Issues letter response, Annex A, page 2
[81] Issues letter response, Annex A, page 4.
[82] The CMA refers to Annex DMT-V1-0020570 to the FMN - **[✂]** - 5-6 April 2022, slide 10, which the CMA understands was prepared for Demant's internal **[✂]**; Annex DMT-V1-0020847 to the FMN - **[✂]** - April 2022, slide 4 and Annex DMT-V1-0020903 to the FMN - **[✂]** - April 2022, slide 3, which the CMA understands were prepared on 20 April 2022 and 21 April 2022 respectively, for an internal presentation for Oticon Medical's **[✂]**.

and presented at a time when Demant's negotiations with Cochlear were well progressed, with the purpose of informing internal management about the Merger and how it would impact Oticon Medical's operations going forward.

61. The CMA also reviewed Demant board notices, investor relations presentations, Demant's press release, and customer announcements, which demonstrate Demant's decision to discontinue Oticon Medical. These documents contain the following:

    (a) 'Demant has taken the decision to discontinue its efforts in hearing implants';[83]

    (b) 'we have decided to withdraw from the business';[84] and

    (c) announcements that Oticon Medical is a 'discontinued operation.'[85]

62. While these documents discuss Demant's exit decision, all of these examples discuss this in the explicit context of Demant agreeing to divest Oticon Medical to Cochlear and were either produced on the date of the Merger announcement or afterwards. Oticon Medical's exit in the context of a sale to Cochlear does not address the counterfactual question of what would happen to Oticon Medical and its assets absent the sale to Cochlear.

63. With regards to Oticon Medical being announced as a 'discontinued operation' at the time of and after the Merger was announced, the CMA considers that whether a business has been designated as a 'discontinued operation' is not in itself determinative of strategic exit.[86] Further, and as already noted, the announcement of Oticon Medical as a discontinued operation in the context of a sale or divestment to Cochlear is not relevant to the counterfactual question of whether Oticon Medical would have exited absent the Merger.

64. The CMA also considered the 28 June 2022 Demant board notice and minutes, which (in terms of chronology) are the first Demant board documents seen by the CMA to categorically refer to Demant's decision to exit the hearing implants business.[87] These documents record that the Merger is not a traditional divestment, but that Demant has decided to exit hearing implants, after which a third-party would need to support its patients.[88] As these documents were produced two months after the Merger announcement and the notification to the CMA, the CMA does not believe they constitute compelling evidence to meet the Phase 1 standard.

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[83] Demant press release – 27 April 2022.
[84] Annex 198 to the FMN - Seller Investor Relations Presentation - April 2022 - Transcript, page 1.
[85] Annex 197 to the FMN - Seller Investor Relations Presentation - April 2022; Annex 199 to the FMN - Seller Interim Report 2022; Annex 200 to the FMN - Seller Interim Management Statement, May 2022.
[86] For example, see Just Eat/Hungry House, Final Report, paragraph 5.30 and footnote 7.
[87] [✂] 28 June 2022, page 10.
[88] [✂] 28 June 2022, page 10.

65. The CMA notes the Parties' submission that to avoid leakage and destabilising Oticon Medical, Demant's senior management kept the decision to exit strictly confidential until a viable solution that protected patients could be presented to the non-executive board, which explains the paucity of documents around the decision to exit.[89] However, this infers that there was a majority decision of the board to exit. Despite the CMA asking Demant to provide its strongest documentary evidence that Oticon Medical would have exited absent the Merger, it has not been able to provide any evidence of these discussions (ie in the form of emails, texts or contemporaneous notes).

Internal documents related to strategic exit

66. The CMA also considers that some of the Demant, Oticon Medical and Cochlear internal documents it has reviewed do not support Demant's submissions that it would have inevitably exited its hearing implants business absent the Merger.

(a) BCS profitability:

(i) While the Parties submitted that the BCS businesses' profitability is overstated, the internal documents indicate that it is profitable and contributing to Demant's revenue growth,[90] and that even since the Merger was announced, BCS sales **[✂]** the previous year.[91]

(ii) The CMA notes that Cochlear is willing to pay approximately £99 million for the BCS division of Oticon Medical. Although this is a significant sum, internal documents suggest that the **[✂]** were estimated to be **[✂]**.[92] While the CMA notes the Parties submission that such documents were based on **[✂]**,[93] the final valuation (which is likely to have been reached following **[✂]**) indicates that the BCS business is an attractive, growing and profitable business. Third-party input into these documents suggests that the BCS business is operating in a segment which attracts strong valuations and significant investor interest. In this context, the CMA would expect a business and its shareholders rationally to seek an option to prevent simply shutting the business down, and Demant has not submitted evidence to support a conclusion that this would be the case.

(iii) Further, the CMA believes that the BCS business would still likely be valuable to Demant, given that Demant had interest from an alternative purchaser for it.[94]

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[89] FMN, paragraphs 12 and 15.
[90] Annex 022 - **[✂]**, slide 3.
[91] **[✂]** 28/29 June 2022, page 10.
[92] Annex COH0000026 to the FMN - **[✂]** - April 2022, slides 7 and 8.
[93] Issues letter response, paragraph 3(e).
[94] FMN, paragraph 120(h).

(b) **Oticon Medical's future in BCS:** While the Parties submitted that Oticon Medical's pipeline active BCS, Sentio, has **[✂]**, at least one internal document from early 2022 shows that Sentio was still being developed, **[✂]**,[95] **[✂]**.[96] Further, as discussed in the competitive assessment at paragraph 112 below, while there may be a gradual shift to active BCS, the evidence suggests there will remain a role for passive BCS in the market. These facts suggest Oticon Medical would continue to have a strong future BCS business absent the Merger.

(c) **Oticon Medical would inevitably exit both CI and BCS:** The CMA found that the Parties' Asset Sale and Purchase Agreement allowed for the **[✂]**. The CMA considers that despite the Parties' claims that this **[✂]**,[97] the separation of the two businesses is a possibility for Demant given the economies of scale, know-how and resources available from the wider Demant group. The CMA notes that while **[✂]**, Demant as the owner of the business already had detailed knowledge of the business when this **[✂]**.

(d) **Neuro Zti CI recall:** The Parties submitted the recall was likely to have impacted Oticon Medical's brand perception and caused concern for stakeholders.[98] As discussed further in the competitive assessment section, while the Neuro Zti recall impacted Oticon Medical's CI **[✂]**, Demant's internal documents indicate that it handled the recall well,[99] and evidence from clinics has indicated that customers would consider Oticon Medical as an alternative supplier of CI going forward, despite the recall.[100] The CMA understands there are no regulatory barriers to Oticon Medical once again selling CIs in the UK, and that it has already sold these devices in the EEA following the recall.[101] The CMA considers that while the recall may have contributed to Oticon Medical's decision to look at options for its future activities in CI, which included selling the business to Cochlear, it does not consider that this evidence indicates its exit was inevitable.

67. To the extent the CMA believes Demant's reasons for strategic exit would impact the competitive position of Oticon Medical in the future, this will be considered in the competitive assessment section.

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[95] Annex DMT-V1-0016362 FMN - **[✂]**- 28 January 2022, slides 30 and 36.
[96] **[✂]** 10 March 2022, page 3.
[97] FMN, paragraph 32; Issues letter response, clause 7.10.
[98] FMN, paragraph 67.
[99] See Annex DMT-V1-0017861 to the FMN, **[✂]** - 8 February 2022; Annex COH0000024 to the FMN, **[✂]** – 31 March 2022, slide 105.
[100] Notes of calls with third parties; Third party responses to the CMA's questionnaire.
[101] Response to the CMA's request for information dated 12 October 2022, pages 3 – 4.

Conclusion on Limb 1

68. As set out in further detail above, the CMA has not seen compelling evidence from Demant that the exit of Oticon Medical was inevitable absent the Merger. Based on the evidence, the CMA believes strategic exit was one of a number of options considered by Demant, and that it decided to try to sell Oticon Medical in the first instance. The CMA does not consider that the evidence shows that Demant decided that Oticon Medical would exit other than by selling the business to Cochlear. Moreover, the CMA also considers it would be commercially irrational for Demant to discontinue the entire hearing implant business given this is worth approximately £99 million without at least fully exploring other options. This question is examined in the next section.

69. The CMA considers that limb 1 of the exiting firm assessment is not met in this case. The two limbs are cumulative conditions.[102] Notwithstanding this, the CMA has also considered limb 2 of the assessment since the evidence on the sales process and the likelihood of an alternative purchaser is an important aspect to the counterfactual assessment in this case.

Limb 2 – would there be an alternative, less anti-competitive purchaser for Oticon Medical?

70. The Parties submitted that Cochlear was the only viable purchaser, given that **[✂]**.[103] Demant submitted that alternative purchasers such as private equity buyers were not a viable option, as a leveraged buy-out or a build-and-buy strategy were too challenging.[104] It further noted that a financial buyer may ultimately look to exit their investment, which would provide less certainty for patients.[105] Demant also considered that hearing aid manufacturers, which were not active in hearing implants, would not have the necessary competencies, resources or distribution network to support patients in the short or medium term.[106]

71. The CMA notes that the sales process for Oticon Medical was limited to Demant informally approaching **[✂]**.[107] Oticon Medical was not marketed to **[✂]**. As such, the CMA considered that Demant did not run a sales process that is meaningful in establishing whether there would be an alternative, less anti-competitive buyer to Cochlear.[108]

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[102] CMA129, paragraph 3.21
[103] FMN, paragraph 17.
[104] Issues letter response, paragraph 7.18.
[105] Issues letter response, paragraph 7.18.
[106] Issues letter response, paragraph 7.17.
[107] FMN, paragraph 120(g).
[108] See Anticipated merger of Nijjar Group Holdings (Acton) Limited and Medina Holdings Limited of 30 March 2022, paragraph 31.

72. In response, Demant submitted that it did not operate a wider sales process given that Oticon Medical **[✂]** and its need to keep the sale confidential until a solution that protected patients could be identified.[109]

73. Demant also submitted that **[✂]** expressed some interest in acquiring the Oticon Medical BCS business but this interest was not pursued by Demant.[110]

74. The very limited sales process and the possibility that **[✂]** could have acquired at least some of Oticon Medical do not provide a basis for the CMA to rule out that there could have been an alternative, less anti-competitive purchaser for one or both of the BCS and CI businesses.

Conclusion on counterfactual

75. Based on the above, the CMA believes that neither of the two limbs of the exiting firm counterfactual are satisfied in this case. The CMA does not believe that there is compelling evidence that Demant would have exited its hearing implants business absent the Merger, and also cannot rule out that there may have been an alternative, less anti-competitive purchaser.

76. As such, the CMA believes that the appropriate counterfactual is the prevailing conditions of competition.

FRAME OF REFERENCE

77. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[111]

78. As noted above, the Parties overlap in the supply of CI and BCS in the UK.

Product scope

The Parties' submissions

79. The Parties submitted that it is appropriate to consider a product frame of reference that includes CI and BCS, alongside other solutions used to treat hearing loss.[112] Further, the Parties have submitted that the CMA, in its competitive assessment,

[109] Issues letter response, paragraph 7.16.
[110] FMN, paragraph 295(d).
[111] CMA129, paragraph 9.4.
[112] FMN, paragraph 199.

should carefully consider the constraint that other forms of hearing solutions, predominantly hearing aids, impose on both CI and BCS.[113]

80. The Parties submitted there are three reasons for considering this:[114]

(a) First, there is no uniform or one-size-fits-all approach to possible treatments, and patients with the same clinical profile can be treated with a range of options (ie hearing aids, cochlear implants and bone conduction solutions). The Parties also highlighted that there is a lack of education among hearing audiologists about hearing implants;[115]

(b) Second, the growth of either CI or BCS comes at the expense of hearing aids, which are by far the most popular solution. The hearing implant segment is currently underserved (ie some patients who currently use hearing aids may be better off, in terms of hearing outcome, receiving a hearing implant);[116] and

(c) Third, any price increase in CI and BCS would likely negatively affect the growth of these segments, given that hearing aids are alternatives for patients that use these types of devices.[117]

The CMA's assessment

81. The CMA considered whether the product frame of reference should include both types of hearing implant (CI and BCS) or if a separate frame of reference for each of CI and BCS is appropriate.

82. The CMA also considered whether other types of hearing solutions could be part of the product frame of reference.

Previous regulator decisions

83. The CMA and OFT had not previously considered any mergers in the hearing implants sector.[118] The European Commission considered the hearing solutions sector in *EQT/Widex*, in which the merger parties overlapped in the manufacture and supply of hearing aids.[119] In this case, the European Commission considered that hearing aids should be distinguished from both CI and BCS, as these solutions are surgically implanted in treating hearing impairment.[120] As a result, the European

[113] FMN, paragraph 197; Issues Letter response, paragraph 1.3(a).
[114] FMN, paragraph 197.
[115] Issues Letter response, paragraphs 2.4, 2.6 and 2.7.
[116] Issues Letter response, paragraph 2.12.
[117] Issues Letter response, paragraph 2.13.
[118] The CMA reviewed Phonak / Comfort Audio in 2014, in which the Parties overlapped in the supply of assistive listening devices.
[119] M.8941 EQT/Widex/JV on 13 February 2019.
[120] M.8941 EQT/Widex/JV on 13 February 2019; paragraph 30.

Commission did not consider hearing implants to be part of the same relevant product market as hearing aids.

Consideration of whether the product frame of reference should include both CI and BCS

84. Third parties indicated that CI and BCS serve distinct clinical patient needs and are not considered substitutable for patients with the same clinical profile.[121] This is because CI are targeted at replacing a severely damaged cochlea, while BCS typically require a patient to have a healthy cochlea to be effective in treating the hearing loss.[122] Further, the Parties submitted that CI and BCS are differentiated as they rely on different technologies and serve different patient needs.[123] The CMA also considers, as stated in the background section above, that CIs and BCSs are categorised in different classes of medical device and therefore require patients to undergo degrees of implant surgery. The CMA also found that internal documents demonstrated that CI and BCS product development and competitive benchmarking are considered separately from each other (and at times in separate documents). These documents also tend to include separate share of supply estimates calculated for each hearing implant type.[124]

85. For the reasons above, the CMA believes that CI and BCS constitute separate product frames of references.

Consideration of whether the product frame of references should include other types of hearing solution

86. Clinic evidence indicates that both CI and BCS products are recommended for patients when hearing aids are no longer able to remedy the hearing impairment.[125] The CMA also found that, while hearing aids do not require a patient to undergo surgery, hearing implants do.[126] The differences between hearing aids and hearing implants are further demonstrated by the significant price differences between such products to the NHS.[127]

87. Evidence from competitors is also broadly consistent with the above.[128] However, competitors also observed that, there may be a very small proportion of patients for whom (superpowered) hearing aids, for example, may be an alternative to both CI and BCS.[129] Competitors submitted that, in practice, CI and BCS solutions are typically recommended after hearing aid solutions have been tried and found not to

[121] Third party responses to the CMA's request for information.
[122] Third party responses to the CMA's questionnaire.
[123] Response to the CMA's request for information dated 17 June 2022, Part 1, pages 6-8.
[124] See, for example, Annex DMT V1 0019855 to the FMN - [✂] - Dec 2020.
[125] Third party responses to the CMA's questionnaire.
[126] Third party response to the CMA's questionnaire.
[127] FMN, paragraph 3(a).
[128] Third party responses to the CMA's request for information.
[129] Third party responses to the CMA's request for information.

be suitable by patients.[130] Further, there is evidence to suggest that there is a different competitor set across both hearing implants and hearing aid providers, with a significant number of suppliers active in hearing aids not being active in supplying hearing implants and vice versa.[131]

88. The CMA found that the Parties' internal documents indicate that while there is some evidence that they consider their hearing implant activities in the context of wider hearing solutions,[132] most documents demonstrate that the Parties' competitive monitoring activities and product strategy documents focus on hearing implant competitors.[133]

89. Based on the above reasons, the CMA considers that the evidence does not demonstrate that there is any material substitution between either CI or BCS and other types of hearing solutions. In particular, the CMA considers the Parties' submissions that the hearing implants segment is small and underserved are not relevant to the assessment of substitutability between the solutions. Indeed, this suggests that continued innovation and competition to ensure higher quality or lower priced hearing implants is particularly important in order to allow more patients to benefit from these devices.

90. The CMA considers the majority of evidence demonstrates that hearing implants are prescribed by clinicians after hearing aids have been trialled, and based on patient's specific clinical needs. As such, the CMA considers that competition between different brands of each hearing implant is predominately driven by innovation in that type of implant over time in order to better serve patients' needs and has not observed any evidence to suggest competitive interaction or substitution between hearing implants and hearing aids.

Conclusion on product scope

91. For the reasons set out above, the CMA has considered the impact of the Merger in the following product frames of reference:

    (a) Supply of BCS.

    (b) Supply of CI.

[130] Third party responses to the CMA's request for information.
[131] See, for example, Annex 011 to the FMN – **[✂]** – March 2021, slide 19; Annex 022 to the FMN – **[✂]** – April 2021, slide 5; Annex 010 to the FMN - **[✂]** – May 2021; slide 17.
[132] See, for example, Annex 011 to the FMN – **[✂]** – March 2021, slide 19; Annex 022 to the FMN – **[✂]** – April 2021, slide 5; Annex 010 to the FMN - **[✂]** - May 2021, slide 17.
[133] See, for example, Annex 046 to the FMN - **[✂]** - July 2020, slide 24; Annex 098 to the FMN - **[✂]** – 12 November 2021, slide 10; Annex 100 to the FMN - **[✂]**; Annex 101 to the FMN - **[✂]**; Annex COH0000001 to the FMN – **[✂]** – 8 September 2022.

Geographic scope

The CMA's assessment

92. In *EQT/Widex*, the European Commission left open whether the geographic market for the wholesale supply of hearing aids was EEA-wide or national.[134]

93. The CMA considers that on the demand side, patient options would generally be limited to those offered in their local clinic, which would offer products in line with the relevant national framework. Further, as noted previously with respect to England, each clinic may have their own arrangements with suppliers.

94. However, the CMA does not consider that segmenting at the subnational level would in practice change its conclusions. Evidence from customers from different nations within the UK indicate that the dynamics of competition appear to be very similar.[135] The CMA is not aware of any significant differences in how the suppliers compete with each other, their relative strengths and the options offered to patients. Further, evidence from internal documents indicates that the Parties assess the competitive dynamics and shares of supply at a UK level, as opposed to a nation-by-nation basis.[136]

95. As such, the CMA has considered the impact of the Merger at the UK level.

Conclusion on frame of reference

96. For the reasons set out above, the CMA has considered the impact of the Merger in the following frames of reference:

    (a) Supply of BCS in the UK.

    (b) Supply of CI in the UK.

COMPETITIVE ASSESSMENT

97. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in: (a) the supply of BCS in the UK and (b) the supply of CI in the UK.

98. The concern under such theories of harm is that the removal of one party as a competitor may reduce competition between suppliers of BCS or CI products in the UK. This may lead to the merged firm having a weaker incentive to innovate, or to

[134] M.8941 EQT/Widex/JV on 13 February 2019, paragraph 71.
[135] Third party response to the CMA's questionnaire; Notes of calls with third parties.
[136] Annex 082 to the FMN - **[✂]** - February 2022, slide 2; Annex 125 to the FMN - **[✂]** – December 2021, slides 3 - 6.

provide favourable contractual terms or competitive prices for customers, which may also result in reduced quality and service in each respective market.

Horizontal unilateral effects in the supply of BCS in the UK

99. In order to assess the likelihood of the Merger resulting in horizontal unilateral effects in the supply of BCS in the UK, the CMA has considered:

    (a) Shares of supply;

    (b) Closeness of competition; and

    (c) Alternative constraints.

Shares of supply

The Parties' submissions

100. The Parties estimated the market size as the sum of volumes of new active, passive and non-surgical BCS implants sold by Cochlear, Oticon Medical and Med-El, where Med-El's sales volume was estimated by Cochlear based on its business knowledge.[137]

101. The Parties submitted that, based on their assessment, the combined share of the Parties for the supply of BCS in the UK is [90-100]% (with Oticon having [60-70]% and Cochlear [20-30]%).[138]

Table 1: Parties' estimates of shares of supply for bone conduction devices in the UK, for NHS Year 2021 (April 2021 to March 2022)

Company	Volume for new BCS implants, NHS Year 2021	Share (%)
Cochlear	**[✂]**	[20-30]
Oticon Medical	**[✂]**	[60-70]
Combined	**[✂]**	**[90-100]**
Med-El	**[✂]**	[0-5]
Total	**[✂]**	100

Source: FMN, Table 14.B.

102. The Parties submitted that this data significantly overstates the strength of Oticon Medical because Demant has announced its intention to discontinue its hearing

[137] FMN, paragraph 211.
[138] FMN, paragraph 213 and Table 14.B.

implants business.[139] The Parties consider Oticon Medical's sales are likely to diminish significantly over the next year, given that healthcare professionals are likely to have reservations about recommending Oticon Medical's products to patients following such an announcement.[140]

103. The Parties also submitted that the shares of supply present a purely static snapshot and historical view of the segment, given that the BCS segment is shifting to an active transcutaneous solution, where Oticon Medical is not currently supplying.[141]

CMA analysis and conclusion on shares of supply

104. The CMA received evidence from third parties that the Parties' share of supply estimates are broadly accurate.[142] The CMA also considers that based on data submitted by the Parties, these combined shares of supply have been consistently very high over the past five years.[143] This is also consistent with the CMA's findings that, despite Med-El entering BCS with an active BCS product in 2019, it has not been able to gain market share from the Parties in the UK.

105. In relation to the Parties' submission that Oticon Medical's sales are likely to diminish following its announcement that it has decided to discontinue its hearing implants business, the CMA has not received evidence from clinics to suggest that clinics have been influenced in their BCS purchasing decisions by this announcement. The CMA notes further that, as discussed above, this announcement was made at the point of announcing the Merger and the CMA has found that there is insufficient evidence to conclude that Oticon Medical would have discontinued the business, or made such an announcement, absent the Merger.

106. Further, the CMA considers that the shares of supply reflect current competitive conditions, given that the CMA has found below, in paragraph 112, that there will continue to exist a need for passive BCS solutions in the foreseeable future. The CMA has also considered Oticon Medical's activities in active BCS as part of the competitive assessment in paragraph 114 below.

107. The CMA believes that the extremely high combined shares of supply with a substantial increment are indicative of competition concerns.[144] The shares indicate

[139] FMN, paragraph 210.
[140] FMN, paragraph 210.
[141] Issues letter response, paragraph 5.2.
[142] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[143] Annex 179 to the FMN.
[144] A firm with a higher share of supply is more likely to be a close competitor to its rivals, and therefore a merger that removes the competitive constraint such a firm exerts on its rivals would be more likely to raise competition concerns. In cases such as this, market shares can represent a readily available source of evidence on which the CMA can base its assessment of closeness. CMA129, paragraph 4.14.

that the Parties account for effectively all sales of BCS in the UK and therefore the Merger would lead to a monopoly provider of BCS in the UK.

Closeness of competition

The Parties' submissions

108. The Parties submitted that Oticon Medical will be a weak competitor for the supply of BCS in the future.[145] The Parties submitted that although Oticon Medical has a strong position in passive BCS, it currently has no active BCS offering. The Parties submitted that sales of active BCS are likely to rapidly grow over time, particularly in developed countries like the UK.[146] However, the Parties do accept that there will be a limited place for passive BCS in the future, but they said that this will largely be focused on developing countries rather than the UK.[147]

109. Oticon Medical is developing 'Sentio', its pipeline active BCS product. As yet, this product is not available. The Parties submitted that:[148]

    (a) Oticon Medical had planned to launch the Sentio product in **[✂]**, but this has been subject to **[✂]**. Currently, the expected product launch date is **[✂]**.[149]

    (b) Even if the Sentio product were to be launched, Oticon Medical would face a disadvantage from being the last supplier to develop an active BCS product, given that Cochlear and Med-El have both developed such products (known as 'Osia' and 'Bonebridge' respectively).

    (c) Demant is not planning to **[✂]**,[150] with **[✂]**.

Internal documents

110. The Parties' internal documents indicate that both Parties monitor each other **[✂]** with regards to new product developments, market share analysis and how the other Party is reacting to key trends in the global BCS market and more specifically in the UK.[151]

[145] FMN, paragraphs 220 – 222; Issues letter response, paragraph 1.3(e).
[146] FMN, paragraphs 220 – 222; Issues letter response, paragraph 1.3(e).
[147] Issues letter response, paragraph 5.6.
[148] FMN, paragraph 224; Issues letter response, paragraph 1.3(e).
[149] Issues letter response, paragraph 5.8.
[150] Annex 115 to the FMN – **[✂]** - 22 April 2021, slide 25. The CMA notes this document was produced while the Merger was in contemplation and only five days before the Merger agreements were finalised.
[151] See, for example, Annex DMT-V1-0001569 to the FMN, **[✂]** – April 2021; Annex DMT-V1-0020109 to the FMN – **[✂]** – 22 April 2021; Annex COH0000062 to the FMN, **[✂]** - April 22; Annex COH0000063 to the FMN, **[✂]** - June 2022 and Annex COH0000047 to the FMN - **[✂]** – 9 July 2020.

111. CMA analysis of the Parties' internal documents confirms that there is evidence of some shift in preferences to active BCS, particularly given it is more aesthetically appealing and less prone to infection as the products do not penetrate the skin.[152]

112. However, the evidence strongly suggests that there will still be a place for passive BCS for the foreseeable future.[153] For example, one internal document notes that the penetration will be very diverse from country to country due to different re-imbursement schemes.[154] In the same document, it also notes that passive BCS will have its place given that treatment can be done under local anaesthesia and can provide better outcomes for lower treatment costs.[155]

113. With regards to the uncertainty as to when Oticon Medical's Sentio product will be released, evidence suggests that Oticon Medical is still planning to introduce the product in the UK for calendar year **[✂]**, subject to it being fully tested, receiving regulatory approval, and being prepared for commercial launch.[156] The CMA notes Demant's submissions that developing an active BCS product comes at a high cost as they are Class III devices and require suitable facilities. However, the CMA considers that with Demant as its parent, Oticon Medical would have access to sufficient funding, and already has suitable facilities because it already produces CI, which are also Class III devices. Further, the CMA notes that Demant has already invested in developing an active BCS product with a sound knowledge of the costs of such development, and the requirement for suitable facilities. The CMA's analysis of Oticon Medical's internal documents is that its drive to create an active BCS was to compete directly with Cochlear's Osia product **[✂]**.[157] In addition, such documents indicate that the Sentio design may have a number of benefits across the **[✂]**.[158]

114. The CMA also considers that, despite there being uncertainty over whether Oticon Medical is likely to launch an active BCS product, there is strong evidence from Cochlear's internal documents to suggest that it considers Oticon Medical's active BCS product as **[✂]**, **[✂]**.[159] One Cochlear internal document notes that a key risk going forward is **[✂]** share to Sentio (Oticon Medical), **[✂]**.[160] The CMA considers this to be consistent with Oticon Medical having gained the size, track record,

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[152] See, for example, Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 20; Annex CH0000049 to the FMN - **[✂]** - 2nd December 2020, slide 10. The CMA has also seen evidence from Cochlear's sales figures to suggest that OSIA accounted for **[✂]**% of Cochlear's new BCS implant sales in NHS Year April 2021 to March 2022, **[✂]** from **[✂]** the year before.
[153] See, for example, Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 20; Annex CH0000049 to the FMN - **[✂]**- 2nd December 2020, slide 10.
[154] See Annex DMT-V1-0002380 to the FMN - **[✂]**.
[155] Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 20.
[156] Response to the CMA's request for information dated 18 July 2022 (**RFI2 response**), Part 1, page 10.
[157] Annex DMT-V1-0000056 to the FMN - **[✂]** - September 2020.
[158] Annex 110 to the FMN – **[✂]** – August 2020, slide 8.
[159] Annex 098 to the FMN – **[✂]** – 12 November 2021, slide 10 and Annex 108 to the FMN - **[✂]** - October 2021.
[160] Annex 151 to the FMN - **[✂]**, slide 12.

customer relationships and resources from its activities in passive BCS, to be able to strongly compete in active BCS.

Third-party evidence

115. Nearly all customers that responded to the CMA's market testing stated that the Parties closely compete with one another and commented that in passive BCS the Parties are currently the only two providers.[161]

116. Nearly all customers indicated that while there is likely to be a shift to active BCS in the future, there will still be a clinical role for passive BCS.[162] Third parties indicated that passive BCS and active BCS broadly serve the same clinical requirements, though active BCS may not be prescribed in some circumstances given that active BCS are generally more expensive and require a patient to tolerate general anaesthetic instead of a local anaesthetic.[163]

117. Nearly all third parties, including clinics, indicated that the Parties compete particularly closely in relation to passive BCS, and also highlighted concerns about the impact of the Merger in BCS.[164]

Conclusion on closeness of competition

118. The CMA considers that the Parties are very close competitors in the supply of BCS in a highly concentrated market. They are two of only three providers participating across passive, active and non-surgical BCS. This is supported by share of supply data that shows the Merged Entity will become the near-monopoly provider, internal documents and third-party evidence.

119. The CMA considers that there is consistent evidence to suggest a need will remain for passive BCS for the foreseeable future. The Parties offer the only solutions available to patients requiring this product. Further, the CMA considers that both passive and active BCS products broadly serve the same clinical requirement. While there may be some instances where one product is more suitable for a patient than the other, the CMA considers that going forward, there will likely be a material proportion of patients for which both passive and active BCS products are alternatives.

120. To the extent that there is a shift towards active BCS, evidence suggests that Oticon Medical expected to introduce its Sentio active BCS in the UK as a direct competitor to Cochlear's Osia active BCS product in the near future. Even if the launch of Oticon Medical's Sentio device was uncertain, the CMA considers that there is strong evidence to suggest that the threat of Oticon Medical's entry imposed a

[161] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[162] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[163] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[164] Notes of calls with third parties.

constraint on Cochlear. The CMA considers this provides further evidence that the Parties are close competitors by way of innovation in the supply of BCS.

Competitive constraints

The Parties' submissions

121. The Parties submitted that Med-El is a strong established competitor that will continue to innovate and constrain the Merged Entity.[165] The Parties submitted that Med-El is, and will continue to be, **[✂]** and Cochlear's **[✂]** competitor in active BCS products and therefore in BCS products overall moving forward.[166] The Parties also submitted that Med-El has a spectrum of acoustic therapies to treat many types and degrees of hearing loss, from non-surgical BCS solutions with its ADHEAR system to its middle ear implants.[167]

Internal documents

122. CMA analysis of the Parties' internal documents indicates that, while Med-El's active BCS, non-surgical BCS and overall activity are monitored **[✂]**, on both a global and UK level,[168] the documents also indicate that the Parties consider each other as **[✂]** drivers of their competitive strategies in relation to BCS.[169] For example, one Oticon Medical internal document refers to Med-El's activities being a 'side business to CI'.[170]

123. Further, the CMA has also considered the nature of and extent to which the Parties monitor Med-El's active BCS product. The CMA's analysis of Oticon Medical's internal documents indicates that its drive to create an active BCS product was to compete **[✂]** and to a more limited extent **[✂]**.[171] The CMA's analysis of one Cochlear internal document indicates that when comparing the specifications of the different active BCS products, **[✂]** was perceived to have more relative weaknesses than **[✂]**, as compared to **[✂]**.[172]

Third-party evidence

124. CMA analysis of third-party evidence indicates that Med-El is generally considered to be a weak constraint, given its focus on active BCS and its lack of a passive

[165] FMN, paragraph 226.
[166] Issues letter response, paragraph 5.12.
[167] Issues letter response, paragraph 5.15.
[168] See, for example, Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 11; Annex 082 to the FMN – **[✂]** – February 2022, page 3.
[169] Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 47; Annex 082 to the FMN – **[✂]** – February 2022.pdf, page 3.
[170] Annex DMT-V1-0002380 to the FMN - **[✂]**, slide 47.
[171] See, for example, Annex DMT-V1-0000056 to the FMN - **[✂]** - September 2020.
[172] Annex 108 to the FMN - **[✂]** - October 2021.

BCS.[173] The evidence reviewed by the CMA has not identified other third parties that would be likely to enter BCS in the UK in the foreseeable future.

Conclusion on alternative constraints

125. The CMA does not believe that the evidence indicates that Med-El would impose a strong competitive constraint on the Merged Entity in the foreseeable future.

126. The CMA considers that Med-El's share of supply is very low. The CMA has received limited evidence to suggest that the constraint that Med-El imposes on the Parties is greater than its low share suggests. Further, it does not offer passive BCS, where the bulk of current sales lie, and the evidence indicates that Med-El's active BCS is not as directly comparable to that of the Parties' current and pipeline products. As such, this evidence overall indicates that its share is likely to be a true reflection of the constraint it imposes on the Parties.

127. Notwithstanding this, even if Med-El were to compete strongly against the Merged Entity (for example, if its active BCS device were to get significantly more traction in the marketplace), the CMA does not consider that a single competitor remaining post-Merger would impose sufficient constraint on the Merged Entity to mitigate the CMA's competition concerns.

128. The CMA has not identified any other material competitive constraints on the Merged Entity, nor any potential entrants likely to enter post-Merger, noting that barriers to entry and expansion in BCS appear to be very high (see from paragraph 172).

Conclusion on horizontal unilateral effects in the supply of BCS in the UK

129. Based on the above, the CMA believes that there is a realistic prospect that the Merger may result a significant lessening of competition in relation to the supply of BCS in the UK, given that it would eliminate the strongest competitor and create a near monopoly supplier in the UK.

130. The CMA considers that while there may be some shift toward active BCS, this shift is not sufficient to mitigate the significant competition concerns. The Parties are currently the only two providers of passive BCS in the UK and the evidence suggests demand will remain for passive BCS within the timeframe of the CMA's assessment. Further, the CMA considers that both passive and active BCS products broadly serve the same clinical requirement.

131. Moreover, the CMA considers there is strong evidence to suggest the Parties could be strong competitors in active BCS in the future. The CMA considers that Oticon Medical's efforts to innovate and launch an active BCS product already provide

[173] Third party responses to the CMA's questionnaire.

Cochlear with a strong incentive to innovate to defend against this threat. The CMA also considers that the Merger would lead to reduced incentives for Cochlear to continue innovating and developing in BCS.

132. The CMA therefore considers that, subject to countervailing factors such as entry or countervailing buyer power, the Merger gives rise to a realistic prospect of an SLC in horizontal unilateral effects in the supply of BCS in the UK. The CMA is concerned that as a result of the Merger, prices to the NHS would increase, and/or service levels and other terms would worsen (relative to the situation without the Merger) and/or innovation would be reduced.

Horizontal unilateral effects in the supply of CI in the UK

133. In order to assess the likelihood of the Merger resulting in horizontal unilateral effects in the supply of CI in the UK, the CMA has considered:

    (a) Shares of supply;

    (b) Closeness of competition; and

    (c) Other competitive constraints.

Shares of supply

The Parties' submissions

134. The Parties used the data published by the British Cochlear Implant Group (**BCIG**) to estimate the total number of new CIs sold in the NHS year 2020 (April 2020 to March 2021).[174] The Parties then combined this data with the Parties' own sales volumes, along with Cochlear's estimate of the sales volumes for the other two suppliers, Med-El and Advanced Bionics.[175]

135. The shares are based on the number of new CIs sold to clinics by each supplier. The Parties submitted that CIs are only compatible with the sound processor of the supplier of the implant, so once a patient receives a given implant, it must purchase all upgrades and sound processors from the supplier of the implant.[176] As such, the Parties submitted that an assessment of shares of supply based on the supply of new CI systems is accurate in capturing the dynamics of competition.[177]

[174] The Parties submitted that the BCIG publishes the number of new implants for unilateral recipients, bilateral simultaneous recipients, and bilateral sequential recipients, separately for adults and children. One patient that is a bilateral simultaneous recipient would require two implants. Thus, the Parties calculated the market size by summing up the number of unilateral and bilateral sequential recipients (both adults and children, and twice the total amount of bilateral simultaneous recipients.
[175] FMN, paragraph 211.
[176] FMN, paragraph 211.
[177] FMN, paragraph 211.

Table 2: Parties' estimates of shares of supply for cochlear implants in the UK, for NHS Year 2020 (April 2020 to March 2021)

Company	Volume for new implant systems, NHS Year 2020	Share (%)
Cochlear	[✂]	[70-80]
Oticon Medical	[✂]	[0-5]
Combined	[✂]	**[70-80]**
Advanced Bionics (Sonova)	[✂]	[10-20]
Med-El	[✂]	[0-10]
Total	[✂]	100

Source: FMN, Table 14.A.

136. The Parties submitted this data significantly overstates the strength of Oticon Medical, because the shares of supply data for Oticon Medical reflect the period before the recall in October 2021.[178] The Parties submitted that for the most recent NHS year to date, Oticon Medical's sales of new CIs in the UK are **[✂]** and sales are not expected to increase significantly for the foreseeable future.[179]

CMA analysis

137. The CMA received evidence from third parties that confirmed that the Parties' share of supply estimates are broadly accurate.[180] The CMA has considered whether the current shares of supply reflect the competitive dynamics in the supply of CI.

138. Consistent with the shares of supply, the CMA understands that Cochlear has an established position as the largest provider of CIs in the UK by far, with a strong and stable installed base of patients, which has resulted in Cochlear accounting for [70-80]% of the total number of CI systems installed over the past five years.[181]

139. The share of supply data is also consistent with some Cochlear internal documents which suggest that Cochlear recognises its strong position at a global level.[182] Further, a number of third parties indicated that Cochlear has a strong position in the supply of CIs in the UK. [183]

140. In relation to Oticon Medical's position, the CMA has considered whether its share of supply of [0-5]% in 2020 (pre-recall) is representative of the true constraint that

[178] FMN, paragraph 210.
[179] FMN, paragraph 210.
[180] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[181] Annex 179 to the FMN.
[182] Annex 078 to the FMN **[✂]** - March 2022, slide 3, 18 and 30.
[183] Third party responses to the CMA's questionnaire; Notes of calls with third parties.

Oticon Medical has on Cochlear currently and in the future. In this regard, the CMA has considered the extent to which Oticon Medical imposes a competitive constraint on Cochlear, and whether that constraint could be greater than is suggested by its small market share. The CMA has considered Oticon Medical's position both before and after the recall of its Neuro Zti CI product.

Closeness of competition

141. As set out in the CMA's Merger Assessment Guidelines, in differentiated markets, horizontal unilateral effects are more likely where the merger firms are close competitors or where their products are close substitutes.[184] Where there is a degree of differentiation between the merger firms' products, they may nevertheless still be close competitors if there are few rivals.[185]

142. The CMA notes that the supply of CI is limited to only four providers and considers the market to be concentrated. It has therefore paid particular attention to the effect of a rival being removed from the market, despite its currently low share of supply. In doing so, the CMA has considered how competition takes place and whether Oticon Medical imposed a constraint on Cochlear that was greater than its share would suggest and whether it had scope to grow.[186]

143. The CMA considers that evidence from internal documents and a number of clinics indicates that an important parameter of competition is through providers innovating, which incentivises other providers to improve or add new features and/or capabilities to their products. [187] There is also evidence of some price competition at the clinic level, although price appears to be a less important factor for clinics in comparison to the reliability and functionality of the devices.[188] The CMA has considered the evidence on these, and whether Oticon Medical's share of supply is actually a good indicator of its strength as a competitor currently and in the future.

144. The CMA has also considered how the recall of the Neuro Zti CI product has affected Oticon Medical's ability to compete and innovate. Oticon Medical launched its CI product in the UK recently in 2018. Oticon Medical discovered an issue with its Neuro Zti CI product, leading to a voluntary recall in October 2021.[189] The CMA has

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[184] CMA129, paragraph 4.8.
[185] CMA129, paragraph 4.10.
[186] For example, where products are more differentiated or customer preferences are more diverse, shares of supply may not provide evidence on the closest alternatives available to the merger firms' customers, as these may be different from the products that achieve the greatest sales across a wider body of customers. CMA129, paragraph 4.15.
[187] Third party responses to the CMA's questionnaire; Notes of calls with third parties; Annex 101 to the FMN - **[✂]**, slide 28 onwards; Annex COH0000056 to the FMN, **[✂]** - October 2021, slide 11.
[188] Third party responses to the CMA's questionnaire.
[189] After addressing the issue, Oticon Medical subsequently relaunched the product in the EEA in July 2022 but has no set relaunch date in the UK. Response to the CMA's request for information dated 5 September 2022, page 1. The Parties also confirmed that there is no regulatory barrier to Oticon Medical selling its CI product in the UK going forward. Response to the CMA's request for information dated 12 October 2022, pages 3-4.

assessed the extent to which the recall has impacted the constraint that Oticon Medical may exert on Cochlear in the future.

Parties' submissions

145. The Parties submitted that Oticon Medical's CI products are of **[✂]** quality and **[✂]** in range compared to Cochlear and other CI manufacturers.[190] As such, the Parties submitted that Oticon Medical was and will continue to remain a weak supplier in the supply of CI in the UK.[191] Further, the Parties submitted that Oticon Medical was **[✂]** in CI innovations and product development, such that it was a weak supplier pre-recall and will continue to remain a weak competitor going forward.[192]

146. The Parties submitted that the recall of any supplier's hearing implant product is likely to have an impact on brand perception and would raise concerns among healthcare professionals regarding Oticon Medical's product quality, in relation to its CI products.[193] The Parties submitted that the degree of the impact and recovery from the recall can be influenced by how the relevant manufacturer handles the recall, the execution of any corrective actions and the transparency of communications.[194] Finally, the Parties submitted that while the market feedback and internal documents seem to have indicated that Demant responded professionally and transparently to the recall, it does not change the key point that Demant had already decided to exit by the time the recall was lifted and does nothing to improve the economic outlook for the business.[195]

Internal documents

147. The internal documentary evidence indicates that the Parties monitor each other and that Cochlear considers Oticon Medical to be one of its competitors in the supply of CI. However, the internal documents overall indicate an asymmetric constraint; showing that Oticon Medical was largely attempting to compete on price;[196] and present limited evidence of Oticon Medical being an innovator that would be able to grow its share in the market to any meaningful extent to threaten and compete with Cochlear.

148. Oticon Medical's competitive monitoring documents indicate that Cochlear is the market leader for CI products globally, and Oticon Medical **[✂]** product benchmarks its CI products in relation to Cochlear.[197] In addition, Oticon Medical CI business

[190] FMN, paragraph 219.
[191] FMN, paragraph 37.
[192] FMN, paragraph 42(a).
[193] RFI2 response, Part 1, page 9.
[194] RFI2 response, Part 1, page 10.
[195] Issues letter response, paragraph 4.7.
[196] Annex 101 to the FMN - **[✂]**, slide 28 onwards; Annex COH0000056 to the FMN - **[✂]** - October 2021, slide 11.
[197] See, for example, Annex DMT-V2-0026761 to the FMN, **[✂]** – 14 April 2022, slide 10; Annex DMT-V1-0001250 to the FMN - **[✂]** – 19 February 2021, slide 3; Annex 114 to the FMN, **[✂]** - 21 September 2020, slide 55.

plan documents tend to **[✂]** monitor and assess Cochlear's business performance to set the context of its own CI business strategy.[198] Further, one internal document notes that Oticon Medical CI has invested **[✂]** in R&D and branding, while the main competitor is setting a very high pace in product innovation.[199]

149. The Parties submitted that in a segment with few players it is entirely normal for Cochlear to monitor Oticon Medical and vice versa, and that this does not change the fact that Oticon Medical imposes an insignificant constraint on Cochlear, whose closest competitors are Advanced Bionics and Med-El.[200] The CMA's assessment of Cochlear's internal documents evidence that Oticon Medical is considered as one of its competitors in competitive benchmarking and monitoring documents, particularly when directly comparing the strengths and weaknesses of product capabilities and monitoring potential future product developments at the EMEA level.

150. While Cochlear's documents discuss Oticon Medical's attempts to compete on price, the CMA notes that price appears to be a less important parameter of competition (as noted in paragraph 143 above) and there is limited third-party evidence to suggest that there will be a loss of price competition between the Parties. The CMA notes that Oticon Medical's attempt to compete on price has not resulted in Oticon Medical gaining a material share of supply. Further, the documents also show that Cochlear considered Oticon Medical to be behind (and therefore a weaker competitor) in terms of technology, in particular relating to MRI compatibility (which is important for patients who need to undergo MRI scans).[201] The documents also show that Cochlear views Oticon Medical as a weaker competitor based on other aspects of the devices (such as ceramic case technology and electrode design).[202]

151. In relation to the recall, the CMA's assessment of the Parties' internal documents indicates that while Oticon Medical's Neuro Zti recall was handled well, it may have been a setback in the growth prospects of its CI business.

152. Oticon Medical's internal documents are indicative of both a reasonable plan to recover from the recall and also the nature of the recall being limited to the manufacturing process as opposed to the fundamental design of the Neuro Zti.[203] The CMA also recognises that Oticon Medical's CI products are available for purchase in the EEA, which the CMA understands are primarily being purchased for

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[198] See, for example, Annex DMT-V1-0001250 to the FMN - **[✂]** – 19 February 2022, slide 3.
[199] Annex 114 to the FMN - **[✂]** - 21 September 2020, slide 55.
[200] Issues letter response, paragraph 4.4.
[201] Annex COH0000056 to the FMN - **[✂]** - October 2021, slide 11.
[202] Annex COH0000020 to the FMN - **[✂]** – 9 July 2021, slide 10.
[203] Annex DMT-V1-0018700 to the FMN - **[✂]** – 28 February 2022, page 2. See, for example, Annex DMT-V1-0018700 to the FMN - **[✂]** – 28 February 2022; Annex DMT-V1-0018974 to the FMN - **[✂]** – March 2022; Annex DMT-V1-0013066 to the FMN - **[✂]** – December 2021.

upgrades or special cases,[204] suggesting that it could relatively easily reintroduce this product in the UK, should Oticon Medical choose to do so.

153. However, the CMA considers that there is some evidence from Demant's internal documents indicating that the CI business was at an early stage of being established in the UK prior to the recall, and that the recall may have setback its development and potential growth even further. For example:

    (a) A February 2021 Demant board document discussed the CI business in particular, and that there was a long way to go until **[✂]**. The board concluded that Oticon Medical was '**[✂]**', and that **[✂]** was taking a lot longer than first assumed, and that the forward plan seemed optimistic.[205]

    (b) Following the recall, a November 2021 Demant business review meeting document identified that the product recall would result in estimated **[✂]** to Oticon Medical.[206] The CMA understands that the CI business made a **[✂]** loss in 2021 amounting to approximately £**[✂]**.[207]

154. Demant also told the CMA that in August 2021, some of its newer board members expressed concern about the **[✂]** of the hearing implants business, especially the CI business, and that in October 2021, its board considered the recall would set years of hard work even further back.[208]

155. Overall, the CMA considers that the internal document evidence indicates the Parties view each other as competitors in the supply of CI products. However, Cochlear's documents in particular indicate that Cochlear views Oticon Medical as a relatively weak competitor.

Third-party evidence

156. In relation to *closeness of competition*, third-party evidence was mixed. Regarding Oticon Medical's product capabilities, the evidence in the round indicates that Oticon Medical's CI does not offer capabilities that other existing alternatives do not currently provide.[209]

157. Some third-party feedback suggested that Oticon Medical's product was technologically advanced, in particular in addressing (relatively rare) facial nerve stimulation issues.[210] The CMA, however, has received limited evidence from customers or competitors to suggest that Oticon Medical is a particularly innovative

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[204] **[✂]** 28-29 June 2022, page 10.
[205] Annex 113 to the FMN, page 5.
[206] Annex 118 to the FMN – **[✂]** – 29 November 2021, slide 3.
[207] DMN, paragraph 9(a).
[208] Issues letter response, Annex A, pages 2 and 3.
[209] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[210] Notes of calls with third parties.

supplier, or that its innovation efforts were likely to drive material innovation in the market in future.

158. The CMA also recognises that a number of clinics expressed concerns about the CI market, however these were focussed on Cochlear's strong position in the UK, as opposed to the loss of Oticon Medical as a constraint.[211] Some third parties considered that the Merger would have limited impact on CI, given Oticon Medical's small presence in the UK.[212] In addition, as discussed further below, the CMA found that other suppliers are closer competitors to the Parties than the Parties are to each other.

159. Evidence from nearly all customers indicated that the recall would not have prevented Oticon Medical being considered as an alternative supplier of CI going forward, noting that recalls are well-recognised occurrences in the CI market.[213] Most customers that responded to the CMA's questionnaire noted that Oticon Medical handled the recall particularly well, given its early and transparent communication.[214] One third-party did note that recalls can damage a supplier's reputation, particularly given Oticon Medical had recently entered the CI market in the UK.[215]

Conclusion on closeness of competition

160. The CMA considers that, while Cochlear has a very significant presence as a supplier of CI, the evidence indicates that Oticon Medical imposed only a weak constraint on Cochlear, and was not likely to impose a more significant constraint in future. The internal document and third-party evidence are supportive of the competitive landscape presented by the shares of supply and suggest that in a market where gains are made by innovating, Oticon Medical was not providing a strong constraint through innovation and had limited prospects in gaining meaningful share in the future. The CMA also considers the evidence overall indicates, across other parameters such as product functionality and price, that Oticon Medical was not providing a strong constraint on Cochlear. The CMA further considers that while the recall did not damage Oticon Medical's reputation irreversibly, as Oticon Medical's CI business was in the early stages of being established in the UK, the recall likely setback its future growth prospects and development as a less established competitor further. The evidence discussed above also indicates that Cochlear imposes a strong constraint on Oticon Medical.

[211] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[212] Third party responses to the CMA's questionnaire; Notes of calls with third parties.
[213] Third party responses to the CMA's questionnaire.
[214] Third party responses to the CMA's questionnaire.
[215] Note of a call with a third party.

Competitive constraints

161. The CMA has considered whether sufficient competitive constraints would exist post-Merger to prevent competition concerns arising as a result of the Merger.

Parties' submissions

162. The Parties submitted that Sonova, through Advanced Bionics, is an established and leading competitor for the supply of CIs in the UK. The Parties further submitted that Advanced Bionics (Sonova) is a **[✂]** bimodal solutions, introducing an MRI compatible CI shortly after Med-El and ahead of Cochlear in 2019, and introducing a dedicated sound processor for children in 2020.[216] As such, the Parties submitted that Advanced Bionics would continue to constrain the Merged Entity.[217]

163. The Parties submitted that Med-El is also an established and leading CI provider in the UK. The Parties consider that **[✂]**, particularly as Med-El was the first to introduce an MRI compatible CI, but also because it offers the widest range of electrode arrays in the market that **[✂]**.[218] As such, the Parties submitted that Med-El will also continue to constrain the Merged Entity.[219]

Internal documents

164. The internal documents indicate that Advanced Bionics (Sonova) and Med-El are considered as competitors by both Parties and seen by Cochlear to be more established than Oticon Medical.

165. Both Advanced Bionics (Sonova) and Med-El feature alongside Oticon Medical and Cochlear as the three main competitors in the Parties' competitive product benchmarking documents at a global level. However, both appear more frequently than Oticon Medical in Cochlear internal documents.[220] In these documents, the Parties closely monitor product developments of all existing participants in the CI market, where the strengths of the two competitors' offerings are that **[✂]**. Further, an internal Cochlear document also notes that **[✂]**.[221]

Third-party evidence

166. Third-party evidence indicates that Cochlear has a strong position in the market and therefore the overall constraints that Cochlear faces in the market are weak.[222]

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[216] FMN, paragraph 42.
[217] FMN, paragraph 226.
[218] FMN, paragraph 42.
[219] FMN, paragraph 226.
[220] See, for example, Annex DMT-V1-0000056 to the FMN - **[✂]**- September 2020, slide 32; Annex DMT-V2-0026761 to the FMN - **[✂]**, slide 10; Annex COH0000002 to the FMN - **[✂]** - November 2021; Annex COH0000020 to the FMN - **[✂]**, slide 9.
[221] Annex COH0000003 to the FMN - **[✂]**. The CMA notes that in the same document, Demant is also described as having strengths in its hearing aid technology.
[222] Third party responses to the CMA's questionnaire; Notes of calls with third parties.

Some third-party evidence shows that both Med-El and Advanced Bionics (Sonova) CI solutions impose a reasonable constraint on Cochlear.[223] The majority of clinics indicated that they rank either Advanced Bionics (Sonova) or Med-El's CI products as stronger alternatives to Cochlear's CI product than Oticon Medical's.[224]

Conclusion on competitive constraints

167. For the reasons described above, the CMA believes that Oticon Medical is a weak constraint, and that these remaining firms offer a greater constraint on Cochlear, in comparison to Oticon Medical.

Conclusion on horizontal unilateral effects in the supply of CI in the UK

168. Based on the above, the CMA believes that the Merger does not result in a realistic prospect of significant competition concerns in relation to the supply of CI in the UK. The CMA may generally be more likely to find an SLC where the merger involves the market leader, and the number of competitors is reduced from four to three.[225] However, in this instance, the CMA considers that Oticon's strength as a competitor both currently and going forward is weak and reflected in its [0-5]% share of supply pre-recall.

169. In particular, there is evidence to suggest that while Cochlear was monitoring Oticon Medical's product developments, Cochlear also perceived Oticon Medical as a far weaker constraint relative to other existing providers.

170. Further, taking into account Oticon Medical's recent recall of its CI product, the CMA believes that while Oticon Medical's reputation has not been irreversibly damaged by the recall, absent the Merger, its CI business development and potential growth prospects have likely been setback.

171. The CMA believes that, in the round, evidence across shares of supply, third-party evidence and internal documents consistently show both Advanced Bionics (Sonova) and Med-El being more established than Oticon Medical. Given Cochlear's strong position in the CI market, the CMA has viewed the strength of these competitors in the context of Cochlear's strong position and the loss of Oticon Medical as a competitive constraint. For the reasons described above, the CMA considers that Oticon Medical is a weak constraint, and that these remaining firms offer a greater constraint on Cochlear in comparison to Oticon Medical.

[223] Third party responses to the CMA's questionnaire.
[224] Third party responses to the CMA's questionnaire.
[225] CMA129, paragraph 2.18(a).

ENTRY AND EXPANSION

172. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[226] In terms of timeliness, the CMA's guidelines indicate that the CMA will look for entry to occur within two years.[227]

173. The Parties submitted that barriers to entry for CI primarily involve developing the required technology, which requires a substantial investment and a long return period (10-15 years) and non-trivial regulatory requirements, considering that CIs are a Class III device.[228] The Parties submitted that the technology for passive BCS is relatively simple and often less highly regulated in comparison to CI.[229] However, across CI and BCS, the Parties submitted that barriers can be overcome by hearing aid providers partnering up with a company with the relevant implant technology.[230]

174. Evidence from the CMA's market testing, the Parties' submissions and the CMA's assessment of internal documents, indicates that barriers to entry and expansion are high in both CI and BCS, given the regulatory requirements that need to be met to enter,[231] high cost of developing required technologies to compete and high concentration in both markets.

175. The CMA found that both Parties' internal documents comment on high barriers to entry. One Cochlear internal document states that it considers that **[✂]**.[232] The document notes Cochlear's competitors, including both Advanced Bionics (Sonova) and Med-El, **[✂]**.[233] Demant internal documents also reference the importance of scale and the difficulty of succeeding in CI and BCS, with one board document noting it is a difficult business and making **[✂]** is taking longer than expected.[234]

176. For the reasons set out above, the CMA considers that barriers to entry and expansion for the supply of both BCS and CI are high. In relation to the supply of CI in the UK, the CMA has considered the existence of high barriers to entry in its competitive assessment above where appropriate as balanced against other factors. In relation to the supply of BCS in the UK, for the reasons stated above, the CMA believes that entry or expansion would not be sufficient, timely or likely to prevent a realistic prospect of an SLC as a result of the Merger.

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[226] CMA129, from paragraph 8.40.
[227] CMA129, paragraph 8.33.
[228] FMN, paragraph 272.
[229] FMN, paragraph 277.
[230] FMN, paragraph 277 and 276.
[231] FMN, paragraph 272 and 276.
[232] Annex 078 to the FMN - **[✂]** - March 2022.
[233] Annex 078 to the FMN - **[✂]** - March 2022, slide 3.
[234] Annex 113 to the FMN - **[✂]**, slide 5.

COUNTERVAILING BUYER POWER

177. The Parties have submitted that companies active in the supply of hearing implants are effectively beholden to the NHS (since the NHS accounts for the acquisition of almost all BCS in the UK) and significantly constrained in relation to maintaining low prices, high product quality, and the need to innovate.[235]

178. The Parties submitted that any attempt to increase prices without a corresponding increase in quality would be rejected by central bodies, which would likely then switch to the other alternatives available, including hearing aids and super powered hearing aids.[236] The Parties submitted that for BCS products, these are procured under the NHS national supply system, via a professional procurement team for high-cost tariff-excluded devices, meaning that pricing is determined centrally by the NHS procurement bodies.[237]

179. The CMA does not consider that buyer power would be sufficient to mitigate an SLC in BCS, given there will be a lack of an effective alternative supplier available to the NHS and/or clinics post-Merger.[238] That is, the CMA does not consider that in the event of degradation of either price, quality or service, the NHS would be able to procure hearing aids or other forms of hearing solutions as effective substitutes for BCS.

180. Further, the CMA has not seen any evidence or examples of the NHS negotiating against any price increases with regards to BCS. The CMA also considers that even if prices are fixed for the duration of the agreement with NHS supply chain, agreements are renegotiated over time, at which point prices may be changed. The CMA considers that the structural change that the Merger brings about is permanent, such that there may be attempts by the Merged Entity to increase prices when the framework agreements expire over time.

CONCLUSION ON SUBSTANTIAL LESSENING OF COMPETITION

181. Based on the evidence set out above, the CMA believes that it is or may be the case that the Merger may be expected to result in an SLC as a result of horizontal unilateral effects in relation to the supply of BCS in the UK.

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[235] Issues letter response, paragraph 1.3.
[236] Issues letter response, paragraph 6.4.
[237] Issues letter response, paragraph 6.4.
[238] CMA129, paragraph 4.20.

DECISION

182. Consequently, the CMA believes that it is or may be the case that (i) arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and (ii) the creation of that situation may be expected to result in an SLC within a market or markets in the United Kingdom.

183. The CMA therefore believes that it is under a duty to refer under section 33(1) of the Act. However, the duty to refer is not exercised while the CMA is considering whether to accept undertakings under section 73 of the Act instead of making such a reference.[239] The Parties have until 13 December 2022[240] to offer an undertaking to the CMA.[241] The CMA will refer the Merger for a phase 2 investigation[242] if the Parties do not offer an undertaking by this date; if the Parties indicate before this date that they do not wish to offer an undertaking; or if the CMA decides[243] by 20 December 2022 that there are no reasonable grounds for believing that it might accept the undertaking offered by the Parties, or a modified version of it.

Sorcha O'Carroll
Senior Director, Mergers
Competition and Markets Authority
6 December 2022

[239] Section 33(3)(b) of the Act.
[240] Section 73A(1) of the Act.
[241] Section 73(2) of the Act.
[242] Sections 33(1) and 34ZA(2) of the Act.
[243] Section 73A(2) of the Act.