

April 16, 2024

## **Case AT.40577 – CSL Vifor (IV Iron Products)**

### **Proposed Commitments**

In accordance with Article 9 of Council Regulation (EC) No 1/2003 (“Regulation 1/2003”), Vifor Pharma Ltd., Vifor Pharma Management Ltd., and Vifor Pharma Deutschland GmbH, and their respective Affiliated Undertakings (together “CSL Vifor”)<sup>1</sup> hereby offer the following commitments (“Commitments”) to address the preliminary concerns expressed by the European Commission (“Commission”) in its Preliminary Assessment of April 8, 2024 in case AT.40577 (“Preliminary Assessment”), and to enable the Commission to adopt a decision confirming that the Commitments meet its concerns (the “Commitments Decision”).

Consistent with Article 9 of Regulation 1/2003, these Commitments do not constitute an acknowledgement that CSL Vifor agrees with the concerns expressed by the Commission in the Preliminary Assessment nor an acknowledgment that CSL Vifor or any of its affiliates have infringed EU competition law. Consistent with Article 9 of Regulation 1/2003, the Commitments are given in the understanding that the Commission will confirm that there are no grounds for further action and will terminate the proceedings in case AT.40577 without concluding whether or not there has been an infringement of competition law. For the avoidance of doubt, CSL Vifor contests that it is dominant on any plausible market or that it has engaged in unlawful conduct contrary to Article 102 TFEU or Article 54 of the EEA Agreement within the EEA. These Commitments are thus without prejudice to CSL Vifor’s position should the Commission or any other party conduct proceedings or commence other legal action against CSL Vifor. These Commitments are offered without any admission of liability.

#### **I. Definitions**

1. For the purpose of the Commitments, the following terms shall have the following meaning:

“AdBoard Materials” refer to materials prepared by CSL Vifor for advisory boards that are used for research and scientific exchange purposes.

“Additional Countries” refer to Finland, Ireland, Portugal, and Romania.

“Affiliated Undertakings” mean undertakings in the EEA controlled by Vifor Pharma Ltd., Vifor Pharma Management Ltd., and Vifor Pharma Deutschland GmbH, whereby the notion of control shall be interpreted pursuant to Article 3 of the Council Regulation (EC) No 139/2004 and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004.

“Clinical Head-to-Head trial” means a randomized controlled clinical trial where two therapies are directly compared against each other, with an appropriate sample size and with peer-reviewed results.

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<sup>1</sup> All current and future legal entities of the CSL group involved in the promotion, marketing, or sale of Ferinject in the EEA during the Commitment Period will also be bound by the Commitments.

“Communication Campaign” refers to the communication campaign defined in Section II of these Commitments.

“Commitment Period” means 10 years from the Entry Into Force of the Commitments.

“Conflict of Interest” means any conflict of interest that impairs the Monitoring Trustee’s objectivity and independence in discharging its duties under the Commitments.

“Contact Email Address” means the CSL Vifor contact email address indicated in the Stakeholder Communication contained in Appendix 1.

“CSL Vifor” means Vifor Pharma Ltd., Vifor Pharma Management Ltd., and Vifor Pharma Deutschland GmbH and their respective Affiliated Undertakings in the EEA.

“Customer Relationship Management system” or “CRM system” refers to the software system used by CSL Vifor to manage interactions with customers.

“EEA” means European Economic Area.

“Entry Into Force” means the date when the Commitment Decision is notified to CSL Vifor.

“External Promotional and Medical Communications” refer to all oral or written external promotional and medical communications, including notably paper and electronic promotional and medical communications used externally, as well as Internal Training Materials and any other internal materials serving as the basis for oral or written external communications by Sales and Medical Field Force with HCP Stakeholders within the EEA.

“First E-mail Communication Campaign” means e-mailing the Stakeholder Communication to the HCP Stakeholders included in CSL Vifor’s CRM system and Payor Stakeholders in the Focus Countries and the Additional Countries as soon as practicable and no later than 30 days of the Entry Into Force.

“First Mail Communication Campaign” means mailing the Stakeholder Communication to the HCP Stakeholders included in CSL Vifor’s CRM system and Payor Stakeholders in the Focus Countries and the Additional Countries as soon as practicable and no later than 30 days of the Entry Into Force.

“Ferinject” means ferric carboxymaltose product commercialized by CSL Vifor under any and all brand names within the EEA.

“Focus Countries” refer to Austria, Germany, the Netherlands, Spain, and Sweden.

“HSR” means hypersensitivity reactions.

“HCP Stakeholders” means the categories of healthcare professionals listed in Appendix 3 in the Focus Countries and the Additional Countries, based on CSL Vifor’s CRM system.

“HQ materials” means materials prepared by CSL Vifor’s headquarter organization.

“Internal Training Materials” refer to paper and electronic materials used to train CSL Vifor’s Sales and Medical Field Force and containing explicit or implied comparison between Ferinject and Monofer.

“Local Partner” means any independent third party involved in the commercialisation and promotion of Ferinject in the EEA on behalf of CSL Vifor.<sup>2</sup>

“MAKAM” means Market Access Key Account Managers.

“Monofer” means isomaltoside product or ferric derisomaltose product commercialized by Pharmacosmos and its partners under any and all brand names within the EEA.

“MSLs” means medical scientific liaison personnel.

“Payor Stakeholders” means the national, regional and local payor organizations listed in Appendix 4 in the Focus Countries and the Additional Countries.

“Prohibited Conduct” refers to the conduct defined in Section III of these Commitments.

“Required Conduct” refers to the conduct defined in Section II of these Commitments.

“Q&A” means document contained in Appendix 2.

“Sales Field Force” refers to CSL Vifor’s field-based employees, such as sales representatives and key account managers, engaged in external communications with HCP Stakeholders within the EEA.

“Sales and Medical Field Force” refers to CSL Vifor’s field-based employees, such as sales representatives, key account managers, and MSLs, engaged in external communications with HCP Stakeholders within the EEA.

“Second E-mail Communication Campaign” means e-mailing the Stakeholder Communication to the HCP Stakeholders included in CSL Vifor’s CRM system in the Focus Countries and the Additional Countries between 90 days and 120 days of the Entry Into Force.

“Second Mail Communication Campaign” means mailing the Stakeholder Communication to the HCP Stakeholders included in CSL Vifor’s CRM system in the Focus Countries and the Additional Countries between 90 days and 120 days of the Entry Into Force.

“SmPC” means Summary of Product Characteristics, which describes the properties and the officially approved conditions of use of a medicine. It provides the basis of information for healthcare professionals on how to use the medicine safely and effectively.

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<sup>2</sup> Excludes local partners not involved in promotional activities such as partners handling warehousing and logistics.

“Stakeholder Communication” means the written communication contained in Appendix 1.

“Pharmacosmos” refers to Pharmacosmos A/S, registered address of Roervangsvej 30, 4300 Holbaek, Denmark.

[Confidential] refers to a third-party cloud-based content management application used by CSL Vifor that enables promotional and non-promotional content creation, review, and approval.

## **II. Required Conduct**

2. CSL Vifor commits to undertaking a comprehensive, multi-channel, clarification communication campaign (“Communication Campaign”), comprised of the following elements:
  - a. Disseminating the Stakeholder Communication in the Additional Countries and Focus Countries through mail and e-mail to HCP Stakeholders included in Appendix 3 and Payor Stakeholders included in Appendix 4. The First Mail Communication Campaign and First E-mail Communication Campaign with HCP Stakeholders and Payor Stakeholders shall take place as soon as practicable and no later than 30 days of the Entry Into Force. The Second Mail Communication Campaign and Second E-mail Communication Campaign with HCP Stakeholders shall take place between 90 days and 120 days of the Entry Into Force. Any follow-up questions from the HCP Stakeholders and Payor Stakeholders related to the content of the Stakeholder Communication shall be responded respectively by CSL Vifor’s Sales and Medical Field Force and CSL Vifor’s MAKAM in line with the Q&A document provided at Appendix 2.
  - b. Publishing the Stakeholder Communication contained in Appendix 1 in the section on iron deficiency of (i) CSL Vifor website’s homepage,<sup>3</sup> and (ii) CSL Vifor’s country websites within the EEA,<sup>4</sup> as soon as practicable and no later than 7 days of the Entry Into Force for a period of 36 months.
  - c. Publishing the Stakeholder Communication contained in Appendix 1 in a leading medical journal with a wide coverage in each of the Focus Countries and the Additional Countries, listed in Appendix 5.
  - d. Allowing third parties, including Pharmacosmos, to use the Stakeholder Communication contained in Appendix 1 (or its translated versions included in Appendixes 1.1-1.23) within the EEA from 31 days of the Entry Into Force, or earlier if the First Mail Communication Campaign and First E-mail Communication Campaign take place earlier, as long as it is reproduced verbatim if communicated in writing.

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<sup>3</sup> The homepage of the section on iron deficiency is currently available at: [www.csl.com/we-are-csl/our-businesses-and-products/csl-vifor/csl-vifor-products](http://www.csl.com/we-are-csl/our-businesses-and-products/csl-vifor/csl-vifor-products).

<sup>4</sup> The global selector of country websites is currently available at: <https://www.csl.com/globalselector>.

- e. For a period of 12 months from the Entry Into Force, delivering the Stakeholder Communication to HCP Stakeholders in the Additional Countries and Focus Countries in one hard copy per HCP Stakeholder during the first in-person meeting that takes place in the ordinary course of business between the Sales Field Force and an HCP Stakeholder.
3. CSL Vifor's compliance with the Required Conduct shall be subject to a Monitoring Trustee mechanism defined in Section VII of these Commitments.

### **III. Prohibited Conduct**

4. For a period of 10 years from the Entry Into Force, CSL Vifor commits not to engage within the EEA in External Promotional and Medical Communications, in writing or orally, about Monofer's safety profile containing information or characteristics (i) not based on information or characteristics included in Monofer's SmPC, or (ii) not derived from a Clinical Head-to-Head trial between Ferinject and Monofer. In addition, CSL Vifor's External Promotional and Medical Communications related to Monofer and Ferinject shall be balanced, objective, and comprehensive. In particular, CSL Vifor shall not directly or indirectly imply or suggest that Monofer is not dextran-free.
5. CSL Vifor commits to undertake best efforts to amend as soon as practicable its agreements with Local Partners to contractually (i) request compliance of Local Partners with the Prohibited Conduct set out at paragraph 4 for the duration of the Commitment Period, (ii) request annual self-certification by Local Partners of their compliance with the Prohibited Conduct set out at paragraph 4 for the duration of the Commitment Period, and (iii) offer Local Partners an annual compliance training for a period of 3 years from the Entry Into Force, focused on good promotional and medical communications practice and compliance with the Commitments.
6. As a means of compliance with the commitment set out at paragraph 4, CSL Vifor commits to the following measures and safeguards. The implementation of measures in paragraphs 6(a), 6(b), and 6(d) shall be reviewed by the Monitoring Trustee within 45 days of its appointment and be subject to reasonable comments from the Monitoring Trustee communicated to CSL Vifor within 60 days of the Monitoring Trustee's appointment. In case of disagreement between the Monitoring Trustee and CSL Vifor on the reasonableness of the comments, the matter shall be escalated to the Commission.
  - a. For a period of 3 years from the Entry Into Force, setting up an internal mechanism to ensure as far as reasonably possible that all HQ External Promotional and Medical Communications related to safety statements about Monofer and/or Ferinject are in line with these Commitments prior to their external use. Setting up an internal mechanism to ensure as far as reasonably possible that all HQ Internal Training Materials related to safety statements about Monofer and/or Ferinject, and AdBoard Materials related to safety statements about Monofer and/or Ferinject, are in line with these Commitments prior to their use.
  - b. For a period of 3 years from the Entry Into Force, setting up an internal mechanism to review as far as reasonably possible any country-specific deviations from HQ External Promotional and Medical Communications related to safety statements about Monofer and/or Ferinject used within the EEA to

ensure that any such deviations are in line with these Commitments prior to their external use. Setting up an internal mechanism to review as far as reasonably possible any country-specific deviations from HQ Internal Training Materials related to safety statements about Monofer and/or Ferinject used for training within the EEA to ensure that any such deviations are in line with these Commitments prior to their internal training use.

- c. For the duration of the Commitment Period, offering a dialogue process between CSL Vifor, Pharmacosmos, and the Monitoring Trustee within 4 weeks of the request from Pharmacosmos, for the purposes of enabling Pharmacosmos to raise and discuss in good faith any alleged deviations from these Commitments within the EEA such as unauthorized miscommunications within the EEA. In case of disagreement between CSL Vifor and Pharmacosmos, the Monitoring Trustee shall issue a formal recommendation on how to resolve the disagreement within 2 weeks of being requested to do so by either Party. In case Pharmacosmos or CSL Vifor disagree with the recommendation of the Monitoring Trustee, they can escalate the matter to the Commission within 1 week of the recommendation of the Monitoring Trustee. The Commission shall then provide appropriate directions binding on CSL Vifor.
- d. For the duration of the Commitment Period, setting up a detailed internal mechanism to review as far as reasonably possible and, if appropriate, withdraw or correct any potential unauthorized miscommunications made by CSL Vifor as soon as practicable and no later than 15 days from when CSL Vifor becomes aware of such potential unauthorized miscommunication.<sup>5</sup> For the duration of the Commitment Period, undertake commercially reasonable efforts to review and, if appropriate, insist with Local Partners on withdrawing or correcting any potential unauthorized miscommunications made by Local Partners as soon as practicable. In the event that CSL Vifor becomes aware of repeated instances of material non-compliance with the Prohibited Conduct by a Local Partner and that the concerned Local Partner does not comply with CSL Vifor's instructions to withdraw or correct the repeated unauthorized miscommunications, CSL Vifor shall terminate the concerned local partnership as soon as practicable (including with due account to reasonable steps required to find a new Local Partner) or take alternative measures if the termination of the concerned local partnership at a reasonably short notice is not practicable, including, in particular, reporting the unauthorized miscommunications to relevant local regulatory authorities or not renewing the local partnership.
- e. For a period of 3 years from the Entry Into Force, conducting an annual internal compliance training of CSL Vifor's senior management<sup>6</sup> and all of CSL Vifor Sales and Medical Field Force involved with Ferinject within the EEA focused on good promotional and medical communications practice and compliance with the Commitments.

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<sup>5</sup> Such incidents, if any, and the respective corrective measures, will be assessed by the Monitoring Trustee, and if necessary by the Commission, in a fair, balanced, and reasonable manner, taking account of all of the circumstances and the full context.

<sup>6</sup> CSL Vifor's senior management comprises of the following roles: [Confidential].

- f. For the duration of the Commitment Period, executing an annual compliance statement within 30 calendar days from the end of the calendar year by each member of CSL Vifor's senior management<sup>7</sup> and the Sales and Medical Field Force in the EEA involved with Ferinject, attesting compliance with the commitment set out at paragraph 4.
7. CSL Vifor's compliance with the Prohibited Conduct shall be subject to a Monitoring Trustee mechanism defined in Section VII of these Commitments for the duration of the Commitment Period, except in relation to measures contained in paragraph 6(a), 6(b), and 6(e) that are put in place for the period of 3 years from the Entry Into Force.
8. For the avoidance of doubt, nothing in these Commitments shall prohibit CSL Vifor from engaging in (a) communications based on information or characteristics included in Monofer's or Ferinject's SmPC, applicable within the EEA at the time of the communication, provided that any comparisons between Ferinject and Monofer are balanced, objective, and comprehensive; or (b) communications about Ferinject that do not include any direct or indirect comparison with Monofer. By way of an example, communicating that Ferinject was the "*first dextran-free high dose IV iron product*" is permitted provided it is allowed under relevant country regulations. In addition, communicating that Ferinject is a nanomedicine is permitted.

#### **IV. Non-Circumvention**

9. CSL Vifor shall not in any way circumvent, directly or indirectly (e.g. through third parties), by actions and/or omissions, any obligations contained in these Commitments. By way of an example, CSL Vifor (i) shall not claim that "*Monofer's marketing authorization is based on Cosmofer, which is a dextran*" (or similar messages to that effect suggesting that Monofer is dextran-based or dextran-derived), or (ii) shall not communicate about Monofer's efficacy outside of its SmPC or outside of a Clinical Head-to-Head trial between Ferinject and Monofer. By way of another example, CSL Vifor shall not directly, or through third parties, generate, sponsor, publish, or promote comparative studies or comparative publications describing Monofer's safety profile in breach of paragraph 4 of the Commitments. For the avoidance of doubt and without prejudice to the general application of EU competition rules and any other applicable rules governing the promotion and/or advertising of pharmaceutical products, these Commitments shall not prevent CSL Vifor from directly, or through third parties:
  - a. generating, sponsoring, publishing, and promoting Real World Evidence that relates to Ferinject only;
  - b. generating, sponsoring, publishing, and promoting comparative Real World Evidence that actually demonstrates non-inferiority of Ferinject compared to Monofer;
  - c. generating and sponsoring (but not publishing or promoting directly or through third parties) comparative Real World Evidence, with the sole aim of submitting

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<sup>7</sup> CSL Vifor's senior management comprises of the following roles: [Confidential].

that evidence to EMA for a regulatory evaluation and potential inclusion in the SmPC.

## **V. Reporting**

10. CSL Vifor commits to provide the Commission and the Monitoring Trustee a report on the implementation of the Required Conduct (as defined at paragraphs 2-3 of these Commitments) as soon as practicable and no later than 30 days of the completion of each Communication Campaign.
11. Any Stakeholder messages related to communications about Monofer adopted by CSL Vifor or its Local Partners after the Entry into Force and received by CSL Vifor at the Contact Email Address shall be provided to the Monitoring Trustee without delay.
12. CSL Vifor commits to provide the Commission and the Monitoring Trustee a report on the implementation of the measures related to the Prohibited Conduct (as defined in Section III of these Commitments) as soon as practicable and no later than 30 days from the end of the calendar year.<sup>8</sup> The reporting obligation is due for the duration of the Commitment Period, except in relation to measures contained in paragraph 6(a), 6(b), and 6(e) that are put in place for the period of 3 years from the Entry Into Force.
13. CSL Vifor commits to provide the Commission and the Monitoring Trustee a report on potential unauthorized miscommunications and, if appropriate, propose adequate remediation measures within the meaning of paragraph 6(d) of these Commitments, as soon as practicable and no later than 15 days from when CSL Vifor becomes aware of such potential unauthorized miscommunication. Any such measures shall then be implemented within 30 days as per paragraph 6(d) of these Commitments. CSL Vifor commits to provide the Commission and the Monitoring Trustee a report on potential unauthorized miscommunications made by Local Partners as soon as practicable and no later than 30 days from when CSL Vifor becomes aware of such potential unauthorized miscommunication and, if appropriate, what adequate remediation measures CSL Vifor proposed to Local Partners within the meaning of paragraph 6(d).

## **VI. Monitoring Trustee**

### **a. Appointment procedure**

14. CSL Vifor shall appoint a Monitoring Trustee to carry out the functions specified below in these Commitments.
15. The Monitoring Trustee shall:
  - i) at the time of appointment, be independent of CSL Vifor and of any competitor of CSL Vifor;
  - ii) possess the necessary qualifications to carry out its mandate; and
  - iii) neither have nor become exposed to a Conflict of Interest.

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<sup>8</sup> For the avoidance of doubt, the first report for calendar year 2024 shall be due by January 31, 2025.

16. The Monitoring Trustee shall be remunerated by CSL Vifor in a way that does not impede the independent and effective fulfilment of its mandate.

Proposal by CSL Vifor

17. No later than two weeks after the Entry Into Force, CSL Vifor shall submit the name or names of one or more natural or legal persons whom CSL Vifor proposes to appoint as the Monitoring Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Monitoring Trustee fulfil the requirements set out at paragraph 15 and shall include:
- i) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Monitoring Trustee to fulfil its duties under these Commitments; and
  - ii) the outline of a work plan which describes how the Monitoring Trustee intends to carry out the mandate.

Approval or rejection by the Commission

18. The Commission shall have the discretion to approve or reject the proposed Monitoring Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Monitoring Trustee to fulfil its obligations. If only one name is approved, CSL Vifor shall appoint or cause to be appointed the person or persons concerned as Monitoring Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, CSL Vifor shall be free to choose the Monitoring Trustee to be appointed from among the names approved. The Monitoring Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

New proposal by CSL Vifor

19. If all the proposed Monitoring Trustees are rejected, CSL Vifor shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection in accordance with paragraphs 15 and 18.

Monitoring Trustee nominated by the Commission

20. If all further proposed Monitoring Trustees are rejected by the Commission, the Commission shall nominate a Monitoring Trustee, whom CSL Vifor shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

**b. Functions of the Monitoring Trustee**

21. The Monitoring Trustee shall act on behalf of the Commission to ensure CSL Vifor's compliance with the Commitments and assume the duties specified in the Commitments. In particular:
- i) As regards the Required Conduct, the Monitoring Trustee shall monitor and verify that the Stakeholder Communication was disseminated in the Focus

Countries and the Additional Countries during each Communication Campaign and published on CSL Vifor website's homepage and CSL Vifor's country websites within the EEA, and in each medical journal listed in Appendix 4; and

- ii) As regards the Prohibited Conduct, the implementation of measures in paragraphs 6(a), 6(b), and 6(e) shall be reviewed by the Monitoring Trustee within 45 days of its appointment and be subject to reasonable comments from the Monitoring Trustee communicated to CSL Vifor within 60 days of the Monitoring Trustee's appointment. In case of disagreement between the Monitoring Trustee and CSL Vifor on the reasonableness of the comments, the matter shall be escalated to the Commission.

For the period of 3 years from the Entry Into Force, the Monitoring Trustee shall also have access to CSL Vifor's [Confidential] database and any other relevant CSL Vifor database to undertake biannual<sup>9</sup> reviews of all of CSL Vifor's External Promotional and Medical materials at HQ and country-level, all of CSL Vifor's Internal Training Materials used for training at HQ and country-level, and all of CSL Vifor's AdBoard Materials related to safety statements about Monofer and/or Ferinject, to monitor and verify that these materials do not include information about Monofer that is not based on information or characteristics included in Monofer's SmPC or not derived from Clinical Head-to-Head trials between Ferinject and Monofer. For the remainder of the duration of the Commitment Period (*i.e.*, after the initial 3 years from the Entry Into Force), the Monitoring Trustee shall have access to CSL Vifor's [Confidential] database and any other relevant CSL Vifor database to undertake annual reviews of a reasonable sample<sup>10</sup> of (i) CSL Vifor's External Promotional and Medical materials at HQ and country-level, (ii) CSL Vifor's Internal Training Materials used for training at HQ and country-level, and (iii) CSL Vifor's AdBoard Materials related to safety statements about Monofer and/or Ferinject, to continue to monitor and verify that CSL Vifor's materials do not include information about Monofer that is not based on information or characteristics included in Monofer's SmPC or not derived from Clinical Head-to-Head trials between Ferinject and Monofer. The Monitoring Trustee shall at least twice a year consult Pharmacosmos, and upon advance notice, CSL Vifor's General Managers and if appropriate CSL Vifor Sales and Medical Field Force, as well as any HCP Stakeholders the Monitoring Trustee deems relevant, to monitor and verify that CSL Vifor did not engage in the Prohibited Conduct within the EEA.

The Monitoring Trustee shall also monitor and prepare a biannual report on CSL Vifor's compliance with the measures set out in Sections III and IV of these Commitments. The reporting obligation is due for the duration of the Commitment Period, except in relation to measures contained in paragraphs in paragraph 6(a), 6(b), and 6(e) that are put in place for the period of 3 years from the Entry Into Force.

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<sup>9</sup> Two times per year.

<sup>10</sup> Up to 5% of the average number of materials reviewed annually in the first 3 years from the Entry Into Force. The sample shall be identified by the Monitoring Trustee.

22. The Commission may, on its own initiative or at the request of the Monitoring Trustee or CSL Vifor, give any orders or instructions to the Monitoring Trustee in order to ensure compliance with the conditions and obligations attached to the Commitment Decision. CSL Vifor may not give instructions to the Monitoring Trustee.

**c. Duties and obligations of the Monitoring Trustee**

23. The Monitoring Trustee shall:
- i) within 60 days from the date of the appointment, provide the Commission (sending CSL Vifor a non-confidential copy at the same time) a first report including a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Commitment Decision; and assessing CSL Vifor's compliance with the Commitments in relation to the First Communication Campaign;
  - ii) propose to CSL Vifor such measures as the Monitoring Trustee considers necessary to ensure CSL Vifor's compliance with the Commitments and the Monitoring Trustee shall propose measures to the Commission in the event that CSL Vifor does not comply with the Monitoring Trustee's proposal within the timeframe set by the Monitoring Trustee;<sup>11</sup>
  - iii) act as a contact point for any requests by Pharmacosmos and other third parties in relation to the Commitments;
  - iv) within 120 days from the date of the appointment, provide the Commission (sending CSL Vifor a non-confidential copy at the same time) a report of any issues or problems which may have arisen in the execution of the Monitoring Trustee's obligations, in particular any issues of non-compliance by CSL Vifor with the Commitments, including notably with respect to the Second Communication Campaign;
  - v) provide the Commission (sending CSL Vifor a non-confidential copy at the same time) bi-annual written reports (starting from calendar year 2025) covering the Monitoring Trustee's fulfilment of its obligations and CSL Vifor's compliance with the Commitments. The reports shall cover any issues or problems which have arisen in the execution of the obligations as Monitoring Trustee, in particular any issues of non-compliance by CSL Vifor with the Commitments.
24. At any time, the Monitoring Trustee will provide to the Commission, at its request (or on the Monitoring Trustee's own initiative), a written or oral report on matters falling within the Monitoring Trustee's mandate. In particular, the Monitoring Trustee shall promptly report in writing to the Commission (sending CSL Vifor a non-confidential version at the same time) if it concludes on reasonable grounds that CSL Vifor is failing

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<sup>11</sup> In case of disagreement between the Monitoring Trustee and CSL Vifor, the matter shall be escalated to the Commission.

to comply with these Commitments. The Monitoring Trustee shall inform CSL Vifor promptly of the content of any oral reports to the Commission.

25. At the expense of CSL Vifor, the Monitoring Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to CSL Vifor's prior written approval (such approval not to be unreasonably withheld or delayed) if the Monitoring Trustee considers the appointment of such advisors necessary or appropriate for the performance of the mandate, provided that any fees and other expenses incurred by the Monitoring Trustee are reasonable. Should CSL Vifor refuse to approve the advisors proposed by the Monitoring Trustee the Commission may approve the appointment of such advisors instead, after having heard CSL Vifor. CSL Vifor is not entitled to issue instructions to the advisors. Such additional advisors must not have any conflict of interest with CSL Vifor.

**d. Duties and obligations of CSL Vifor**

26. CSL Vifor shall provide, shall cause its advisors to provide, and shall undertake best efforts to cause its Local Partners to provide the Monitoring Trustee with all such cooperation, assistance, and information as the Monitoring Trustee may reasonably require to perform the mandate, including for example access to internal documents, training documents, contact details of any healthcare professionals contacted by CSL Vifor and/or its Local Partners, as far as reasonably possible, in the context of the commercialisation of Ferinject in the EEA, management and other personnel, and facilities, except information protected under EU legal privilege rules.
27. All confidential information is provided by CSL Vifor to the Monitoring Trustee subject to due respect by the Monitoring Trustee of the confidentiality of such information.
28. On reasonable request and notice, CSL Vifor shall make available to the Monitoring Trustee appropriate offices on their premises. CSL Vifor shall be available for meetings in order to provide the Monitoring Trustee with all information necessary for the performance of the mandate.
29. CSL Vifor shall indemnify the Monitoring Trustee and its employees and agents, as well as its advisors, and hold each of them harmless against, and hereby agrees that they shall have no liability to CSL Vifor for, any liabilities arising out of the performance of the Monitoring Trustee of the mandate, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Monitoring Trustee, its employees, agents or advisors.
30. CSL Vifor agrees that the Commission may share any confidential information which is proprietary to CSL Vifor with the Monitoring Trustee. The Monitoring Trustee shall

not disclose such information and the principles contained in Article 28 of Regulation No. 1/2003 apply *mutatis mutandis*.

31. CSL Vifor agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties of the identity and the tasks of the Monitoring Trustee.
32. Without prejudice to the Commission's investigative powers set out in Regulation No. 1/2003, for the Commitment Period, the Commission may request all information from CSL Vifor that is reasonably necessary to monitor the effective implementation of these Commitments.

**e. Replacement, discharge, and reappointment of the Monitoring Trustee**

33. If the Monitoring Trustee ceases to perform its functions under the Commitments, ceases to perform its functions under the mandate, acts in breach of the mandate or for any other good cause, including the exposure of the Monitoring Trustee to a Conflict of Interest, which the Monitoring Trustee shall disclose to CSL Vifor and to the Commission without delay:
  - i) the Commission may, after hearing the Monitoring Trustee, require CSL Vifor to replace the Monitoring Trustee; or
  - ii) CSL Vifor may, with the prior approval of the Commission, replace the Monitoring Trustee. If the Monitoring Trustee is discharged according to paragraph 32, the Monitoring Trustee may be required to continue its mandate until a new Monitoring Trustee is in place to whom the Monitoring Trustee has effected a full hand over of all relevant information to carry out the mandate. The new Monitoring Trustee shall be appointed in accordance with the procedure referred to in paragraphs 14-20 (inclusive).
34. Unless removed in accordance with paragraph 32, the Monitoring Trustee shall cease to act as Monitoring Trustee only after the Commission has discharged it from the mandate at the end of the Commitment Period and after all the Commitments have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

**VII. Review**

35. Pursuant to Article 9(2)(a) of Regulation 1/2003, CSL Vifor may request the Commission to re-open the proceedings with a view to modifying these Commitments where there has been a material change in any of the facts on which the Commitment Decision was based, including if Article 102 TFEU is no longer applicable to CSL Vifor or if significant changes in the European regulatory or legislative framework support

the generation and publication of comparative Real World Evidence for a regulatory evaluation and potential inclusion in the SmPC.

**VIII. Commitment Period**

36. Unless provided otherwise, the term of these Commitments will be 10 years from the Entry Into Force.

April [ ], 2024

Duly authorized for and on behalf of CSL Vifor

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Hervé Gisserot, Senior Vice President and General Manager CSL Vifor

## **Appendix 1 – Stakeholder Communication**

*Subject: Clarifications In Relation To CSL Vifor’s Communications About Monofer*

*“Dear Sir/Madam,*

*As you may know, the European Commission has been investigating CSL Vifor in relation to potentially misleading communications comparing Ferinject to Monofer. This investigation has been concluded without an infringement finding against CSL Vifor or admission of liability from CSL Vifor. However, CSL Vifor has agreed to a number of commitments including that CSL Vifor disseminates this communication to you by mail and e-mail on two separate occasions within a 4-month period.<sup>12</sup>*

*In the context of its investigation, the European Commission raised preliminary concerns that CSL Vifor has been disseminating potentially misleading information regarding the safety of Monofer. In this regard, CSL Vifor makes the following clarifications in order to remove any possible confusion caused by its past communications about Monofer’s safety:*

- *There is no scientific basis to consider Ferinject to have a superior safety profile compared to Monofer.*
- *There is no basis to suggest that Monofer has a limited evidence base that would call into question its safety, which is apparent from Monofer’s marketing authorisation and from the successive reviews of intravenous iron medicines by the European Medicine Agency.*
- *Pursuant to Monofer’s SmPC, which was approved by the competent regulatory authorities, Monofer is not a dextran, dextran-derived, or dextran-based product. Furthermore, Monofer does not have increased risk of HSR compared to Ferinject.*

*We hope that this letter clarifies any potentially misleading past communications about Monofer.*

*Should you have any questions about the above or about any future communications by CSL Vifor on Monofer, please contact: [Confidential]*

*Sincerely,*

*CSL Vifor”*

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<sup>12</sup> Appendix 1 sent to Payors Stakeholders will be sent once and thus shall refer to “dissemination by mail and e-mail”.

## **Appendixes 1.1-1.23 – Stakeholder Communication**

### **Translations**

[To add Appendixes 1.1-1.23 for each official language within the EEA, namely Bulgarian, Croatian, Czech, Danish, Dutch, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish]

**Appendix 2 – Q&A**

[Confidential]

### **Appendix 3 – Categories Of Healthcare Professionals**

<b>AUSTRIA</b>	
<b>Description</b>	<b>Total</b>
<b>Prescribers</b>	
Anaesthesiology	[Confidential]
Dermatology	[Confidential]
Dietetics	[Confidential]
Dialysis	[Confidential]
Analysis	[Confidential]
Cardiology	[Confidential]
Clinical Serology & Transfusion Med	[Confidential]
Emergency Medicine	[Confidential]
General Medicine	[Confidential]
Internal Medicine	[Confidential]
Neurology	[Confidential]
Gynaecology	[Confidential]
Internship	[Confidential]
Genetics	[Confidential]
Geriatrics	[Confidential]
Nuclear Medicine	[Confidential]
Pathology	[Confidential]
Pneumology	[Confidential]
Ophthalmology	[Confidential]
Radiology	[Confidential]
Paediatrics	[Confidential]
Radiotherapy	[Confidential]
Psychiatry	[Confidential]
Rehabilitation	[Confidential]
Traumatology	[Confidential]
Surgery	[Confidential]
Toxicology	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Midwife	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>9907</b>

GERMANY	
Description	Total
<b>Prescribers</b>	
Analysis	[Confidential]
Angiology	[Confidential]
Anaesthesiology	[Confidential]
Biochemistry	[Confidential]
Cardiology	[Confidential]
Care Manager	[Confidential]
Biology	[Confidential]
Clinical Pharmacology	[Confidential]
Clinical Serology & Transfusion Med	[Confidential]
Dentistry	[Confidential]
Dermatology	[Confidential]
Endocrinology	[Confidential]
Ear-nose-throat diseases	[Confidential]
Dialysis	[Confidential]
Emergency Medicine	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
Genetics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Homeopathy	[Confidential]
Hygiene	[Confidential]
Internal Medicine	[Confidential]
Neurology	[Confidential]
Microbiology	[Confidential]
Miscellaneous	[Confidential]
Neonatology	[Confidential]
Nephrology	[Confidential]
Neuroradiology	[Confidential]
Non Conventional Medicine / Alternative Med	[Confidential]
Nuclear Medicine	[Confidential]
Occupational Health	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Orthodontology	[Confidential]
Orthopaedics	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Pathology	[Confidential]
Perinatology	[Confidential]
Pharmacology	[Confidential]
Phoniarty	[Confidential]
Pneumology	[Confidential]
Psychiatry	[Confidential]
Psychosomatic	[Confidential]
Psychotherapy	[Confidential]
Radiology	[Confidential]
Radiotherapy	[Confidential]
Rehabilitation	[Confidential]
Rheumatology	[Confidential]
Surgery	[Confidential]
Toxicology	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Nurse	[Confidential]
Medical Assistant	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
Other	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>86403</b>

<b>GERMANY</b>	
<b>Physician organisations</b>	
BNK: Bundesverband Niedergelassener Kardiologen	<a href="https://www.bnk.de/">https://www.bnk.de/</a>
DGK: Deutsche Gesellschaft für Kardiologie – Herz-und Kreislaufforschung e.V. – German Cardiac Society	<a href="https://dgk.org/">https://dgk.org/</a>
DGHO: Startseite – Deutsche Gesellschaft für Hämatologie und med. Onkologie e.V.	<a href="https://www.dgho.de/">https://www.dgho.de/</a>
BHI: Aktuelles – Bundesverband Hausärztlicher Internisten e.V.	<a href="https://www.hausarzt-bhi.de/aktuelles.html">https://www.hausarzt-bhi.de/aktuelles.html</a>
DGIM: Deutsche Gesellschaft für Innere Medizin e.V.	<a href="https://www.dgim.de/">https://www.dgim.de/</a>
DGN: Der Berufsverband für niedergelassene Nephrologinnen und Nephrologen	<a href="https://www.dnev.de/">https://www.dnev.de/</a>
DGVS: Deutsche Gesellschaft für Gastroenterologie, Verdauungs- und Stoffwechselkrankheiten	<a href="https://www.dgvs.de/">https://www.dgvs.de/</a>
BDA: Berufsverband Deutscher Anästhesisten e.V.	<a href="https://www.bda.de/">https://www.bda.de/</a>
<b>Pharmacist organisations</b>	
ABDA: Deutscher Apothekerverband (DAV)	<a href="https://www.abda.de/">https://www.abda.de/</a>
ADKA: Bundesverband Deutscher Krankenhausapotheker e.V.	<a href="https://www.adka.de/">https://www.adka.de/</a>

IRELAND	
Description	Total
<b>Prescribers</b>	
Adult Psychiatry	[Confidential]
Anaesthesiology	[Confidential]
Cardiology	[Confidential]
Care of the Elderly	[Confidential]
Clinical Pharmacology	[Confidential]
Diabetology	[Confidential]
Diabetology	[Confidential]
Dietetics	[Confidential]
Emergency Medicine	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
General Practice	[Confidential]
Geriatrics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Healthcare Administration	[Confidential]
Hepatology	[Confidential]
Histopathology	[Confidential]
Immunology	[Confidential]
Internal Medicine	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Orthopaedics	[Confidential]
Paediatrics	[Confidential]
Pathology	[Confidential]
Pneumology	[Confidential]
Psychiatry	[Confidential]
Radiology	[Confidential]
Rehabilitation	[Confidential]
Respiratory Medicine	[Confidential]
Rheumatology	[Confidential]
Surgery	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Midwife	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>1942</b>

FINLAND	
Description	Total
<b>Prescribers</b>	
Allergology	[Confidential]
Anaesthesiology	[Confidential]
Cardiology	[Confidential]
Care Manager	[Confidential]
Clinical Chemistry	[Confidential]
Dermatology	[Confidential]
Diabetology	[Confidential]
Diseases	[Confidential]
Emergency Medicine	[Confidential]
Endocrinology	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
Geriatrics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Insurance Medicine	[Confidential]
Intensive Care	[Confidential]
Internal Medicine	[Confidential]
Maternity	[Confidential]
Microbiology	[Confidential]
Miscellaneous	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Neurophysiology	[Confidential]
Nuclear Medicine	[Confidential]
Occupational Health	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Pain Care	[Confidential]
Pathology	[Confidential]
Perinatology	[Confidential]
Physiology	[Confidential]
Pneumology	[Confidential]
Psychiatry	[Confidential]
Radiology	[Confidential]
Radiotherapy	[Confidential]
Rehabilitation	[Confidential]
Rheumatology	[Confidential]
School Health Care	[Confidential]
Sports Medicine	[Confidential]
Student	[Confidential]
Substance Abuse	[Confidential]
Surgery	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Allied Health Professionals	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>7479</b>

NETHERLANDS	
Description	Total
<b>Prescribers</b>	
Anaesthesiology	[Confidential]
Assistant	[Confidential]
Cardiology	[Confidential]
Care Manager	[Confidential]
General Medicine	[Confidential]
Clinical Chemistry	[Confidential]
Dietetics	[Confidential]
Emergency Medicine	[Confidential]
Gastroenterology	[Confidential]
Geriatrics	[Confidential]
Gynaecology	[Confidential]
Internal Medicine	[Confidential]
Neurology	[Confidential]
Paediatrics	[Confidential]
Pneumology	[Confidential]
Radiology	[Confidential]
Rehabilitation	[Confidential]
Rheumatology	[Confidential]
Sports Medicine	[Confidential]
Surgery	[Confidential]
Technology	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>3089</b>

ROMANIA	
Description	Total
<b>Prescribers</b>	
Adult Psychiatry	[Confidential]
Anaesthesiology	[Confidential]
Cardiology	[Confidential]
Care of the Elderly	[Confidential]
Clinical Pharmacology	[Confidential]
Diabetology	[Confidential]
Diabetology	[Confidential]
Dietetics	[Confidential]
Emergency Medicine	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
General Practice	[Confidential]
Geriatrics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Healthcare Administration	[Confidential]
Hepatology	[Confidential]
Histopathology	[Confidential]
Immunology	[Confidential]
Internal Medicine	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Orthopaedics	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Pathology	[Confidential]
Pneumology	[Confidential]
Psychiatry	[Confidential]
Radiology	[Confidential]
Radiotherapy	[Confidential]
Rehabilitation	[Confidential]
Rheumatology	[Confidential]
Surgery	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non- Prescribers</b>	
Administrator	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>5189</b>

SWEDEN	
Description	Total
<b>Prescribers</b>	
Allergology	[Confidential]
Cardiology	[Confidential]
Company Health Care	[Confidential]
Clinical Chemistry	[Confidential]
Anaesthesiology	[Confidential]
Andrology	[Confidential]
Dermatology	[Confidential]
Diabetology	[Confidential]
Endocrinology	[Confidential]
Gastroenterology	[Confidential]
Emergency Medicine	[Confidential]
Esthetics and Cosmetology	[Confidential]
Dialysis	[Confidential]
Ear-nose-throat diseases	[Confidential]
Forensic Sciences	[Confidential]
General Medicine	[Confidential]
Haematology	[Confidential]
Intensive Care	[Confidential]
Geriatrics	[Confidential]
Internship	[Confidential]
Gynaecology	[Confidential]
Maternity	[Confidential]
Internal Medicine	[Confidential]
Miscellaneous	[Confidential]
Neuropsychiatry	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Nutrition Medicine	[Confidential]
Occupational Health	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Pain Care	[Confidential]
Physiology	[Confidential]
Pneumology	[Confidential]
Pharmacology	[Confidential]
Psychiatry	[Confidential]
Radiology	[Confidential]
Rehabilitation	[Confidential]
Unit	[Confidential]
School Health Care	[Confidential]
Rheumatology	[Confidential]
Surgery	[Confidential]
Urology	[Confidential]
Virology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Nurse	[Confidential]
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Midwife	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>6250</b>

SPAIN	
Description	Total
<b>Prescribers</b>	
Allergology	[Confidential]
Anaesthesiology	[Confidential]
Angiology	[Confidential]
Biochemistry	[Confidential]
Cardiology	[Confidential]
Family Medicine	[Confidential]
Care Manager	[Confidential]
Clinical Analyses	[Confidential]
Dermatology	[Confidential]
Endocrinology	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
Geriatrics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Immunology	[Confidential]
Intensive Care	[Confidential]
Internal Medicine	[Confidential]
Microbiology	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Nuclear Medicine	[Confidential]
Occupational Health	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Pathology	[Confidential]
Pharmacology	[Confidential]
Pneumology	[Confidential]
Preventive Medicine	[Confidential]
Psychiatry	[Confidential]
Radiology	[Confidential]
Radiotherapy	[Confidential]
Rehabilitation	[Confidential]
Rheumatology	[Confidential]
Sports Medicine	[Confidential]
Surgery	[Confidential]
Traumatology	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Allied Health Professionals	[Confidential]
Pharmacist	[Confidential]
Midwife	[Confidential]
Nurse	[Confidential]
Other	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>45576</b>

PORTUGAL	
Description	Total
<b>Prescribers</b>	
Allergology	[Confidential]
Anaesthesiology	[Confidential]
Anatomical Pathology	[Confidential]
Cardiology	[Confidential]
Clinical Analyses	[Confidential]
Dermatology	[Confidential]
Emergency Medicine	[Confidential]
Endocrinology	[Confidential]
Family Medicine	[Confidential]
Gastroenterology	[Confidential]
General Medicine	[Confidential]
Genetics	[Confidential]
Gynaecology	[Confidential]
Haematology	[Confidential]
Immunology	[Confidential]
Intensive Care	[Confidential]
Internal Medicine	[Confidential]
Internship	[Confidential]
Nephrology	[Confidential]
Neurology	[Confidential]
Neurosurgery	[Confidential]
Occupational Health	[Confidential]
Oncology	[Confidential]
Ophthalmology	[Confidential]
Orthopaedics	[Confidential]
Otorhinolaryngology	[Confidential]
Paediatrics	[Confidential]
Pathology	[Confidential]
Physical Medicine and Rehabili	[Confidential]
Pneumology	[Confidential]
Public Health	[Confidential]
Radiology	[Confidential]
Radioncology	[Confidential]
Rheumatology	[Confidential]
Sports Medicine	[Confidential]
Surgery	[Confidential]
Urology	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>Non-Prescribers</b>	
Administrator	[Confidential]
Chemist	[Confidential]
Nurse	[Confidential]
Pharmacist	[Confidential]
Pharmacist Assistant / Technician	[Confidential]
Paramedical	[Confidential]
<b>TOTAL</b>	[Confidential]
<b>GRAND TOTAL</b>	<b>12401</b>

## Appendix 4 – Payor Organizations

**Table 1. List of Payors in Germany**

<b>National Payor</b>
Gemeinsamer Bundesausschuss, G-BA (The Federal Joint Committee)
<b>Subnational Payors</b>
[Confidential]

**Table 2. List of Payors in Austria**

<b>National Payor</b>
Dachverband der österreichischen Sozialversicherungen, DSV (Austrian Social Insurance)
<b>Subnational Payors</b>
[Confidential]

**Table 3. List of Payors in The Netherlands**

<b>National Payor</b>
Zorginstituut Nederland, ZIN (The National Health Care Institute)
<b>Subnational Payors</b>
[Confidential]

**Table 4. List of Payors in Sweden**

<b>National Payor</b>
Tandvårds- och läkemedelsförmånsverket, TLV (The Dental and Pharmaceutical Benefits Agency)
<b>Subnational Payors</b>
[Confidential]

**Table 5. List of Payors in Finland**

<b>National Payor</b>
FIMEA (Finnish Medicines Agency)
<b>Subnational Payors</b>
[Confidential]

**Table 6. List of Payors in Ireland**

<b>National Payor</b>
National Centre for Pharmacoeconomics, NCPE
HSE national and regional offices
<b>Subnational Payors</b>
[Confidential]

**Table 7. List of Payors in Portugal**

<b>National Payor</b>
Autoridade Nacional do Medicamento e Produtos de Saude, I.P., INFARMED (National Authority of Medicines and Health Products)
<b>Subnational Payors</b>
[Confidential]

**Table 8. List of Payors in Spain**

<b>National Payor</b>
Dirección General de Farmacia, DGFPS (Directorate-General for Pharmacy)
<b>Subnational Payors</b>
[Confidential]

**Table 9. List of Payors in Romania**

<b>National Payor</b>
Agentia Nationala a Medicamentului, ANM (National Medicines Agency)
<b>Subnational Payors</b>
[Confidential]

### Appendix 5 – Leading Medical Journals

<b>Country</b>	<b>Medical Journal</b>
Austria	<a href="https://aerztezeitung.at">https://aerztezeitung.at</a>
Finland	<a href="https://www.laakarilehti.fi/english/">https://www.laakarilehti.fi/english/</a>
Germany	<a href="https://www.aerzteblatt.de/">https://www.aerzteblatt.de/</a> <a href="https://www.aerztezeitung.de/">https://www.aerztezeitung.de/</a> <a href="https://www.medical-tribune.de/">https://www.medical-tribune.de/</a> <a href="https://www.arzt-wirtschaft.de/">https://www.arzt-wirtschaft.de/</a>
Ireland	<a href="https://imj.ie/">https://imj.ie/</a>
Portugal	<a href="https://www.actamedicaportuguesa.com/eng/amp">https://www.actamedicaportuguesa.com/eng/amp</a>
Romania	<a href="https://www.medicina-interna.ro/">https://www.medicina-interna.ro/</a>
Spain	<a href="https://mgyf.org/">https://mgyf.org/</a>
Sweden	<a href="https://lakartidningen.se/">https://lakartidningen.se/</a>
The Netherlands	<a href="https://www.ntvg.nl/">https://www.ntvg.nl/</a>