EUROPEAN COMMISSION

Brussels, 9.10.2023
C(2023) 6858 final

PUBLIC VERSION

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

Cochlear Limited
1 University Avenue
Macquarie University
2109 New South Wales
Australia

Subject: **Case M.10966 – COCHLEAR / OTICON MEDICAL**
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]

Dear Sir or Madam,

(1) On 4 September 2023, the European Commission received notification of a proposed concentration pursuant to Article 4 of the Merger Regulation by which Cochlear Limited ("Cochlear" or the "Notifying Party", Australia) will acquire within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of the cochlear implant business of Oticon Medical ("Oticon CI" or the "Target", Denmark) (the "Transaction").[3] Cochlear and Oticon CI are designated hereinafter as the "Parties" or post-Transaction as the "Merged Entity".

[1] OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ('TFEU') has introduced certain changes, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this decision.
[2] OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').
[3] Publication in the Official Journal of the European Union No C 323, 13.9.2023, p. 16.

1. THE PARTIES AND THE OPERATION

(2) **Cochlear** is an Australian publicly listed company and the parent company of the Cochlear Group. Cochlear supplies a range of implantable hearing solutions, including cochlear implants ("CIs") and related sound processors. Cochlear operates globally and has local affiliates in several EEA countries.

(3) **Oticon CI** develops, manufactures, and sells CIs and related sound processors. Oticon CI operates globally and has production sites in France and Poland. Oticon CI is part of Oticon Medical, the hearing implants business division of the Danish group Demant.

(4) Pursuant to the Asset and Share Purchase Agreement ("ASPA") entered into by Cochlear and Demant on 25 May 2022, and in particular its Clause 15.4.1,[4] Cochlear will acquire sole control over Oticon CI. Therefore, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

2. JURISDICTION

(5) On 25 May 2022, the Cochlear and Demant entered into the ASPA, which initially anticipated a transaction structure through which Cochlear would acquire the entirety of Oticon Medical including its two business divisions: CIs and bone conduction solutions ("BCS") (the "Initial Transaction").

(6) The Initial Transaction did not have a Union dimension within the meaning of Article 1 of the Merger Regulation as the Parties' turnover does not meet the thresholds of Article 1(2) or 1(3) of the Merger Regulation.[5]

(7) The Initial Transaction was notifiable to the Spanish National Markets and Competition Commission ("Spanish NCA").[6] On 27 October 2022, the Commission received a referral request from the Spanish NCA pursuant to Article 22(1) of the Merger Regulation. The national competition authorities of Bulgaria, Denmark, Finland, France, Ireland, Italy, Lithuania, the Netherlands, Norway, Poland, Portugal and Sweden (together with Spain, the "Affected Jurisdictions") subsequently joined the request made by the Spanish NCA. On 6 December 2022, the Commission accepted the request and therefore acquired jurisdiction to examine the Transaction pursuant to Article 22(3) of the Merger Regulation.[7]

(8) Following the partial prohibition of the Initial Transaction by the UK's Competition and Markets Authority ("CMA"),[8] which raised competition concerns with regard to Cochlear's acquisition of Oticon's BCS business on 22 June 2023,[9]

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4 In particular, Clause 15.4.1 of the ASPA, invoked on 22 June 2023. For further details, see paragraph 8.

5 For the avoidance of doubt, the Transaction in its current form also does not have a Union dimension.

6 The Initial Transaction was notified to the Spanish NCA on 19 October 2022 on the basis it met the applicable thresholds under Spanish competition rules.

7 Please see the Commission's press release at: Daily News 7 / 12 / 2022 (europa.eu).

8 The Initial Transaction is also subject to review by the Australian competition authority. At the time of the adoption of this Decision, this review is still on-going.

9 Please see for more details on the CMA's website: https://www.gov.uk/cma-cases/cochlear-slash-oticon-merger-inquiry. The Parties have given final undertakings to the CMA on amongst others a monitoring trustee overseeing the proposed separation of the CI and BCS business of Oticon which

Cochlear and Demant on 22 June 2023 modified the Initial Transaction by invoking Clause 15.4.1 of the ASPA. That clause foresees that if any competition authority does not approve the transfer of Oticon Medical in its entirety, then the parties to the ASPA agree to pursue the transaction in a revised form whereby Cochlear shall accept a sale of Oticon Medical's CI business only and Oticon Medical's BCS business shall remain with Demant and be excluded from the transaction. As a consequence, pursuant to the notified transaction, Cochlear will acquire only the CI business division of Oticon while Oticon Medical's BCS business will remain with Demant (the "Transaction", as also defined above in paragraph 1).

(9) Nevertheless, the Transaction is still implemented pursuant to the original ASPA governing the Initial Transaction, which included the Clause 15.4.1 providing for the carve-out and sale of only the CI business as an alternative transaction in case of regulatory opposition to the Initial Transaction. The modification of the Initial Transaction, therefore, does not amount to a complete abandonment of that transaction, but only to a partial amendment thereof. Since the Commission's jurisdiction was properly established prior to any amendment of the Initial Transaction based on the Article 22 referral (see paragraph 7 above) and given that the Parties did not abandon that transaction, the Commission retains jurisdiction to review the (amended) Transaction.

(10) Furthermore, as Clause 15.4.1 of the ASPA was invoked prior to the notification of the Transaction to the Commission on 4 September 2023, the Commission's competitive assessment is limited to the Transaction as notified irrespective of the fact that the Initial Transaction would have led to an additional overlap in BCS.

(11) Therefore, the Commission's assessment will focus on Cochlear's acquisition of Oticon's CI business.

3. MARKET DEFINITION

3.1. Introduction

(12) As explained in paragraphs (5)-(9) above, the Transaction concerns the sector of hearing solutions and in particular CIs.

(13) The type and degree of hearing loss of a patient will impact the diagnosis and range of potential treatments available.

(14) Types of hearing loss include: (i) sensorineural hearing loss, where the inner ear (cochlea) or the hearing nerve is damaged or does not work properly, generally making it more difficult to hear quiet sounds and/or reducing the quality of sound that can be heard (which can be sub-categorised to high-frequency hearing loss and single-sided deafness); (ii) conductive hearing loss, where the outer ear or middle ear blocks or restricts sound vibrations from reaching the inner ear (cochlea), generally causing sounds to feel plugged or muffled; and (iii) mixed hearing loss, a combination of conductive and sensorineural hearing loss, where there is damage in both the outer or middle ear and the inner ear.

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have been accepted by the CMA. Please see the CMA's website: https://www.gov.uk/cma-cases/cochlear-slash-oticon-merger-inquiry#final-undertakings.

(15) When it comes to the degree of hearing loss, there is no uniformly used categorisation, although the World Health Organisation ("WHO") has categorised the degree of hearing loss into certain grades that range from normal hearing (hearing thresholds of 20 dB or better in both ears) to complete or total hearing loss/deafness (hearing thresholds of 95 dB or greater).[10]

(16) Once a person has been diagnosed with hearing loss, there are a range of clinical, rehabilitative, and environmental interventions and solutions currently available.[11] Treatment options include: (i) hearing aids: medical devices designed to improve a patient's ability to hear by amplifying and delivering acoustic signals to the ear; (ii) assistive listening devices: a range of listening devices that boost hearing in everyday situations and are often wireless communication systems generally consisting of a radio transmitter/microphone used to bring distant sound signals directly into the wearer's ear and to eliminate background noise; (iii) implantable hearing solutions, such as (a) CIs; (b) BCS; (c) middle ear implants ("MEI"); and (d) auditory brainstem implants ("ABI"); as well as (iv) reconstructive surgery.[12]

(17) Both Parties manufacture and commercialise a variety of CIs.[13] CIs are electronic devices designed to mimic the function of a healthy inner ear (or cochlea) by replacing the function of damaged sensory hair cells to help provide clear sound. Rather than making sound louder (as with most hearing aids), cochlear implants typically bypass the damaged portions of the ear to stimulate the auditory nerve directly. CIs are primarily used for patients with severe to total hearing loss and consist of two components: an external processor and an implanted system.

(18) The Transaction gives rise to a horizontal overlap with regard to the Parties' activities relating to CIs in the Affected Jurisdictions.

3.2. Product Market Definition

3.2.1. The Commission's decisional practice

(19) Whilst the Commission has not previously assessed specifically the relevant market for CIs, in a past case concerning hearing aids, the Commission indicated that hearing aids are distinguished from: (i) CIs and BCS that are surgically implanted to treat hearing impairment; (ii) personal sound amplification products; and (iii) assistive listening devices.[14]

3.2.2. The Notifying Party's view

(20) The Notifying Party submits that when assessing competition in the CI segment, it is important to take into account the competitive pressure from other forms of hearing solutions because: (i) CIs are a small part of a broad range of products that are designed to reduce the impact of hearing loss and there is no uniform approach to possible treatments, and patients with the same clinical profile may be treated

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10 WHO has categorised the degree of hearing loss into certain grades in a World Report on Hearing dated 3 March 2021, available at: https://www.who.int/teams/noncommunicable-diseases/sensory-functions-disability-and-rehabilitation/highlighting-priorities-for-ear-and-hearing-care, page 38.

11 Form CO, paragraph 25.

12 Form CO, paragraph 26.

13 Cochlear: Nucleus Profile Plus, Nucleus Profile, Nucleus CI24RE (implants) and Nucleus 5-8, Nucleus Kanso and Kanso 2 (sound processors). Oticon: Zti MRI ET (implants) and Neuro 2 BTE (sound processor).

14 M.8941 – *EQT/Widex*, paragraph 30.

with a range of options (including hearing aids, CIs, BCS, etc.); (ii) there are multiple, simultaneous constraints upon CI suppliers, in particular from hearing aids, which are used for even the most serious degrees of hearing loss and which remain the default treatment for the overwhelming majority of patients (in fact, patients often receive a hearing aid when the best solution to address their hearing loss may actually be a CI); and (iii) any price increase in CIs would negatively affect the growth of this segment.[15]

(21) The Notifying Party further submits that it would be inappropriate to sub-segment the CIs market by patient type between children and adults as CIs are readily available to adults and children as per labelling, CIs by their very nature come in a variety of shapes and sizes, and all suppliers provide products available to all age groups. It would also be inappropriate to distinguish between implants and processors or accessories because the accessories and services, including digital services, offered as part of any treatment related to CIs are ancillary to such treatment and are purchased either alongside, or as a follow-up to the original treatment.[16]

3.2.3. The Commission's assessment

(22) During pre-notification, the Commission conducted a series of calls with medical experts (key opinion leaders or "KOLs") in the field of CIs as well as with competitors of the Parties and reached out to the national reimbursement authorities in various EEA countries. Following the notification of the Transaction, the Commission conducted a market investigation by communicating questionnaires to competitors and customers (i.e., hospitals) of CIs in the Affected Jurisdictions.

(23) The Commission's investigation indicated that likely there exists a separate market for the manufacturing and supply of CIs, distinct from manufacturing and supply of other hearing implants and solutions. Specifically, the results of the market investigation revealed that CIs are not substitutable with other types of hearing solutions as the majority of both competitors and customers indicated that patients using CIs would not generally be able to use other types of hearing solutions (including hearing aids, other implantable hearing solutions or reconstructive surgery) and achieve audiological results comparable to those achieved with CIs.[17] The Commission's investigation further confirmed that depending on the specific patient needs, clinical characteristics and types of hearing loss, different types of implantable hearing solutions are prescribed.[18]

(24) In addition, the Commission's investigation confirmed the Notifying Party's view that it would be inappropriate to distinguish CIs by patient type, as no competitor supplies adult-only or child-only CIs, most customers do not make separate purchases for adult and child CIs and there is no evidence of any other substantial difference between CIs for adults and children.[19] The Commission's investigation

15 Form CO, paragraph 133.
16 Form CO, paragraph 137.
17 Responses to Question D.A.1 of the Questionnaires to Customers and Question C.A.1 of the Questionnaire to competitors.
18 Minutes of a call with a KOL on 30 January 2023, minutes of a call with a KOL on 9 January 2023, and minutes of a call with a KOL on 27 January 2023.
19 Responses to Questions D.A.2 and D.A.3 of the Questionnaires to Customers and Questions C.A.2 and C.A.3 of the Questionnaire to competitors.

did not reveal any evidence that a distinction between implants based on processors or accessories would be appropriate.[20]

(25) Based on all available evidence, the Commission considers, for the purposes of this decision, that the relevant product market is the market for CIs.

3.3. Geographic Market Definition

3.3.1. The Commission's decisional practice

(26) Whilst the Commission has not previously specifically assessed the relevant geographic market for CIs, in previous cases concerning medical devices, the Commission has considered the geographic scope of the relevant markets as being national in scope.[21]

3.3.2. The Notifying Party's view

(27) The Notifying Party submits that the relevant geographic market for CIs is national because: (i) the specific indications for CIs may vary between EEA countries; (ii) customers' purchasing behaviour differs from one EEA country to another; (iii) the sales, clinical and customer service organisations of CI manufacturers are national in scope; (iv) it is important to have national sales, clinical and customer service organisations to provide customer and patient support before and after surgery and aftercare support; and (v) the presence of specific reimbursement systems across the EEA has resulted in service, support, and price variations between EEA countries.[22]

3.3.3. The Commission's assessment

(28) The market investigation largely confirmed the Notifying Party's arguments. In particular, competitors indicated that medical indications, purchasing behaviours, reimbursement systems and prices differ across EEA countries.[23] Virtually all competitors and customers that responded to the market investigation considered local presence as very important, underlining the significance of local customer and patient support services.[24] In addition, pre-notification contacts with reimbursement authorities and KOLs further confirmed that reimbursement and purchasing takes place at a national level and varies among different EEA countries.[25]

(29) In conclusion, for the purpose of this decision, the Commission will assess the market for the manufacturing and supply of CIs at national level.

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20 Responses to Questions D.A.2 to D.A.3 of the Questionnaires to Customers and Questions C.A.1 to C.A.3 of the Questionnaire to competitors.

21 M.8394 - *Essilor/Luxottica*; M.3687 - *Johnson & Johnson/Guidant*.

22 Form CO, paragraph 142. 3.

23 Responses to Question C.B.1 of the Questionnaire to competitors.

24 Responses to Questions D.B.1 and D.B.2 of the Questionnaire to customers and Questions C.B.2 and C.B.3 of the Questionnaire to competitors.

25 Responses received by reimbursement authorities of six EEA countries (Bulgaria, Lithuania, Poland, Ireland, Denmark and Sweden). Minutes of a call with a KOL on 27 January 202 and minutes of a call with a KOL on 16 January 2023.

4. COMPETITIVE ASSESSMENT

4.1. The Parties' activities

(30) Both Parties are or were active in the supply of CIs in most of the Affected Jurisdictions. Table 1 shows the Parties' sales of CIs, in units, across the Affected Jurisdictions, in the last four years.

Table 1: The Parties' sales of CIs in the Affected Jurisdictions, in units, 2019 - 2022

Affected Jurisdiction	Cochlear				Oticon CI			
	2019	2020	2021	2022	2019	2020	2021	2022
Bulgaria	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Denmark	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Finland	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
France	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Ireland	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Italy	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Lithuania	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Netherlands	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Norway	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Poland	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Portugal	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Spain	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]
Sweden	[…]	[…]	[…]	[…]	[…]	[…]	[…]	[…]

Source: Form CO, Annex 7.1.

Notes: Product returns are recorded as negative sales. Therefore, in the periods where negative sales are observed, the number of returns exceeded the number of CIs sold.

(31) As shown by Table 1 above, the Target's sales have decreased significantly since 2019, from […] across the Affected Jurisdictions in 2019 to only […] in 2022.

(32) In October 2021, the Target identified serious performance issues with its Neuro Zti range (its primary CI range), leading to an immediate recall of around 4 000 CI implants. Following the recall, Demant announced in April 2022 that it had decided to discontinue its hearing implants business and had negotiated an agreement with the intention to sell Oticon Medical to Cochlear.[26]

(33) While the recall had an impact on the Target's sales in 2021, the sales had been decreasing significantly already in the period before the recall. That is, the Target's sales in the Affected Jurisdictions had decreased from […] implants in 2019 to […] implants in 2020 (a 51% yearly decrease) and then further to […] implants in 2021 (a further 32% yearly decrease). During this period, the Target also recorded substantial financial losses, likely due to the lack of sufficient scale. Therefore, Oticon Medical's decision to exit the market was likely driven by several factors relating to its deteriorating performance, and not only the difficulties caused by the recall.

[26] See the press release at the following link: https://www.oticonmedical.com/about-oticon-medical/latest-news/corporate-news-articles/2022/disinvest-oticon-medical

(34) The recall was lifted in May 2022, following the implementation of corrective and preventive measures, and the Neuro Zti range has been relaunched in certain jurisdictions in July 2022. However, the Target's sales have been limited with supplies consisting only of repairs and the fulfilment of pre-existing obligations.

(35) As a result of Oticon's *de facto* exit of the market for CIs, in 2022, the Target only had sales in […] amongst the Affected Jurisdictions. Such sales were made mainly for specific reasons:[27] (i) implantations that were scheduled before the decision to exit the market; (ii) re-implantations of implants in patients who already have a CI of the Target; and (iii) implantations of implants in the second ear where a patient already had the Target's CI device implanted in the other ear.

4.2. The Notifying Party's view

(36) The Notifying Party submits that the Transaction cannot be said to reduce competition in the market for CIs, mainly for the following reasons:[28]

(a) Following the product recall in 2021, the Target has effectively exited the market for CIs. The Target is not proactively selling or marketing CIs and is not acquiring new users. Even prior to the recall, the Target had long been unprofitable.

(b) If not for the Transaction, Demant would have decided to exit the market for CIs, and has periodically reaffirmed such potential decision in its public communications. Cochlear was the only viable purchaser of the Target, able to ensure continued support for Oticon's existing base of CI patients by seeking to develop products that will be compatible with the Target's existing implants.

(c) The Merged Entity will continue being constrained by two competitors active in the supply of CIs – Med-El and Advanced Bionics, which are both established and leading players across Europe and provide a stronger constraint on Cochlear than the Target does.

4.3. The Commission's assessment

(37) The market for CIs in most of the Affected Jurisdictions has traditionally been served by four CI suppliers (including the Parties). In addition to the Parties, the other two competitors include:

(a) Med-El, which is a specialized manufacturer of hearing implants, based in Austria and privately owned;

(b) Advanced Bionics ("AB"), a provider of cochlear implants based in Switzerland and part of the Sonova Group, which is active in a variety of hearing solutions.

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27 Minutes of a call with a KOL on 9 January 2023.

28 Form CO, paragraphs 6 ff, paragraph 52, paragraphs 106 ff.

(38) Table 2 below shows the Parties' and competitors' estimated market shares in the market for CIs in the Affected Jurisdictions, in 2022, based on the number of implants / volume.[29]

Table 2: The Parties' and competitors' estimated market shares in CIs in the Affected Jurisdictions, in implants units, 2022

Country	Cochlear Market Shares (implants units)	Oticon CI Market Shares (implants units)	Med-EL Market Shares (implants units)	AB Estimated Market Shares (implants units)
Bulgaria	[80-90]%	[0-5]%	[0-5]%	[10-20]%
Denmark	[90-100]%	[0-5]%	[0-5]%	[5-10]%
Finland	[70-80]%	[0-5]%	[10-20]%	[10-20]%
France	[60-70]%	[0-5]%	[20-30]%	[10-20]%
Ireland	[90-100]%	[0-5]%	[0-5]%	[5-10]%
Italy	[50-60]%	[0-5]%	[30-40]%	[10-20]%
Lithuania	[40-50]%	[0-5]%	[40-50]%	[10-20]%
Netherlands	[60-70]%	[0-5]%	[5-10]%	[20-30]%
Norway	[80-90]%	[0-5]%	[10-20]%	[0-5]%
Poland	[40-50]%	[0-5]%	[50-60]%	[5-10]%
Portugal	[50-60]%	[0-5]%	[20-30]%	[20-30]%
Spain	[60-70]%	[0-5]%	[20-30]%	[10-20]%
Sweden	[60-70]%	[0-5]%	[30-40]%	[0-5]%

Source: Form CO, Annex 7.1.

(39) However, the 2022 market shares are affected by the Target's decision to exit the market for CIs, which was publicly announced in April 2022, and the recall of Oticon CIs in 2021. Therefore, Table 3 with 2019 - 2021 market shares is provided below, providing an overview of the competitive landscape prior to the recall and the exit announcement. The 2021 market shares are also already affected by the recall of CI implants by the Target in October 2021.

[29] The Notifying Party's submissions indicate that the Parties' and competitors' market shares estimated based on implants revenue do not differ materially from the estimated volume market share. In particular, the Notifying Party provides estimated value market shares, by estimating competitors' implants revenues as their estimated volume multiplied by the estimated average selling price of Cochlear's CIs. The assumption that the average prices of competitors' and Cochlear's CIs are comparable thereby leads to value market shares not differing materially from volume market shares.

Table 3: The Parties' and competitors' estimated market shares in CIs in the Affected Jurisdictions, in implants units, 2019 - 2021

Country	Cochlear			Oticon CI			Med-El			AB		
	2019	2020	2021	2019	2020	2021	2019	2020	2021	2019	2020	2021
Bulgaria	[90-100]%	[50-60]%	[50-60]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[40-50]%	[30-40]%	[0-5]%	[0-5]%	[5-10]%
Denmark	[70-80]%	[80-90]%	[80-90]%	[10-20]%	[0-5]%	[0-5]%	[5-10]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[10-20]%
Finland	[70-80]%	[60-70]%	[60-70]%	[0-5]%	[5-10]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%
France	[40-50]%	[40-50]%	[40-50]%	[10-20]%	[10-20]%	[5-10]%	[10-20]%	[10-20]%	[10-20]%	[10-20]%	[20-30]%	[20-30]%
Ireland	[90-100]%	[90-100]%	[90-100]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%	[0-5]%
Italy	[50-60]%	[50-60]%	[50-60]%	[5-10]%	[5-10]%	[0-5]%	[20-30]%	[20-30]%	[20-30]%	[10-20]%	[10-20]%	[10-20]%
Lithuania	[40-50]%	[40-50]%	[50-60]%	[0-5]%	[5-10]%	[0-5]%	[30-40]%	[30-40]%	[30-40]%	[10-20]%	[10-20]%	[10-20]%
Netherlands	[60-70]%	[60-70]%	[60-70]%	[5-10]%	[0-5]%	[0-5]%	[5-10]%	[5-10]%	[5-10]%	[10-20]%	[20-30]%	[20-30]%
Norway	[70-80]%	[80-90]%	[80-90]%	[0-5]%	[0-5]%	[0-5]%	[10-20]%	[5-10]%	[5-10]%	[0-5]%	[5-10]%	[5-10]%
Poland	[40-50]%	[30-40]%	[30-40]%	[5-10]%	[5-10]%	[5-10]%	[40-50]%	[40-50]%	[40-50]%	[0-5]%	[0-5]%	[5-10]%
Portugal	[40-50]%	[40-50]%	[50-60]%	[0-5]%	[5-10]%	[5-10]%	[20-30]%	[10-20]%	[20-30]%	[30-40]%	[20-30]%	[20-30]%
Spain	[50-60]%	[50-60]%	[60-70]%	[5-10]%	[0-5]%	[0-5]%	[20-30]%	[20-30]%	[20-30]%	[5-10]%	[10-20]%	[10-20]%
Sweden	[70-80]%	[50-60]%	[50-60]%	[0-5]%	[5-10]%	[0-5]%	[20-30]%	[30-40]%	[30-40]%	[0-5]%	[0-5]%	[10-20]%

Source: Form CO, Annex 7.1.

(40) The Commission's competitive assessment of the CI market in individual Affected Jurisdictions (provided in Sections 4.3.1 – 4.3.12) is based on the following considerations, which are relevant for all of the Affected Jurisdictions.

(41) *First*, the Target is by far the smallest supplier of CIs in the vast majority of the Affected Jurisdictions and has *de facto* exited the market in 2022. In 2022, the Target had sales only in […], which are residual sales that are expected to further diminish. Accordingly, the share increment contributed by the Target is at most [0-5]% and in the vast majority of the Affected Jurisdictions the Transaction will not result in any incremental share.

(42) *Second*, even prior to the recall in 2021, the Target was the last entrant and the smallest player in the market, with its sales decreasing considerably already in the pre-recall period (e.g. between 2019 and 2020 the Target's sales decreased from […] to […] implants unit, representing a 34% yearly decrease in sales). At the same time, the Target has long been loss-making and has failed to profitably invest in innovation and R&D. Competitors explain that CI manufacturers require a certain scale to profitably invest in innovation, which the Target did not have, even pre-recall. For example, according to one competitor:[30] *"According to our market observation [Oticon] never had more than 5.5% market share in EEA, maximum in 2017, decreasing after that even before the recall. […] It is not easy to gain market shares in an established market dominated by bigger players as the one with the smallest market share, and it would require much bigger investments into*

30 Response to Question D.1 of the Questionnaire to Competitors.

innovations". This is consistent with the fact that, as further discussed below, the Target is perceived to be the least innovative player in the market.

(43) *Third*, the Target is not expected to be able to recover its pre-recall market position. The market investigation suggests that typically with an appropriate response, it is possible for players to recover their sales after a recall. However, the majority of the market investigation respondents anticipate that, in absence of the Transaction, the Target's position would continue to decline.[31] They explain that the Target specifically would be less likely to be able to recover from the recall because its response after the recall (including due to the announced decision to exit the market) did not provide reassurance and certainty needed for a successful comeback. For example, a competitor explains:[32] *"Would expect that OM´s market share in terms of CI sales for new candidates would recover to 3% and slightly decline thereafter unless a big and costly amount of innovation would take place soon requiring big investments into all present and upcoming categories of the CI."* Further, the Target has long been loss-making due to the lack of scale and is perceived to have weak innovation capabilities, which further hampers its ability to recover from the recall. Therefore, absent the Transaction, the Target is expected to remain a weak competitor with a diminishing competitive role.

(44) *Fourth*, the Commission's investigation confirmed that the Target's very low market shares (even before the product recall in 2021) appropriately reflect the lack of competitive constraint that the Target poses on the other players in the market, including Cochlear. In particular, the respondents to the market investigation consistently rate the Target as the least competitive player, lagging significantly behind the other players.[33] In addition, all the KOLs who participated in the Commission's investigation perceive the Target as the weakest player in the market, some explaining that the quality of the Target's CIs is perceived as lower as compared to that of its competitors'. One KOL, for example, states:[34] *"Oticon's CIs are not considered of comparable quality to those of the other providers […]"* and another one that:[35] *"department has not used Oticon CI because they are not convinced that the product is of sufficient quality"*.

(45) *Fifth*, the Merged Entity will continue facing competition from two competitors, Med-El and AB, which exert significantly stronger competitive pressure on Cochlear than does the Target. For example, one KOL explains that:[36] *"Advanced Bionics and Med-El entered the market for CI not too long after Cochlear and are also considered as important players in the field."* With respect to Med-El, the market investigation respondents estimate its competitive strength to be similar to that of Cochlear, despite its lower market share.[37] Given that Med-El's innovation capabilities are perceived to be comparable to that of Cochlear (see paragraph (46) below), its competitive strength is expected to at least remain at current levels or further increase. For example, market respondents describe Med-El's strengths

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31 Responses to Question E.4 of the Questionnaires to Customers and Question D.4 of the Questionnaire to competitors.

32 Response to Question D.5 of the Questionnaire to Competitors.

33 Responses to Question E.1 of the Questionnaires to Customers and Question D.1 of the Questionnaire to competitors.

34 Minutes of a call with a KOL on 9 January 2023.

35 Minutes of a call with a KOL on 24 January 2023.

36 Minutes of a call with a KOL on 23 January 2003.

37 Responses to Question E.1 of the Questionnaires to Customers and Question D.1 of the Questionnaire to competitors.

as:[38] *"ground-breaking innovations"*, *"Very surgeon oriented; largest electrode portfolio, marketing complete cochlear coverage, participates in low ASP tenders"* and *"great investment in research"*. With respect to AB, the respondents estimate its competitive strength to be slightly below that of Cochlear and Med-El, but above the Target's strength.[39] Market participants describe AB's main strengths as:[40] *"AB is the only cochlear implant manufacturer that is fully integrated with a hearing aid company, Sonova Group, to provide bimodal products that cover individuals' hearing loss needs"* and *"many years in the market, reliable solution"*. In light of the presence of Med-El and AB, the majority of the responding customers consider that there will remain a sufficient number of CI manufacturers to ensure competitive outcomes of their purchasing processes.[41] Similarly, virtually all reimbursement agencies that responded to the investigation confirm that a sufficient number of CI manufacturers would remain in their countries post-Transaction.[42]

(46) *Sixth*, in addition to the Target being the smallest player, the Target is also perceived as the least innovative player. The respondents to the market investigation consistently rate the Target as the least competitive player, lagging significantly behind the other players.[43] Instead, Cochlear and Med-El are perceived as the most innovative by the majority of respondents, followed by AB.[44] Similarly, KOLs do not perceive the Target as a particularly strong innovator, but mention AB and Med-El as strong innovators alongside Cochlear.[45]

(47) *Finally*, the majority of the respondents to the market investigation consider that the Transaction will not have an impact on the markets for CIs in the Affected Jurisdictions, mainly due to Oticon CI's current marginal competitive role and lack of scale to profitably invest in innovation.[46] Additionally, none of the reimbursement authorities have voiced concerns for competition related to the Transaction.[47] They have mostly stated that Cochlear is currently facing competition mainly from Med-El and AB, which indicates that the Target already has a negligible role in the competitive landscapes in these jurisdictions.

(48) The following sections provide the Commission's competitive assessment of the market for the manufacture and supply of CIs in individual Affected Jurisdictions.

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38 Responses to Question E.2 of the Questionnaires to Customers and Question D.2 of the Questionnaire to competitors.

39 Responses to Question E.1 of the Questionnaires to Customers and Question D.1 of the Questionnaire to competitors.

40 Responses to Question E.2 of the Questionnaires to Customers and Question D.2 of the Questionnaire to competitors.

41 Responses to Questions F.1 and F.2 of the Questionnaires to Customers.

42 Responses received by reimbursement authorities of six EEA countries (Bulgaria, Lithuania, Poland, Ireland, Denmark and Sweden).

43 Responses to Question E.3 of the Questionnaires to Customers and Question D.3 of the Questionnaire to competitors.

44 Ibid.

45 Minutes of calls with KOLs on 23 January 2023 and 8 February 2023.

46 Responses to Question F.3 of the Questionnaires to Customers and Question F.1 of the Questionnaire to competitors.

47 Responses received by reimbursement authorities of six EEA countries (Bulgaria, Lithuania, Poland, Ireland, Denmark and Sweden).

4.3.1. Bulgaria and Norway

(49) From 2019 to 2022, the Target […]. As a result, […].

(50) In any event, the market investigation confirmed this conclusion as the Target […], and it was not expected to increase its market presence.[48] All responding market participants confirmed that there would be a sufficient number of CI suppliers in their respective jurisdictions after the Transaction.[49]

(51) Therefore, regarding the Bulgarian and Norwegian markets for CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.2. Denmark

(52) In 2022, Cochlear achieved a market share of [90-100]%, while the Target […] in Denmark.[50] In 2020, Cochlear achieved a market share of [80-90]% while the Target's market share amounted to [0-5]%. The Target's market share had, therefore, already dropped before the recall and exit from [10-20]% in 2019. Cochlear is the largest supplier of CIs in Denmark followed by AB. AB had a market share of [5-10]% in 2022 and [5-10]% in 2020, followed by Med-El with a market share of [0-5]% in 2020.[51]

(53) The limited importance of the Target's presence on the market for CIs in Denmark and the limited impact of the Transaction on the Danish CIs market is also corroborated by the results of the market investigation.

(54) *First*, customers of CIs rated Cochlear and Med-El as the most competitive players on the Danish market, followed by AB.[52] *Second*, Danish customers rated Oticon as the least innovative supplier of CIs, while Cochlear and Med-El were perceived as significantly innovative, followed by AB.[53] *Third*, the majority of customers of CIs that responded to the market investigation considered that with Cochlear, Med-El and AB, sufficient CI players would remain on the Danish market.[54]

(55) Therefore, regarding the Danish market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

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48 Please see for example, responses to Question E.1 of the Questionnaire to Customers in Bulgaria.

49 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Bulgaria, and Minutes of a call with a KOL on 24 January 2023.

50 In fact, Oticon made a recall of […] units in Denmark.

51 Med-El made no CI sales in 2022 in Denmark.

52 Responses to Question E.1 of the Questionnaire to Customers in Denmark.

53 Responses to Question E.3 of the Questionnaire to Customers in Denmark.

54 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Denmark. Please see also Responses received by the reimbursement authority of Denmark indicating that the transaction would not have a big impact on the market.

4.3.3. Finland

(56) In 2022, Cochlear achieved a [70-80]% market share, while the Target achieved […] in Finland that year. In 2020, Cochlear achieved a market share of [60-70]% while Oticon Medical's market share amounted to [5-10]%. The Target had only a [0-5]% market share in 2019. Cochlear has historically been the largest supplier of CIs in Finland and the Target the smallest. This is evidenced by the position of the Parties' main competitors in 2019, 2020 and 2022 for the provision of CIs in Finland, Med-El (with a market share of [10-20]% in 2022, [10-20]% in 2020 and [10-20]% in 2019) and AB (with a market share of [10-20]% in 2022, [10-20]% in 2020 and [10-20]% in 2019).

(57) The limited importance of the Target's presence on the market for CIs in Finland and the limited impact of the Transaction on the CIs market is also corroborated by the results of the market investigation.

(58) *First*, Finnish customers of CIs rated Cochlear as the most competitive supplier, followed by Med-El and AB, while the Target was rated as the least competitive player.[55] *Second*, although customers indicated that the Target remains an innovative player, there is no substantiated evidence that the Transaction may have any negative effects on innovation.[56] A KOL specifically indicated that Cochlear will continue to innovate further and may combine the Target's CI technology to its own portfolio.[57] *Third*, a KOL specifically indicated that price competition between the three other suppliers is strong and that the Transaction will have little to no impact on CI prices.[58] The Commission's investigation also revealed that sufficient CI suppliers would remain.[59]

(59) Therefore, regarding the Finnish market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.4. France

(60) In 2022, Cochlear achieved a [60-70]% market share, while the Target achieved a minimal market share of [0-5]% in France. In 2020, Cochlear achieved a market share of [40-50]% while the Target's market share amounted to [10-20]%. In 2019, Cochlear had a similar market share with [40-50]% and the Target's market share amounted to a slightly higher [10-20]%, which shows that its market position was already weakening. Cochlear has been historically the largest supplier of CIs in France. The Parties' main competitors in 2020 and 2022 for the provision of CIs in France were Med-El ([20-30]% market share in 2022, [10-20]% in 2020 and [10-20]% in 2019) and AB ([10-20]% market share in 2022, [20-30]% in 2020 and [10-20]% in 2019).

(61) The limited importance of the Target's presence on the market for CIs in France and the limited impact of the Transaction on the CIs market is also corroborated by the results of the market investigation.

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55 Responses to Question E.1 of the Questionnaire to Customers in Finland. Minutes of a call with a KOL on 23 January 2023.

56 Responses to Question E.3 of the Questionnaire to Customers in Finland.

57 Minutes of a call with a KOL on 23 January 2023.

58 Minutes of a call with a KOL on 23 January 2023.

59 Responses to Questions F.1, F.2 and F.3 of the Questionnaire to Customers in Finland.

(62) *First*, French customers of CIs rated Cochlear as the most competitive player, followed by AB and Med-EL.[60] Moreover, a French KOL mentioned that certain of the Target's CIs that are implanted in France are implanted for patient-specific reasons, such as reimplantation for patients who already have an Oticon implant or a second implant for patients who already have an Oticon implant in one ear. In general, taking into account the low perceived quality of Oticon, the KOL is expecting its role to further diminish.[61]*Second*, French customers rated the Target as the least innovative supplier of CIs, while Cochlear and Med-El were perceived as significantly innovative, followed by AB.[62] *Third*, in line with the Target's declining market share in the French market, the majority of customers of CIs that responded to the market investigation consider that sufficient CI players would remain on the French market and that the impact of the Transaction on the market would be neutral.[63] Similarly, a KOL based in France also indicated that "*the impact of the Transaction will be limited"* due to the fact that the Target is not a strong player.[64]

(63) Therefore, regarding the French market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.5. Ireland

(64) From 2019 to 2022, the Target has barely been active, only selling […] in the country. As a result, while Cochlear is the largest supplier in Ireland, the horizontal overlap on the Irish market is minimal due to the Target's very limited presence.

(65) In any event, the market investigation confirmed this conclusion as the Target had almost no presence in Ireland, and it was not expected to increase its market presence.[65] Responding customers confirmed that there would be a sufficient number of CI suppliers in Ireland after the Transaction.[66]

(66) Therefore, regarding the Irish market for CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.6. Italy

(67) In 2022, Cochlear achieved a market share of [50-60]% in Italy, which has remained similar since 2020. In contrast, the Target's market share has been decreasing over the years, from [5-10]% in 2019 to [5-10]% in 2020 and to [0-5]% in 2022. Cochlear is the largest supplier of CIs in Italy, followed by Med-El (with [30-40]% in 2022) and AB (with [10-20]% in 2022).

(68) The limited importance of the Target's presence on the market for CIs in Italy and the limited impact of the Transaction on the Italian CIs market is also corroborated by the results of the market investigation.

60 Responses to Question E.1 of the Questionnaire to Customers in France.
61 Minutes of a call with a KOL on 9 January 2023.
62 Responses to Question E.3 of the Questionnaire to Customers in France.
63 Responses to Questions F.1, F.2 and F.3 of the Questionnaire to Customers in France.
64 Minutes of a call with a KOL on 9 January 2023, paragraph 21.
65 Please see for example, responses to Question E.1 of the Questionnaire to Customers in Ireland.
66 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Ireland.

(69) *First*, the Target was rated the least competitive and innovative player on the Italian market compared to Cochlear, Med-El and AB, who all had a better rating.[67] *Second*, respondents referred to the Target's *"severe hardware failures and limited innovations"* as weaknesses, all indicating that its future market position would keep declining.[68] *Third*, all customers of CIs that responded to the market investigation considered that sufficient CI players would remain on the Italian market.[69]

(70) Therefore, regarding the Italian market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.7. Lithuania

(71) In 2022, Cochlear achieved a market share of [40-50]%, while the Target […] in Lithuania. Similarly to other jurisdictions, the Target's market share has been very low over the years ([5-10]% in 2020 to [0-5]% in 2022). In Lithuania, Cochlear and Med-El are the two largest competitors ([40-50]% and [40-50]% in 2022 respectively), followed by AB ([10-20]% in 2022). In 2019, the Target had […] in Lithuania.

(72) The market investigation found no evidence that would suggest that the Transaction may significantly impede effective competition. Indeed, a public authority considered that, for example, "*Cochlear and Med-El are main CI providers in Lithuania … the Transaction should not affect the availability of CI procurement*".[70] The Target's declining market position in Lithuania was also confirmed, indicating it was the least competitive player on the Lithuanian market.[71]

(73) Therefore, regarding the Lithuanian market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.8. The Netherlands

(74) In 2022, Cochlear achieved a market share of [60-70]% in the Netherlands. In 2020, Cochlear achieved a market share of [60-70]% in the Netherlands ([60-70]% in 2019). While Cochlear's market share has remained stable, this contrasts with the Target's market presence, which has decreased over the years, from [5-10]% in 2019 and [0-5]% in 2020 to [0-5]% in 2022. Cochlear is the largest supplier of CIs in the Netherlands followed by AB and Med-El, which achieved a market share of [20-30]% and [5-10]% respectively in the Netherlands in 2022.

(75) The limited importance of the Target's presence on the market for CIs in the Netherlands and the limited impact of the Transaction on the Dutch CIs market is also corroborated by the results of the market investigation.

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67 Responses to Questions E.1 and E.3 of the Questionnaire to Customers in Italy.

68 Responses to Questions E.2, E.4 and E.5 of the Questionnaire to Customers in Italy.

69 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Italy.

70 Responses received by the reimbursement authority of Lithuania.

71 Responses to Questions E.1, E.4 and E.5 of the Questionnaire to Customers in Lithuania.

(76) *First*, customers of CIs rated Cochlear as the most competitive player in the Dutch market, followed by Med-El and AB.[72] The Target is perceived as the least competitive player on the Dutch market for CIs. *Second*, Dutch customers rated the Target as the least innovative supplier of CIs, while Med-El is ranked first in terms of innovation, followed by Cochlear and AB.[73] *Third*, the majority of customers of CIs that responded to the market investigation consider that sufficient CI players would remain on the Dutch market.[74]

(77) Therefore, regarding the Dutch market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.9. Poland

(78) In 2022, Cochlear achieved a market share of [40-50]% in Poland. In 2020, Cochlear achieved a market share of [30-40]% in Poland ([40-50]% in 2019). While Cochlear's market share has remained stable, the Target's market presence has decreased over the years, from [5-10]% in 2019 to [5-10]% in 2020 to [0-5]% in 2022. Cochlear is the second largest supplier in the country, after Med-El ([50-60]% market share in 2022) and followed by AB ([5-10]% in 2022).

(79) The limited importance of the Target's presence on the market for CIs in Poland and the limited impact of the Transaction on the Polish CIs market is also corroborated by the results of the market investigation.

(80) *First*, customers of CIs have rated Cochlear and Med-El as the most competitive players in the Polish market, followed by AB.[75] The Target is perceived as the least competitive player on the Polish market for CIs. *Second*, Polish customers rated the Target as the least innovative supplier of CIs, while Cochlear and Med-El were perceived as significantly innovative, followed by AB.[76] *Third*, the majority of customers of CIs that responded to the market investigation considered that sufficient CI players would remain on the Polish market; one respondent referring to the Target's role on the market as "*marginal*".[77]

(81) Therefore, regarding the Polish market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.10. Portugal

(82) In 2022, Cochlear achieved a market share of [50-60]% in Portugal, and, in 2020, a share of [40-50]% in Portugal. The Target's market presence has decreased over the years, from [5-10]% in 2020 to [0-5]% in 2022. Cochlear is the largest supplier of CIs in Portugal, followed by AB ([20-30]% market share in 2022) and Med-El ([20-30]% in 2022). In 2019, the Target had […] in Portugal.

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72 Responses to Question E.1 of the Questionnaire to Customers in the Netherlands.
73 Responses to Question E.3 of the Questionnaire to Customers in the Netherlands.
74 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in the Netherlands.
75 Responses to Question E.1 of the Questionnaire to Customers in Poland.
76 Responses to Question E.3 of the Questionnaire to Customers in Poland.
77 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Poland.

(83) The Target's limited market presence for CIs in Portugal and the limited impact of the Transaction on the Portuguese CIs market are also corroborated by the results of the market investigation. Market participants rated Cochlear as the most competitive followed by Med-El and AB, the Target having the lowest rating.[78] In addition, most customers of CIs considered that sufficient CI players will remain that can "*serve the needs of the Portuguese market*".[79]

(84) Therefore, regarding the Portuguese market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.11. Spain

(85) In Spain, Cochlear achieved a market share of [50-60]% in 2019, [50-60]% in 2020, and [60-70]% in 2022. The Target's market presence has decreased over the years, from [5-10]% in 2019 to [0-5]% in 2020 to [0-5]% in 2022. On the Spanish market, Cochlear is the largest supplier of CIs, followed by Med-El and AB, which achieved a market share of [20-30]% and [10-20]% in 2022 respectively.

(86) The limited importance of the Target's presence on the market for CIs in Spain and the limited impact of the Transaction on the Spanish CIs market are also corroborated by the results of the market investigation.

(87) *First*, customers of CIs rated Cochlear and Med-El as the most competitive in the Spanish market, some respondents referring to the Target as having a "*limited product offering*" and "*less effective sales service*".[80] *Second*, in terms of innovation capabilities, Spanish customers rated the Target as the least innovative supplier of CIs, while Cochlear and Med-El were perceived as significantly innovative, followed by AB.[81] *Third*, most customers of CIs considered that sufficient CI players would remain on the Spanish market.[82]

(88) Therefore, regarding the Spanish market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

4.3.12. Sweden

(89) In 2022, Cochlear achieved a market share of [60-70]%, while the Target […] in Sweden. In 2020, Cochlear achieved a market share of [50-60]% ([70-80]% in 2019) while the Target's market share amounted to [5-10]% ([0-5]% in 2019). Cochlear is the largest supplier of CIs in Sweden followed by Med-El. Med-El had a market share of [30-40]% in 2022, AB […] in 2022 […] in 2020 and 2021.[83]

78 Responses to Question E.1 of the Questionnaire to Customers in Portugal; Responses to Question D.1 of the Questionnaire to Competitors.

79 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Portugal.

80 Responses to Question E.1 of the Questionnaire to Customers in Spain; Responses to Question D.1 of the Questionnaire to Competitors in Spain.

81 Responses to Question E.3 of the Questionnaire to Customers in Spain.

82 Responses to Questions F.1 and F.2 of the Questionnaire to Customers in Spain.

83 AB made no CI sales in 2022 in Sweden.

(90) The market investigation found no evidence that would suggest that the Transaction may significantly impede effective competition. For example, a public authority in Sweden confirmed that the Target is not a strong supplier, mentioning that its products are not used, and that a sufficient number of competitors would remain on the market.[84]

(91) Therefore, regarding the Swedish market for the manufacture and supply of CIs, the Transaction does not raise serious doubts as to its compatibility with the internal market.

5. CONCLUSION

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

For the Commission

(Signed)
Didier REYNDERS
Member of the Commission

[84] Responses received by the reimbursement authority of Sweden.