Decision to accept commitments offered by Vifor in relation to the supply of high-dose intravenous iron

Case number 51377

23 May 2025

CMA
Competition & Markets Authority

[✂] Some information has been removed for confidentiality purposes.

CONTENTS

ANNEX

1. INTRODUCTION

1.1 In this decision (the '**Decision**') made under section 31A of the Competition Act 1998 (the '**CA98**'), the Competition and Markets Authority (the '**CMA**') accepts the commitments offered by Vifor Pharma UK Limited, Vifor Pharma Management Limited, Vifor Pharma Limited and CSL Limited ('**Vifor**'), as set out in the Annex to this decision (the '**Commitments**').

1.2 Vifor has not made any admission of wrongdoing, liability or infringement of the prohibition in section 18(1) of the CA98 (the '**Chapter II prohibition**'). Nevertheless, the Commitments were offered by Vifor to address the competition concerns identified by the CMA: namely, that between 2010 and 2024 (the '**Relevant Period**'), Vifor had engaged in conduct that may have abused a suspected dominant position in the market for the supply of high-dose intravenous ('**IV**') iron in the UK. Specifically, the CMA's competition concerns were that Vifor may have abused a suspected dominant position contrary to the Chapter II prohibition by making potentially misleading claims about the relative safety profile of Pharmacosmos' high-dose IV iron product (Monofer),[1] as compared with Vifor's own high-dose IV iron product (Ferinject) (the '**Suspected Conduct**').

1.3 The Commitments will ensure that:

(a) The potential adverse financial impact on the NHS arising from the Suspected Conduct will be addressed, through an ex gratia payment of £23 million to the NHS.

(b) Any potential confusion or misunderstanding arising from the Suspected Conduct will be clarified, through a multi-channel communication campaign to clarify the position in respect of the relative safety profile of Monofer (the '**Required Conduct**').

(c) Future dissemination of any potentially misleading claims relating to the relative safety profile of Monofer will be prevented, through various steps to ensure that Vifor's future promotional communications do not make claims about the safety profile of Monofer (the '**Prohibited Conduct**').

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[1] From 27 March 2023 until October 2024, Pharmacosmos sold Monofer under the name 'ferric derisomaltose Pharmacosmos': see, for example, the Summary of Product Characteristics last updated on 3 April 2023 and the Patient Information Leaflet last updated on 4 April 2023. Pharmacosmos now sells under the Monofer brand name again; see, for example, Summary of Product Characteristics dated 21 October 2024 on the website of the Medicines and Healthcare products Regulatory Agency.

1.4 This Decision follows a public consultation on proposed commitments offered by Vifor (the '**Proposed Commitments**'). On 10 December 2024, the CMA gave notice, under paragraph 2 of Schedule 6A to the CA98, that it intended to accept the Proposed Commitments offered by Vifor and invited views from persons likely to be affected (the '**Consultation**').

1.5 The CMA received four responses to the Consultation. A summary of the points raised in those responses is set out in Chapter 6 below.

1.6 Further to the CMA's consideration of responses to the Consultation, the CMA sought from Vifor minor revisions to the Proposed Commitments to:

(a) clarify the situation if the preferred medical journal (the BMJ[2]) declines to publish the Stakeholder Communication (defined in Chapter 5 below). In response, the Commitments were amended to include 'or other suitable leading medical journal'; and

(b) include the scientific name for each of Ferinject (ferric carboxymaltose) and Monofer (ferric derisomaltose) in the Stakeholder Communication.

1.7 Those revisions do not materially vary the Proposed Commitments.

1.8 For the reasons set out in this Decision, the CMA, having fully assessed in the round the evidence and responses to the Consultation against the factors set out in the Guidance on the CMA's investigation procedures in Competition Act 1998 cases (the '**Procedural Guidance**'),[3] has concluded that it is appropriate to accept the Commitments to address the competition concerns it has identified. As a result of accepting the Commitments, the CMA has discontinued its investigation (the '**Investigation**') with no decision made as to whether Vifor infringed the Chapter II prohibition.

1.9 Acceptance of the Commitments does not prevent the CMA from taking any action in relation to competition concerns which are not addressed by the Commitments. Further, acceptance of the Commitments would not prevent the CMA from restarting the Investigation, making an infringement decision, or giving a direction in circumstances where the CMA has reasonable grounds for:

- believing that there had been a material change of circumstances since the Commitments were accepted;

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[2] Formerly, the British Medical Journal.
[3] Guidance on the CMA's investigation procedures in Competition Act 1998 cases, (CMA8, 19 December 2024).

- suspecting that a person had failed to adhere to one or more of the terms of the Commitments; or
- suspecting that information which led the CMA to accept the Commitments was incomplete, false or misleading in a material particular.[4]

1.10 The possible consequences of failing to adhere to the Commitments are set out in sections 31E, 35A and 35B of the CA98. They include:

(a) a power for the CMA to impose a penalty on a person from whom the CMA has accepted the Commitments if the CMA considers that the person has, without reasonable excuse, failed to adhere to the Commitments;[5] and

(b) a power for the CMA to apply for a court order enforcing the Commitments if a person from whom the CMA has accepted the Commitments fails without reasonable excuse to adhere to the Commitments.[6]

1.11 The remainder of this Decision provides:

- an overview of the CMA's investigation (Chapter 2);
- background information regarding Vifor and the relevant market context (Chapter 3);
- details of the CMA's competition concerns (Chapter 4);
- a summary of the Commitments (Chapter 5);
- the CMA's assessment of whether the Commitments are appropriate in this case (Chapter 6);
- the CMA's decision to accept the Commitments (Chapter 7); and
- the text of the Commitments (Annex).

[4] Pursuant to section 31B of the CA98.
[5] CA98, section 35A. Any penalty will be calculated in accordance with section 35B of the CA98.
[6] CA98, section 31E.

2. THE CMA'S INVESTIGATION

A. The Investigation

2.1 On 31 January 2024, the CMA launched a formal investigation under section 25 of the CA98, having established there were reasonable grounds for suspecting that the Chapter II prohibition of the CA98 might have been infringed.

2.2 During the Investigation, the CMA undertook various investigative steps to gather evidence from Vifor and third parties. Those steps included sending formal notices requiring the production of documents and provision of information under section 26 of the CA98, as well as obtaining further information through other correspondence.

B. The European Commission's investigation

2.3 In June 2022, the European Commission opened an investigation into certain entities forming part of the Vifor undertaking concerning the Suspected Conduct covering several EEA countries[7] but excluding the UK.[8] In April 2024, the European Commission announced its intention to accept commitments that entities forming part of the Vifor undertaking had proposed to address the European Commission's competition concerns.[9] The European Commission adopted the proposed commitments in July 2024,[10] and published its decision on 6 November 2024.[11] Those commitments (the '**EC Commitments**') mirror the commitments that Vifor proposed to the CMA and that are the subject of this Decision, except for the proposed ex gratia payment to the NHS, which is specific to the UK.

C. Disputes between Pharmacosmos and Vifor

2.4 Separately, Pharmacosmos filed damages actions against Vifor in relation to the Suspected Conduct. In 2024, Vifor and Pharmacosmos reached a commercial settlement, which brought those actions to an end. The terms of that commercial settlement are confidential.

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[7] Austria, Finland, Germany, Ireland, Portugal, Romania, Spain, Sweden and The Netherlands.
[8] European Commission Press Release, 'Antitrust: Commission opens investigation into possible anticompetitive disparagement by Vifor Pharma of iron medicine', 20 June 2022, last accessed [20 May 2025].
[9] European Commission Press Release, 'Commission seeks feedback on commitments offered by Vifor over possible anticompetitive disparagement of iron medicine', 19 April 2024, last accessed [20 May 2025].
[10] European Commission Press Release, 'Commission accepts commitments by Vifor to address possible anticompetitive disparagement of iron medicine', 22 July 2024, last accessed [20 May 2025].
[11] Case AT.40577 – Vifor (IV iron products), Commission decision of 22 July 2024.

D. The Proposed Commitments

2.5 After the launch of the Investigation and following an offer of commitments made to the European Commission in its parallel investigation, Vifor indicated an intention to offer commitments to address the CMA's competition concerns. Accordingly, and in line with the Procedural Guidance,[12] the CMA proceeded to discuss with Vifor the scope of any commitments which the CMA considered would be necessary to address the competition concerns it had identified.

2.6 On 23 October 2024, Vifor provided proposed commitments to the CMA to address the CMA's competition concerns.

2.7 On 10 December 2024, the CMA issued a Notice of Intention to Accept Commitments (the '**NIAC**'), setting out its provisional view that the Proposed Commitments would address its competition concerns, and inviting interested third parties to give their views before the CMA would decide whether to accept the Proposed Commitments.

2.8 The Consultation ran until 17 January 2025, with the CMA receiving four responses. The responses to the Consultation and the CMA's consideration of them are summarised in Chapter 6 of this Decision.

E. The Commitments

2.9 Section 31A of the CA98 provides that, for the purposes of addressing the competition concerns it has identified, the CMA may accept, from such person or persons concerned as it considers appropriate, commitments to take such action (or refrain from taking such action) as it considers appropriate. The Procedural Guidance describes the circumstances in which the CMA is likely to consider it appropriate to accept commitments and the process by which parties to an investigation may offer commitments to the CMA.[13]

2.10 In accordance with the Procedural Guidance, a business under investigation can offer commitments at any time during the course of the investigation until a decision on infringement is made. In this case, no decision on infringement has been made.

2.11 The Commitments are set out in the Annex to this Decision.

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[12] Procedural Guidance, paragraph 10.22.
[13] Procedural Guidance, paragraphs 10.18 to 10.30.

2.12 Having considered the Commitments, along with responses to the Consultation, the CMA considers that they address its competition concerns for the reasons set out in this Decision, and that it is appropriate for the CMA to close the Investigation by way of a formal decision accepting the Proposed Commitments. As a result, the CMA has closed the Investigation, and will not proceed to a decision on whether or not the Suspected Conduct infringed the Chapter II prohibition.

3. BACKGROUND

A. The party under investigation

3.1 Vifor is a global pharmaceutical company active in the supply of, among other products, IV iron. In the UK, Vifor is active through Vifor Pharma UK Limited, whose ultimate parent company is CSL Limited, which is registered in Australia. Vifor Pharma Limited (a Swiss-based company), the immediate parent company of and the previous ultimate parent company of Vifor Pharma UK Limited, was acquired by CSL Limited in 2022.

B. Industry background

3.2 Iron deficiency and iron deficiency anaemia are conditions where a lack of iron in the body reduces the number of red blood cells, causing complications such as heart failure, impaired muscular performance, and adverse effects on immune status and morbidity from infection. In the UK, it is estimated that 3% of men and 8% of women have iron deficiency anaemia.[14]

3.3 In many cases, the first line of treatment for iron deficiency and iron deficiency anaemia is oral iron supplements, such as iron tablets that patients swallow and can take without needing to visit a healthcare professional ('**HCP**').[15] However, for some patients, oral therapy is either inappropriate or ineffective.[16] For such patients, iron instead tends to be administered by IV injection or infusion. IV iron has to be administered by trained staff in a clinical setting.[17]

3.4 IV iron products can be distinguished by how much iron can be given to a patient in a single clinic or hospital visit. A distinction exists between high-dose and low-dose IV iron products, with high-dose IV iron products requiring less clinic or hospital visits to achieve iron repletion.[18] The Investigation concerns high-dose IV iron products only.

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[14] See, for example, National Institute for Health and Care Excellence (NICE), 'Anaemia – iron deficiency – How common is it?', last accessed [20 May 2025].
[15] Healthcare professionals include, among others, consultants, nurses, pharmacists and specialists.
[16] https://bnf.nice.org.uk/treatment-summaries/anaemia-iron-deficiency/, last accessed [20 May 2025].
[17] Intravenous iron and serious hypersensitivity reactions: strengthened recommendations - GOV.UK, last accessed [20 May 2025].
[18] For example, a patient may only require one or two clinic or hospital visits with a high-dose IV iron product to replenish iron, as compared to low-dose IV iron products, which may require many more administrations.

3.5 Currently and throughout most of the Relevant Period, there are only two high-dose IV iron products available in the UK:

(a) Ferinject (scientific name: ferric carboxymaltose), sold by Vifor; and

(b) Monofer (scientific name: ferric derisomaltose, also known as iron isomaltoside 1000), sold by Pharmacosmos.[19]

3.6 NHS Trusts[20] and hospitals are the main customers of high-dose IV iron products in the UK. HCPs can prescribe and administer high-dose IV iron for patients where high-dose IV iron products are on a formulary.[21] HCPs therefore act as the key decision maker for which treatment a patient receives.

Competition between pharmaceutical products

3.7 When selecting a treatment for a patient, HCPs may take a number of factors into account besides price. These factors include product characteristics, such as safety, efficacy, convenience and administration regimes.

3.8 The understanding of a medicine's safety will likely affect a HCP's willingness to prescribe, dispense and administer it, as well as a patient's readiness to accept it.[22]

3.9 In respect of branded medicines, a key feature of competition between medicines suppliers is the advertising and/or promoting of their medicines to HCPs.

3.10 The advertising and promotion of prescription-only medicines in the UK is governed by both regulations[23] and an industry voluntary code – the Association of the British Pharmaceutical Industry Code of Practice for the Pharmaceutical Industry (the '**ABPI Code**') – which is administered and

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[19] A third high-dose IV iron product (Rienso (scientific name: ferumoxytol), sold by Takeda) was approved for use in the EU (including in the UK) in June 2012, before being voluntarily withdrawn in March 2015 for commercial reasons.

[20] NHS Trusts are organisational units within the NHS in the UK.

[21] A formulary is a repository of medicines approved for use for a specific NHS Trust.

[22] For example, the EU Court of Justice recognised that, 'given the characteristics of the medicinal products market', it is likely that the dissemination of misleading information about a medicine's safety profile would 'encourage doctors to refrain from prescribing that product, thus resulting in the expected reduction in demand for that type of use': Case C-179/16, *F. Hoffmann-La Roche and Novartis v Autorità Garante della Concorrenza e del Mercato*, ECLI:EU:C:2018:25, paragraph 93.

[23] Relevant regulations are primarily overseen and enforced by the Medicines and Healthcare products Regulatory Agency.

overseen by the Prescription Medicines Code of Practice Authority (the '**PMCPA**').[24]

3.11 The ABPI Code explicitly recognises the importance of information presented to HCPs through advertising and promotional activity, particularly information related to safety, being balanced, accurate and complete.[25] This is to be expected given that HCPs are primarily concerned with safely and effectively treating a patient's condition to help improve their quality of life. It is important that HCPs are provided with accurate information regarding a medicine's clinical characteristics and are not provided with misleading information regarding matters such as its safety. As is explained in Chapter 4 below, from a competition law perspective, where the supplier of a medicine holds a dominant position, it risks abusing that dominance if it provides false or misleading information regarding the safety of a competing treatment.

C. The relevant market

3.12 In assessing the impact on competition, the CMA considered the competitive constraints faced by suppliers of high-dose IV iron treatment in the UK. The CMA considered the substitutability of high-dose and low-dose IV iron treatment, as well as the substitutability between high-dose IV iron treatment and oral iron.

3.13 HCPs will typically choose which treatment to give to a patient based on what is therapeutically most appropriate and effective (that is, the treatment available that would best treat a patient's condition).

3.14 The CMA considers that:

(a) Low-dose IV iron treatments are significantly differentiated from high-dose IV iron treatments, such that they are only an effective substitute in limited circumstances.

(b) There appears to be limited demand-side substitutability between oral iron and high-dose IV iron treatments. These treatments appear to have significantly different profiles, are used in different clinical settings,

[24] The PMPCA is a self-regulatory body which administers the ABPI Code, covering the promotion of medicines for prescribing to both HCPs and other relevant decision makers. Members of the Association of the British Pharmaceutical Industry (the '**ABPI**'), a trade association for pharmaceutical companies in the UK, are required to adhere to the ABPI Code. More information on the PMPCA can be found on its website. The ABPI Code has undergone a number of iterations over the years and the most recent version came into effect in October 2024. Since the 2024 version of the ABPI Code was only adopted towards the end of the Relevant Period, the CMA refers to the provisions of the 2021 version in this Decision.
[25] 2021 ABPI Code, Clause 6(1).

and have distinct therapeutic uses, with high-dose IV iron being prescribed in circumstances where oral iron is ineffective or unsuitable.

3.15 On that basis, the CMA's preliminary view is that the relevant product market is no wider than the supply of high-dose IV iron.

3.16 In line with its previous decisions relating to the supply of medicines, the CMA's preliminary view is that the relevant geographic market is the UK.

D. Vifor's position on the relevant market

3.17 The CMA's preliminary view is that Vifor held a dominant position during the Relevant Period in the market for the supply of high-dose IV iron in the UK, on the basis of:

(a) high and stable market shares, with Ferinject having consistently held market shares of above 50% both by value and volume throughout the Relevant Period;

(b) its pricing behaviour, as reflected in its ability to sustain a constant price premium for Ferinject over Monofer throughout the Relevant Period; and

(c) other relevant factors including high barriers to entry (particularly the time and investment needed to develop and introduce a new product) and expansion (particularly the need to establish a reputation that the product is safe and effective), and the absence of sufficient countervailing buyer power.

E. The Suspected Conduct

3.18 Vifor started selling Ferinject in the UK in 2007.[26] At that point, Ferinject was the only high-dose IV iron product available in the UK.[27] In 2010, Monofer entered the UK market as an alternative high-dose IV iron treatment to Ferinject.

[26] Vifor initially sold Ferinject in the UK through a distributor, before establishing its own UK affiliate and selling directly in the UK from 2010.
[27] Both low-dose IV iron products and oral iron products were available in the UK when Ferinject entered the UK market.

Suspected misleading claims

3.19 In response to the competitive threat posed by Monofer's entry, Vifor appeared to have engaged in a communication campaign that included making potentially misleading claims about the safety of Monofer to HCPs in the UK (the '**Claims**').

3.20 The Claims focused on the relative safety profile of Monofer as compared to Ferinject and may have called into question the safety of using Monofer. In particular:

(a) A claim that Monofer was a dextran, dextran-based or dextran-derived product, as compared to Ferinject being dextran-free. Those communications may have linked Monofer with historical negative safety connotations associated with earlier generation dextran-based IV iron products, which carried a higher risk of adverse events when administered to patients.[28]

(b) A claim that Monofer was associated with a higher incidence of hypersensitivity reactions[29] as compared to Ferinject.

Decisions by the Prescription Medicines Code of Practice Authority

3.21 The Suspected Conduct was the subject of a number of adverse findings by the PMCPA and its Appeal Board in the period 2008 to 2024. These decisions found that Vifor disseminated misleading claims about the safety of both Monofer and Ferinject to HCPs in the UK during the Relevant Period.[30]

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[28] See, for example, Michael Auerbach and Iain C. Macdougall, 'Safety of intravenous iron formulations: facts and folklore' Blood Transfus. 2014 Jul;12(3): 296-300.

[29] Hypersensitivity reactions (also called allergic reactions) refer to undesirable reactions produced by the normal immune system, including allergies and autoimmunity. These reactions may be damaging, uncomfortable, or occasionally fatal. Hypersensitivity reactions are often graded by severity. See, for example: Annex II, Assessment report for: Iron containing intravenous (IV) medicinal products, European Medicines Agency ('**EMA**'), p.36.

[30] See, for example, the following decisions of the PMCPA: PMCPA case report AUTH/2442/10/11 Pharmacosmos v Vifor, last accessed [20 May 2025]; PMCPA case report AUTH/2828/3/16 - Clinical Nurse Specialist v Vifor, last accessed [20 May 2025]; PMCPA case report AUTH/2830/3/16 - Pharmacosmos v Vifor, last accessed [20 May 2025]; and PMCPA case report, AUTH/3224/7/19 - Pharmacosmos v Vifor, last accessed [20 May 2025].

4. THE CMA'S COMPETITION CONCERNS

4.1 For the reasons set out below, the CMA was concerned that the Suspected Conduct is likely to amount to an abuse of a suspected dominant position, contrary to the Chapter II prohibition of the CA98.

A. Dissemination of misleading claims as an abuse

4.2 Section 18(2) of the CA98 sets out a list of conduct that may amount to an abuse of a dominant position. This list, however, is not exhaustive and the courts have consistently held that the categories of abuses are not closed.[31]

4.3 The dissemination of misleading claims by dominant undertakings to public authorities, HCPs, customers and other relevant stakeholders in the pharmaceutical context could fall outside of competition on the merits and, therefore, constitute an abuse of a dominant position in certain circumstances: for instance, where the misleading claims relate to a relevant parameter of competition, or otherwise artificially raise barriers to competitors seeking to compete on the merits.[32]

4.4 The assessment of whether a claim is misleading (and therefore potentially abusive) must also account for the specific circumstances of a case, including the applicable regulatory framework.[33] The advertising of medicines in the UK is governed by applicable regulations, which help inform what might constitute a misleading claim within the pharmaceutical context. In particular, '[a]ll advertising and promotion of medicines, both for self-medication and to healthcare professionals where medical prescription is required, must be responsible and of the highest standard'.[34]

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[31] Case 6/72, *Europemballage Corp and Continental Can Co Inc v Commission*, EU:C:1973:22, paragraph 26; Case C-333/94P, *Tetra Pak v European Commission*, EU:C:1996:436, paragraph 37. See also Case HC-2013-000090, *Streetmap.eu Limited v. Google*, [2016] EWHC 253 (Ch), paragraph 58.

[32] See, for example, Case C-457/10 P, *AstraZeneca v Commission*, EU:C:2012:770, paragraphs 18, 62, 98 and 105-113. The EU Court of Justice and General Court upheld the European Commission's finding that the misleading representations by AstraZeneca to national authorities could lead them wrongly to extend the patent protection for its drug omeprazole, thereby hindering the entry of generic competition. The Court of Justice held that a dominant undertaking that has 'recourse to highly misleading representations with the aim of leading public authorities into error' is 'manifestly not consistent with competition on the merits and the specific responsibility on such an undertaking not to prejudice, by its conduct, effective and undistorted competition'.

[33] Case C-165/19 P, *Slovak Telekom*, EU:C:2021:239 paragraphs 42 and 54-57 ('it should be considered that a regulatory obligation can be relevant for the assessment of abusive conduct, for the purposes of Article 102 TFEU, on the part of a dominant undertaking that is subject to sectoral rules').

[34] See chapter 1.3 (Regulation of advertising) of The Blue Guide (*Advertising and Promotion of Medicines in the UK*), published and maintained by the Medicines and Healthcare products Regulatory Agency, Third Edition, third version published in August 2012, last updated in November 2020.

4.5 The Human Medicines Regulations 2012[35] provide that (emphasis added below in bold):

(a) 'A person may not publish an advertisement for a medicinal product unless the advertisement encourages the rational use of the product by **presenting it objectively and without exaggerating its properties**'.[36]

(b) 'A person may not publish an advertisement for a medicinal product that is misleading'.[37]

(c) 'A person may not include any information in written material' as part of the promotion of a medicinal product unless it is '**accurate**', '**up-to-date**', '**can be verified**' and '**sufficiently complete to enable the recipient to form an opinion of the therapeutic value of the product to which it relates**'.[38]

4.6 The ABPI Code similarly provides that (emphasis added below in bold):

(a) 'Information, claims and comparisons must be **accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly**' and '**must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis**'.[39]

(b) '**A comparison is only permitted in promotional material if: it is not misleading**' and '[p]romotion must encourage the rational use of a medicine by **presenting it objectively and without exaggerating its properties**'.[40]

4.7 Accordingly, the applicable medicinal advertising rules specifically reflect the need for suppliers to compete on the basis of clear, accurate, verifiable and non-misleading information, and to ensure that comparisons with competing products do not mislead, distort or exaggerate. This is important background for assessing whether the Suspected Conduct was consistent with competition on the merits in this sector.

4.8 Against this regulatory context, a dominant pharmaceutical company that makes misleading statements about the safety and other relevant

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[35] The Human Medicines Regulations 2012.
[36] 2012 Regulations, Regulation 280(2).
[37] 2012 Regulations, Regulation 280(3).
[38] 2012 Regulations, Regulation 297.
[39] 2021 ABPI Code, Clause 6(1).
[40] 2021 ABPI Code, Clauses 14.1 and 14.4.

characteristics of a rival product, including to HCPs, does not compete on the merits.

4.9 Once it has been established that a dominant undertaking's claims are misleading, it is not necessary to show that the targeted recipients of the misleading claims were in fact misled by them.[41] Rather, it is sufficient to show that the misleading claims, at the time they were made, were capable of restricting competition.

4.10 Where misleading claims are made as part of a strategy designed with the objective of hindering the uptake of a competing product, this will be strong evidence of their capability to restrict competition at the time they were made.

4.11 Accordingly, conduct by a dominant undertaking can constitute an abuse of a dominant position where it:

(a) consists in the dissemination of objectively misleading information; and

(b) is capable of restricting competition.

B. The CMA's competition concerns regarding the Suspected Conduct

4.12 The CMA's competition concerns arose from the Suspected Conduct and reflected the evidence that the CMA has reviewed to date.

4.13 As set out above, the CMA's preliminary view was that, during the Relevant Period, Vifor held a dominant position in the market for the supply of high-dose IV iron products in the UK.

4.14 For the reasons set out below, the CMA was concerned that Vifor may have abused a suspected dominant position by making potentially misleading claims to HCPs in the UK about the relative safety of Monofer as compared to Ferinject. In particular, the CMA's preliminary view was that Vifor made the following claims, directly or indirectly, including by implication through the selective or incomplete presentation of information, to HCPs during the Relevant Period:

(a) Monofer was a dextran, dextran-based or dextran-derived product, as compared to Ferinject being dextran-free; and

[41] Case C-457/10 P, *AstraZeneca v Commission*, EU:C:2012:770, paragraph 111.

(b) Monofer was associated with a higher incidence of hypersensitivity reactions as compared to Ferinject.

4.15 The CMA, having regard to the decisions of both the PMCPA and its Appeal Board, was concerned that the Claims may have been objectively misleading because they were inaccurate, unsupported by the respective Summary of Product Characteristics ('**SmPC**') for Ferinject and Monofer,[42] inconsistent with findings and decisions by relevant health authorities (notably the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency) and/or were otherwise unsupported or contradicted by clinical or scientific evidence. The CMA also notes that Vifor agreed to issue clarifications to HCPs clarifying these Claims as part of the EC Commitments.

4.16 The CMA's preliminary view was that the Claims were specifically intended to influence decisions by relevant HCPs as to whether to select Ferinject or Monofer, and that Vifor would have been aware that HCPs were guided by safety considerations in making such decisions. In these circumstances (and based on the evidence reviewed so far), the CMA was concerned that the Claims were capable of influencing the decisions of HCPs and, as a result, capable of having an effect on competition between Ferinject and Monofer.

4.17 For the purposes of demonstrating an infringement, it is not necessary to show that the Suspected Conduct produced actual effects or resulted in harm to the NHS as the ultimate purchaser of high-dose IV iron products. However, the CMA was also concerned that, by impacting the ability of Monofer to compete effectively with Ferinject, the Claims could have had a financial impact on the NHS. This is because:

(a) Monofer was cheaper than Ferinject throughout the Relevant Period; and

(b) for some patients, Monofer was cheaper to administer[43] than Ferinject because Monofer had a higher maximum single dose compared to Ferinject and therefore required fewer infusions and hospital visits per patient than Ferinject.

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[42] Summaries of Product Characteristics (SPCs or SmPCs) is a description of a medicinal product's properties and the conditions attached to its use. It explains how to use and prescribe a medicine. It is used by HCPs. See, for example: Find product information about medicines - GOV.UK, last accessed [20 May 2025].
[43] The cost of administering a high-dose IV iron treatment includes not only the cost of the medicine but also, among other things, staff costs and consumables (such as cannulas and wound dressings).

5. THE COMMITMENTS

5.1 In this section, the CMA summarises the Commitments (which are set out in full in the Annex to this Decision).

A. The payment to the Department of Health and Social Care[44]

5.2 Under the Commitments, Vifor will make an ex gratia payment of £23 million to the NHS, via the Department of Health and Social Care (the '**DHSC**') within 20 working days from the date when the CMA notifies Vifor of its Commitments Decision.

5.3 [✂].

B. The Communication Campaign[45]

5.4 Under the Commitments, Vifor will undertake a comprehensive, multi-channel clarification communication campaign (the '**Communication Campaign**') which aims at addressing and clarifying the potentially harmful effects of the Suspected Conduct (the '**Required Conduct'**).

5.5 As part of the Required Conduct, Vifor will:

(a) disseminate a clarificatory communication (the '**Stakeholder Communication**')[46] via mail and e-mail (where e-mail addresses are available) to a number of HCPs[47] and the Chief Pharmacist or person with equivalent responsibilities at various NHS Trusts[48] in the UK;

(b) publish the Stakeholder Communication on Vifor's UK website (www.cslvifor.uk) for a period of 36 calendar months;

(c) publish the Stakeholder Communication in the BMJ or other suitable leading medical journal as soon as reasonably practicable;

(d) allow third parties, including Pharmacosmos, to use the Stakeholder Communication;

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[44] Commitments, Section III.
[45] Commitments, Section IV.
[46] Contained in Commitments, Appendix 1.
[47] Listed in Commitments, Appendix 3
[48] Listed in Commitments, Appendix 4.

(e) deliver the Stakeholder Communication in hard copy to each HCP[49] in the UK during the first in-person meeting which takes place in the ordinary course of business; and

(f) respond to any follow-up questions received from HCPs[50] and NHS Trusts[51] relating to the content of the Stakeholder Communication in line with the Q&A document.[52]

5.6 The first mail and e-mail Communication Campaign with HCPs[53] and NHS Trusts[54] in the UK shall take place in May 2025. The second mail and e-mail Communication Campaign with HCPs in the UK shall take place in July 2025. The third mail and e-mail Communication Campaign with HCPs in the UK shall take place in September 2025.[55]

C. Forwarding-looking commitments[56]

5.7 Under the Commitments, Vifor will not engage in the UK in external promotional communications and external medical communications, in writing or orally, about Monofer's safety profile containing information that is

(a) not based in Monofer's SmPC, or

(b) not derived from randomised, controlled clinical head-to-head trials between Ferinject and Monofer (together the '**Prohibited Conduct**').

5.8 Further, Vifor will implement a number of measures and safeguards to ensure compliance with the Prohibited Conduct. This includes setting up:

(a) an internal mechanism to ensure that all relevant external promotional and medical communications in the UK, as well as internal training materials, are in line with the Commitments prior to their use;

(b) a dialogue process between Vifor and Pharmacosmos, as well as the Monitoring Trustee, to allow Pharmacosmos to raise and discuss in good faith any alleged deviations from the Commitments in the UK;

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[49] Listed in Commitments, Appendix 3.
[50] Listed in Commitments, Appendix 3.
[51] Listed in Commitments, Appendix 4.
[52] Contained in Commitments, Appendix 2.
[53] Listed in Commitments, Appendix 3.
[54] Listed in Commitments, Appendix 4.
[55] This only applies to HCPs in the UK who did not receive the Stakeholder Communication during the first or second mail and e-mail Communication Campaigns.
[56] Commitments, Section V.

(c) an internal mechanism to review and, if appropriate, withdraw or correct any potential unauthorised communications made by Vifor;

(d) annual internal compliance training on good promotional and medical communications practice and compliance with the Commitments; and

(e) an annual compliance statement at the end of each calendar year attesting to compliance with the Commitments.

5.9 The annual internal compliance training and annual compliance statement must be carried out by Vifor's senior management in the UK with responsibility for Ferinject and all Vifor Sales Field Force[57] and medical scientific liaison personnel involved with Ferinject in the UK.

D. Non-circumvention[58]

5.10 Under the Commitments, Vifor shall not circumvent, either directly or indirectly by any act or omission, any obligations contained in the Commitments.

E. Duration

5.11 The term of the Commitments will be until 22 July 2034.[59] This is subject to any earlier variation or release pursuant to sections 31A(3) and 31A(4) of the CA98 or in accordance with paragraphs 10 to 13 of the Commitments (discussed below).

F. Compliance, monitoring and reporting[60]

5.12 The Commitments provide that an independent monitoring trustee (the '**Monitoring Trustee**') will be appointed to monitor compliance with the Commitments. The CMA will have discretion to approve or reject the appointment of the Monitoring Trustee and its proposed mandate.

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[57] Third-party contracted field force and customer engagement managers engaged in external promotional communications about Ferinject with HCP Stakeholders in the UK.
[58] Commitments, Section VI.
[59] The end date for the Commitments is aligned with the end date for the EC Commitments. The EC Commitments last for 10 years from the date on which they were adopted. Because the EC Commitments are already in force, the remaining duration is less than 10 years.
[60] Commitments, Sections VII and VIII.

5.13 Under the Commitments, the Monitoring Trustee shall provide the CMA with written reports on the fulfilment of the Monitoring Trustee's obligations and Vifor's compliance with the Commitments.

5.14 As part of the Commitments, Vifor will:

(a) Provide and cause its advisors to provide the Monitoring Trustee with all such co-operation, assistance, and information as the Monitoring Trustee may reasonably require to perform the mandate. For instance, the Monitoring Trustee shall have access to internal documents, training documents, contact details of any HCPs contacted by Vifor, as far as reasonably possible, in the context of the commercialisation of Ferinject in the UK, management and other personnel, and facilities, except information protected under legal privilege rules.

(b) Make available to the Monitoring Trustee appropriate offices on Vifor's premises, on reasonable request and notice, and meet with the Monitoring Trustee to provide all necessary information for the performance of the mandate.

(c) Agree that the contact details of the Monitoring Trustee are published on the CMA's website and inform interested third parties of the identity and the tasks of the Monitoring Trustee.

(d) Comply with any requests by the CMA to provide specified documents or information which the CMA considers reasonably necessary to monitor the effective implementation of the Commitments.

5.15 Finally, Vifor will provide the CMA and the Monitoring Trustee with:

(a) A report on the implementation of the Required Conduct within 30 working days of the completion of each Communication Campaign.

(b) Another report on the implementation of the measures related to the Prohibited Conduct no later than 30 working days from the end of each calendar year.

(c) A report on potential unauthorised communications and suggest adequate remediation measures, where appropriate, within 15 working days from when Vifor becomes aware of the potential unauthorised communications. The remedial measures must then be implemented within 30 working days.

6. THE CMA'S ASSESSMENT OF THE COMMITMENTS AND THE CONSULTATION RESPONSES

6.1 For the reasons set out below, the CMA considers that accepting the Commitments would be an appropriate way to address its competition concerns.

A. The CMA's Guidance

6.2 Pursuant to section 31A of the CA98, for the purposes of addressing the competition concerns it has identified, the CMA may accept from such person (or persons) as it considers appropriate, commitments to take such action (or refrain from taking such action) as it considers appropriate.

6.3 The Procedural Guidance states that the CMA is likely to consider it appropriate to accept commitments only in cases where:

(a) the competition concerns are readily identifiable;

(b) the competition concerns will be addressed by the commitments offered; and

(c) the commitments can be implemented effectively, and, if necessary, within a short period of time.[61]

6.4 The CMA will not accept commitments where:

(a) compliance with them and their effectiveness would be difficult to discern; and/or

(b) the CMA considers that not to complete its investigation and make a decision would undermine deterrence.[62]

B. The CMA's assessment

6.5 The CMA has assessed the Commitments against the criteria referred to in paragraph 6.3 of this Decision, having also taken into account all the relevant evidence including views received in response to the Consultation, and sets out its conclusions below.

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[61] Procedural Guidance, paragraph 10.19.
[62] Procedural Guidance, paragraph 10.21.

Whether the competition concerns are readily identifiable

6.6 The CMA considers that the competition concerns are readily identifiable. The Claims giving rise to those competition concerns are set out in Chapter 4 of this Decision.

Whether the Commitments address the CMA's competition concerns

6.7 The CMA considers that the Commitments, once implemented, will address the CMA's competition concerns in relation to the Suspected Conduct:

(a) The Required Conduct, comprising the Communication Campaign (as set out in Section IV of the Commitments), will clarify the Claims in order to remove any confusion. This will remedy any possible ongoing confusion or misunderstanding caused by the Claims regarding the relative safety of Monofer, and ensure that competition between Monofer and Ferinject is not distorted by the ongoing impact of the Claims.

(b) The Prohibited Conduct (as set out in Section V of the Commitments) will prevent future dissemination of the Claims to HCPs for approximately 10 years. The Commitments will comprehensively prevent the Claims from being repeated in the future. Vifor has also committed to a number of measures (as set out in paragraph 5.8 of this Decision) that will help ensure ongoing compliance with the Commitments.

6.8 Vifor Pharma does not accept that the NHS has suffered harm, but is prepared to make an ex gratia payment. The ex gratia payment by Vifor of £23 million to the NHS will address the CMA's concerns that the Claims may have had an adverse financial impact on the NHS, as described in paragraph 4.17 of this Decision. In particular, the CMA considers that the payment reflects the range of potential financial harm suffered by the NHS as a result of the Suspected Conduct, and is high enough to ensure that deterrence is not undermined.

Whether the Commitments are capable of being implemented effectively and, if necessary, within a short period of time

6.9 The CMA considers that the Commitments would be capable of being implemented effectively and within a reasonable period of time.

6.10 Vifor has undertaken to act in accordance with the Commitments from the date the CMA notifies Vifor of its decision to accept the Commitments.

6.11 Vifor commits to undertake a Communication Campaign in order to comply with the Required Conduct. This will be implemented in various stages as set out in paragraph 5.6 of this Decision. The content of the Communication Campaign has already been drafted and agreed between Vifor and the European Commission (see Appendix 1 of the Commitments) and therefore, this element of the Commitments is capable of being implemented effectively, within the proposed timescales. Further, Vifor's effective compliance with the Required Conduct will be subject to the monitoring obligations set out in paragraphs 5.14 and 5.15 of this Decision.

6.12 From entry into force of the Commitments, Vifor commits not to engage in the Prohibited Conduct. The obligations on Vifor are clear and, therefore, this element of the Commitments can be implemented within a very short time frame. Vifor will implement the measures and safeguards set out in paragraph 5.8 of this Decision in order to ensure compliance with the Commitments. These will be reviewed by the Monitoring Trustee within 45 days of its appointment.

6.13 Regarding the ex gratia payment to the NHS, Vifor will make this payment in full within 20 working days from the date the CMA notifies Vifor of its decision to accept the Commitments, which the CMA considers is timely implementation.

6.14 The CMA also notes that the EC Commitments have been or are being implemented in the EEA already. Accordingly, the effective and speedy implementation of the Commitments in the UK should benefit from the progress that has already been made by Vifor in implementing the EC Commitments.

Whether compliance with the Commitments and their effectiveness would be difficult to discern

6.15 The CMA considers that the monitoring and reporting processes that will be implemented and undertaken pursuant to Sections VII and VIII of the Commitments mean that Vifor's compliance with the Commitments and their effectiveness will not be difficult to discern.

6.16 Vifor's compliance with the Commitments will be carefully monitored, as described in paragraph 5.15 of this Decision.

6.17 The CMA further notes that:

(a) it is incumbent on Vifor to undertake best efforts to co-operate with, assist and provide the Monitoring Trustee with all such information it reasonably requires to perform the mandate and monitor compliance;

(b) the CMA will engage with the Monitoring Trustee and Vifor throughout the duration of the Commitments regarding the monitoring of compliance; and

(c) Vifor may be required by the CMA to produce specified documents and/or information which the CMA considers relates to any matter relevant to the exercise of its powers set out in Chapter III of the CA98 should Vifor decline any request for information made by the Monitoring Trustee.

Whether acceptance of the Commitments would undermine deterrence

6.18 The CMA will not accept commitments if it considers that not completing its investigation and proceeding to an infringement decision would undermine deterrence.[63] The CMA has considered deterrence both specifically in relation to Vifor, and more generally in relation to other business which might consider engaging in similar conduct.

6.19 The CMA considers that a decision to accept the Commitments will not undermine deterrence regarding Vifor. The Commitments place a material burden on Vifor to address any ongoing effect of the Claims, and condition its conduct going forward. Additionally, the CMA considers that the payment to the NHS is of a level sufficient to ensure that deterrence is not undermined.

6.20 The CMA is also concerned to avoid undermining deterrence for other businesses which might seek a competitive advantage by making misleading claims or providing misleading information to customers. Making misleading claims about competing products has the potential to prevent customers from taking informed choices, to disincentivise entry or expansion and generally to distort competition. The CMA considers that its Investigation and the Commitments, which include a significant payment to the NHS, send a strong signal to businesses that the CMA takes this type of conduct extremely seriously. This Decision also indicates to businesses how the CMA will assess this type of conduct in the future.

[63] Procedural Guidance, paragraph 10.21.

6.21 Finally, acceptance of the Commitments would not preclude the CMA from investigating and potentially taking enforcement action (including taking an infringement decision and imposing a financial penalty) in relation to other suspected competition law breaches by Vifor.

Responses to the Consultation

6.22 As explained in Chapter 1 above, the CMA received four responses to the Consultation. For the reasons set out below, the CMA considers that those responses either did not raise any issue that suggested that the Commitments would not address the CMA's competition concerns or were addressed through minor revisions to the Proposed Commitments. The CMA is therefore of the view that the Commitments would address the competition concerns it has identified and that it is appropriate to accept the Commitments.

6.23 One response concerned medical issues that are outside of the scope of the CMA's competition concerns.

6.24 Two responses raised concerns regarding [✂]. The responses also raised concerns regarding possible [✂]. The CMA has not investigated the [✂] raised by these responses and, therefore, has no basis to conclude whether or not those concerns are correct. Regardless of whether those concerns are correct, the CMA considers that some of the concerns described in the responses fall outside the scope of its competition concerns and, to the extent that the [✂] may be in scope, the Commitments contain suitable mechanisms to resolve them, particularly given the role of the Monitoring Trustee.

6.25 One response raised issues relating to the effective application of the Proposed Commitments. The response suggested that:

(a) The Stakeholder Communication should be published on Vifor's global website, in addition to the UK website, and that the UK website should contain a link to the global website. After careful consideration, the CMA has concluded that the multi-channel nature of the Communication Campaign will mean that the Stakeholder Communication will have sufficient prominence. In particular, the CMA does not have concerns that HCPs will not be able to receive or access the Stakeholder Communication. Further, Vifor provided the CMA with an example of how the Stakeholder Communication will be displayed

on the UK website,[64] which provides further assurance that the Stakeholder Communication will be prominently positioned for any HCP visiting Vifor's UK website and HCPs will be able to access the Stakeholder Communication.

(b) The Commitments should ensure that the Stakeholder Communication is published in a suitable alternative medical journal if the BMJ declines to publish it. In response to this issue, Vifor proposed a minor revision to paragraphs 10(c) and 29(i) of the Proposed Commitments, to ensure that the Stakeholder Communication will be published in an 'other suitable leading medical journal' if the BMJ declines to publish it. The CMA considers that this minor revision sufficiently addresses the issue raised.

(c) The scientific name for Monofer should be included in the Stakeholder Communication, for clarity, completeness and as a matter of good practice. In response, Vifor proposed to include the scientific name of each of Ferinject and Monofer in the Stakeholder Communication. The CMA considers that this minor revision sufficiently addresses the issue raised.

[64] CSL Vifor's Austrian website.

7. THE CMA'S DECISION TO ACCEPT THE COMMITMENTS

7.1 For the reasons set out above, the CMA has concluded that the Commitments address the CMA's competition concerns and that it is appropriate to accept the Commitments for the purposes of addressing those competition concerns. Accordingly, the CMA:

(a) has decided to accept the Commitments by means of this Decision; and

(b) will discontinue its Investigation with effect from the date of this Decision.

Signed

[✂]

Juliette Enser

Senior Responsible Officer and Executive Director of Competition Enforcement

For and on behalf of the Competition and Markets Authority

23 May 2025

ANNEX: THE COMMITMENTS

The Commitments are appended on the pages below.

Case AT-51377 – Vifor Pharma (IV Iron Products)
Commitments to the CMA

I. Introduction

1. On 31 January 2024, the UK Competition and Markets Authority (the "CMA") opened an investigation into Vifor Pharma UK Limited, Vifor Pharma Management Limited and CSL Limited (collectively "Vifor Pharma") under Chapter 2 of the Competition Act 1998 (the "Act") in relation to the supply of intravenous ("IV") iron deficiency treatments for National Health Service ("NHS") patients in the United Kingdom (the "UK") (the "Investigation").

2. Vifor Pharma agrees to make the following Commitments to address the CMA's concerns in the UK identified in the Investigation, subject to the following conditions: (i) the Commitments are accepted by the CMA in a Commitments Decision; (ii) the CMA makes no finding of infringement or liability; and (ii) [✂].

3. In particular, Vifor Pharma agrees to:

    a. [✂], make an ex-gratia payment of £23 million to the DHSC (the "DHSC Payment Commitment" set out in in Section III below).

    b. To undertake a comprehensive, multi-channel, clarification communication campaign concerning Monofer's safety profile (the "Required Conduct" set out in Section IV below).

    c. Not to engage in External Promotional Communications and External Medical Communications about Monofer's safety profile containing information or characteristics that are: (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 (the "Prohibited Conduct" set out in further detail in Section V below).

4. The Commitments are offered by Vifor Pharma under section 31A of the Act to address the CMA's competition concerns in the UK identified in the Investigation (as described in the accompanying Notice of Intention to Accept Binding Commitments), as provisionally set out in the CMA's Notice of Intention to Accept Binding Commitments and should be interpreted accordingly.

5. The giving of the Commitments by Vifor Pharma does not constitute an admission of any wrongdoing or liability or infringement of competition laws or causation of loss or damage in relation to the CMA's Investigation. These Commitments are without prejudice to Vifor Pharma's position should the CMA or any other party commence or conduct proceedings or other legal action against Vifor Pharma in relation to any matters that are the subject of, or directly or indirectly linked to, the Investigation.

II. Definitions

6. For the purpose of the Commitments, the following terms shall have the following meanings:

    "ABPI" means the Association of the British Pharmaceutical Industry.

"AdBoard Materials" refer to materials prepared by Vifor Pharma for advisory boards held in the UK that are used for research and scientific exchange purposes.

"CEMs" means Vifor Pharma's Customer Engagement Managers in the UK engaged in External Promotional Communications about Ferinject with HCP Stakeholders in the UK.

"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.

"CMA" means the Competition and Markets Authority.

"Communication Campaign" means the communication campaign defined in Section IV of these Commitments.

"Commitment Period" means the period from the Entry into Force of the Commitments until 22 July 2034.

"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 Vifor Pharma contact email address indicated in the Stakeholder Communication contained in Appendix 1.

"Customer Relationship Management system" or "CRM system" means the [✂] software system used by Vifor Pharma to manage interactions with customers.

"DHSC Payment Commitment" refers to Vifor Pharma's commitment to make an ex-gratia payment of £23 million to the DHSC set out in in Section III, and subject to the conditions set out in these Commitments.

"Entry into Force" means the date when the Commitments Decision is notified to Vifor Pharma by the CMA.

"External Promotional Communications" mean all oral or written external promotional communications, including paper and electronic promotional communications used externally in the UK, as well as Internal Training Materials and any other internal materials serving as the basis for oral or written external communications by Vifor Pharma's Sales Field Force in the UK, with HCP Stakeholders in the UK.

"External Medical Communications" mean all oral or written external medical communications, including paper and electronic medical communications used externally in the UK, as well as Internal Training Materials and any other internal materials serving as the basis for oral or written external communications by Vifor Pharma's MSLs in the UK, with HCP Stakeholders in the UK.

"First E-mail Communication Campaign" means e-mailing the Stakeholder Communication to the HCP Stakeholders in the UK (whose e-mail addresses are included in Vifor Pharma's CRM system or are commercially available to be used by

IQVIA for the purpose of sending of a regulatory/legal communication, except to HCP Stakeholders who opted out of receiving e-mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out) and to NHS Trusts in May 2025.

"First Mail Communication Campaign" means mailing the Stakeholder Communication to the HCP Stakeholders in the UK included in Vifor Pharma's CRM system (except to HCP Stakeholders who opted out of receiving mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out) and to NHS Trusts in May 2025.

"Ferinject" means ferric carboxymaltose product commercialized by Vifor Pharma under any and all brand names in the UK.

"HSR" means hypersensitivity reactions.

"HCP Stakeholders" means the categories of healthcare professionals in the UK listed in Appendix 3,[1] being healthcare professionals who were contacted by Vifor Pharma in the period from 1 January 2018 to 31 December 2024 as per internal records in Vifor Pharma's CRM system and who, according to information available to Vifor Pharma and/or to IQVIA, are actively practising as healthcare professionals at the time of undertaking the respective Communication Campaign.

"Internal Training Materials" mean paper and electronic materials used to train Vifor Pharma's Sales Field Force and MSLs in the UK, and containing explicit or implied comparison between Ferinject and Monofer.

"IQVIA" is a global provider of biopharmaceutical development, professional consulting and commercial outsourcing services.

"KAMs" or "Key Account Managers" means third-party contracted field force engaged in External Promotional Communications about Ferinject with HCP Stakeholders in the UK on behalf of Vifor Pharma.

"Monofer" means isomaltoside product or ferric derisomaltose product commercialized by Pharmacosmos and its partners under any and all brand names in the UK.

"MSLs" means medical scientific liaison personnel engaged in External Medical Communications about Ferinject with HCP Stakeholders in the UK.[2]

"NHS" means the National Health Service of the UK.

"NHS Trusts" means the NHS Trusts listed in Appendix 4.

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[1] The total number of active HCP Stakeholders contacted in each Communication Campaign may vary compared with the information included in Appendix 3 as a result of possible inaccuracies in Vifor Pharma's CRM system, HCPs retiring or otherwise leaving the profession, the availability of email addresses, or potential technical and logistical issues with communication channels (*e.g.*, e-mail bounce, letters returned as undeliverable and similar).

[2] Also referred to as "field-based medical advisors" within Vifor Pharma.

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

"Prohibited Conduct" refers to the conduct defined in Section V of these Commitments.

"Real-World Data" means health-related data (including the effects of health interventions) collected from patients, caregivers or routine clinical practice in a non-interventional setting.

"Real-World Evidence" means clinical evidence regarding the usage and potential benefits or risks of a medicinal product derived from the analysis of Real-World Data.

"Required Conduct" refers to the conduct defined in Section IV of these Commitments.

"Q&A" means document contained in Appendix 2.

"Sales Field Force" refers to KAMs and CEMs engaged in External Promotional Communications about Ferinject with HCP Stakeholders in the UK.

"Second E-mail Communication Campaign" means e-mailing the Stakeholder Communication to the HCP Stakeholders in the UK (whose e-mail addresses are included in Vifor Pharma's CRM system or commercially available from IQVIA for the purpose of sending of a regulatory/legal communication, except to HCP Stakeholders who opted out of receiving e-mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out) in July 2025.

"Second Mail Communication Campaign" means mailing the Stakeholder Communication to the HCP Stakeholders in the UK included in Vifor Pharma's CRM system (except to HCP Stakeholders who opted out of receiving mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out) in July 2025.

"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.

"Stakeholder Communication" means the written communication contained in Appendix 1.

"Third E-mail Communication Campaign" means e-mailing the Stakeholder Communication in September 2025 only to the HCP Stakeholders in the UK who did not receive the Stakeholder Communication by mail during the First Mail Communication Campaign or the Second Mail Communication Campaign, and for whom an email address is included in Vifor Pharma's CRM system or commercially available from IQVIA for the purpose of sending of a regulatory/legal communication (except to HCP Stakeholders who opted out of receiving e-mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out).

"Third Mail Communication Campaign" means mailing the Stakeholder Communication in September 2025 only to the HCP Stakeholders in the UK who did not receive the Stakeholder Communication by e-mail during the First E-mail Communication Campaign or the Second E-mail Communication Campaign, and who are included in Vifor Pharma's CRM system (except to HCP Stakeholders who opted out of receiving mails and where there is no practicable avenue for Vifor Pharma or IQVIA to override such opt out).

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

"Working Day" means any day other than a Saturday, Sunday or any other day that is a public holiday in England.

III. DHSC Payment Commitment

7. [✂], Vifor Pharma commits to make an *ex gratia* payment of £23 million to the DHSC within 20 Working Days from the Entry into Force.

8. Vifor Pharma shall notify the CMA no later than two Working Days following completion of the DHSC Payment described in paragraph 7 above, providing at the same time evidence that such payment has been made.

9. The CMA will confirm that Vifor Pharma has complied with the DHSC Payment Commitment as soon as reasonably practicable following receipt of notification from the DHSC that the DHSC Payment described in paragraph 7 above has been made.

IV. Required Conduct

10. Vifor Pharma commits to undertake a comprehensive, multi-channel, clarification communication campaign ("Communication Campaign"), comprised of the following elements:

    a. Disseminating the Stakeholder Communication in the UK through mail and e-mail to HCP Stakeholders included in Appendix 3 and the Chief Pharmacist or person with equivalent responsibilities (the "NHS Trust Stakeholder") at each of the NHS Trusts included in Appendix 4. The First Mail Communication Campaign and First E-mail Communication Campaign with HCP Stakeholders in the UK and NHS Trusts in the UK shall take place in May 2025. The Second Mail Communication Campaign and Second E-mail Communication Campaign with HCP Stakeholders in the UK shall take place in July 2025. The Third Mail Communication Campaign and the Third E-mail Communication Campaign shall take place in September 2025. Any follow-up questions received at the Contact Email Address referenced in Appendix 1 will be addressed by e-mail. Any in-person follow-up questions from the HCP Stakeholders and NHS Trust Stakeholders in the UK related to the content of the Stakeholder Communication shall be responded by Vifor Pharma's Sales Field Force and MSLs. All responses (by e-mail and in-person) shall be in line with the Q&A document provided in Appendix 2.

b. Publishing the Stakeholder Communication contained in Appendix 1 on Vifor Pharma's UK website (https://www.cslvifor.uk) within 15 Working Days of the Entry into Force for a period of 36 calendar months from the date of publication.

c. Publishing the Stakeholder Communication contained in Appendix 1 in The BMJ or other suitable leading medical journal, as soon as reasonably practicable but no later than 1 September 2025 (unless extended by the CMA upon Vifor Pharma's reasoned request).

d. For the duration of the Commitment Period, allowing third parties, including Pharmacosmos, to use the Stakeholder Communication contained in Appendix 1 in the UK from 1 June 2025, or earlier if the First Mail Communication Campaign and the First E-mail Communication Campaign take place earlier, as long as it is reproduced verbatim if communicated in writing.

e. For a period of 12 months from the Entry into Force, delivering the Stakeholder Communication to HCP Stakeholders in the UK in one hard copy per HCP Stakeholder during the first in-person meeting that takes place in the ordinary course of business between the Vifor Pharma's Sales Field Force involved with Ferinject in the UK at the time of the respective visit and a HCP Stakeholder in the UK, regardless of whether Ferinject is discussed during such visit.

11. Vifor Pharma's compliance with the Required Conduct shall be subject to a Monitoring Trustee mechanism defined in Section VIIIVIII of these Commitments.

V. Prohibited Conduct

12. From the Entry into Force until 22 July 2034, Vifor Pharma commits not to engage in the UK in External Promotional Communications and External 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, Vifor Pharma's External Promotional Communications and External Medical Communications related to Monofer and Ferinject shall be balanced, objective, and comprehensive. In particular, Vifor Pharma shall not directly or indirectly imply or suggest that Monofer is not dextran-free.

13. As a means of compliance with the commitment set out at paragraph 12, Vifor Pharma commits to the following measures and safeguards. The implementation of measures in paragraphs 13(a) and 13(c) shall be reviewed by the Monitoring Trustee within 45 Working Days of their appointment and be subject to reasonable comments from the Monitoring Trustee communicated to Vifor Pharma within 60 Working Days of the Entry into Force. In case of disagreement between the Monitoring Trustee and Vifor Pharma on the reasonableness of the comments, the matter shall be escalated to the CMA.

a. For a period of three years from the Entry into Force, setting up an internal mechanism to ensure as far as reasonably possible that all UK External Promotional Communications and External 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 UK 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 the duration of the Commitment Period, offering a dialogue process between Vifor Pharma, Pharmacosmos, and the Monitoring Trustee within 30 Working Days of the request from Pharmacosmos, for the purposes of enabling Pharmacosmos to raise and discuss in good faith any alleged deviations from these Commitments in the UK such as unauthorized miscommunications in the UK. In case of disagreement between Vifor Pharma and Pharmacosmos, the Monitoring Trustee shall issue a formal recommendation on how to resolve the disagreement within 10 Working Days of being requested to do so by either Party. In case Pharmacosmos or Vifor Pharma disagree with the recommendation of the Monitoring Trustee, they can escalate the matter to the CMA within 5 Working Days of the recommendation of the Monitoring Trustee. The CMA shall then provide appropriate directions binding on Vifor Pharma.

c. 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 Vifor Pharma in the UK as soon as practicable and no later than 10 Working Days (unless reasonably extended by the Monitoring Trustee on a case-by-case basis in exceptional circumstances upon a reasoned request by Vifor Pharma) from when Vifor Pharma becomes aware of such potential unauthorized miscommunication.[3]

d. For a period of three years from the Entry into Force and in line with the ABPI's requirements,[4] conducting an annual internal compliance training of Vifor Pharma's senior management in the UK with responsibility for Ferinject in the UK [5] and all Vifor Pharma Sales Field Force and MSLs involved with Ferinject in the UK focused on good promotional and medical communications practice and compliance with the Commitments.

e. For the duration of the Commitment Period, executing an annual compliance statement within 30 Working Days from the end of the calendar year by each member of Vifor Pharma's senior management in the UK involved with Ferinject in the UK[6] and the Sales Field Force and MSLs in the UK involved with Ferinject, attesting compliance with the commitment set out at paragraph 12.

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3 Such incidents, if any, and the respective corrective measures, will be assessed by the Monitoring Trustee and, if necessary, by the CMA, in a fair, balanced, and reasonable manner, taking account of all the circumstances and the full context.

4 *See* clause 9 on training, available at: https://www.abpi.org.uk/publications/code-of-practice-for-the-pharmaceutical-industry-2024/.

5 Vifor Pharma's senior management in the UK with responsibility for Ferinject comprises of the following roles: [✂]

6 *Ibid*.

14. Vifor Pharma's compliance with the Prohibited Conduct shall be subject to a Monitoring Trustee mechanism defined in Section VIII of these Commitments for the duration of the Commitment Period, except in relation to measures contained in paragraph 13(a) and 13(d) that are put in place for the period of 3 years from the Entry into Force.

15. For the avoidance of doubt, nothing in these Commitments shall prohibit Vifor Pharma from engaging in (a) communications based on information or characteristics included in Monofer's or Ferinject's SmPC, applicable in the UK 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. In addition, communicating that Ferinject is a nanomedicine is permitted.

VI. Non-Circumvention

16. Vifor Pharma 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, Vifor Pharma (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, Vifor Pharma 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 12 of the Commitments. For the avoidance of doubt and without prejudice to the general application of competition rules and any other applicable rules governing the promotion and/or advertising of pharmaceutical products, these Commitments shall not prevent Vifor Pharma 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 (but not superiority) 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 that evidence to MHRA or other regulatory bodies for a regulatory evaluation and potential inclusion in the SmPC.

VII. Reporting

17. Vifor Pharma commits to provide the CMA and the Monitoring Trustee a report on the implementation of the Required Conduct (as defined at paragraphs 10-11 of these

Commitments) as soon as practicable and no later than 30 Working Days of the completion of each Communication Campaign.

18. Any Stakeholder messages in the UK related to communications about Monofer adopted by Vifor Pharma after the Entry into Force and received by Vifor Pharma at the Contact Email Address shall be provided to the Monitoring Trustee without delay.

19. Vifor Pharma commits to provide the CMA and the Monitoring Trustee a report on the implementation of the measures related to the Prohibited Conduct (as defined in Section V of these Commitments) as soon as practicable and no later than 30 Working Days from the end of the calendar year.[7] The reporting obligation is due for the duration of the Commitment Period, except in relation to measures contained in paragraphs 13(V.a) and 13(V.d) that are put in place for the period of three years from the Entry into Force.

20. Vifor Pharma commits to provide the CMA and the Monitoring Trustee a report on potential unauthorized miscommunications and, if appropriate, propose adequate remediation measures within the meaning of paragraph 13(c) of these Commitments, as soon as practicable and no later than 15 Working Days (unless reasonably extended by the Monitoring Trustee on a case-by-case basis in exceptional circumstances upon a reasoned request by Vifor Pharma) from when Vifor Pharma becomes aware of such potential unauthorized miscommunication. Any such measures shall then be implemented within 30 Working Days as per paragraph 13(c) of these Commitments.

VIII. Monitoring Trustee

21. Vifor Pharma shall appoint a Monitoring Trustee in accordance with the provisions below.

22. The appointment procedure described below shall apply *mutatis mutandis* to the appointment of a new monitoring trustee following the replacement or discharge of the Monitoring Trustee as described in Section eVIII(e) below.

a. Appointment procedure

23. Vifor Pharma shall appoint a Monitoring Trustee to carry out the functions specified below in these Commitments.

24. The Monitoring Trustee shall:

i) at the time of appointment, be independent of Vifor Pharma and of any competitor of Vifor Pharma;

ii) possess the necessary qualifications to carry out its mandate; and

iii) neither have nor become exposed to a Conflict of Interest.

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

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[7] The first report shall be due by 31 January 2026.

Proposal by Vifor Pharma

25. Vifor Pharma shall submit the name or names of one or more natural or legal persons whom Vifor Pharma proposes to appoint as the Monitoring Trustee to the CMA for approval within 30 working days from the Entry into Force. The proposal shall contain sufficient information for the CMA to verify that the person or persons proposed as Monitoring Trustee fulfil the requirements set out at paragraph 24 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 CMA

26. The CMA 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, Vifor Pharma shall appoint or cause to be appointed the person concerned as Monitoring Trustee, in accordance with the mandate approved by the CMA. If more than one name is approved, Vifor Pharma 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 CMA's approval, in accordance with the mandate approved by the CMA.

New proposal by Vifor Pharma

27. If all the proposed Monitoring Trustees are rejected, Vifor Pharma 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 24 and 26.

Monitoring Trustee nominated by the CMA

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

b. **Functions of the Monitoring Trustee**

29. The Monitoring Trustee shall act on behalf of the CMA to ensure Vifor Pharma'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 UK during each Communication Campaign and published on Vifor Pharma's UK website, and in The BMJ (formerly The British Medical Journal) or other suitable leading medical journal); and

ii) As regards the Prohibited Conduct, the implementation of measures in paragraphs 13(V.a) and 13(V.d) shall be reviewed by the Monitoring Trustee within 45 Working Days of its appointment and be subject to reasonable comments from the Monitoring Trustee communicated to Vifor Pharma within 60 Working Days of the Entry Into Force. In case of disagreement between the Monitoring Trustee and Vifor Pharma on the reasonableness of the comments, the matter shall be escalated to the CMA.

For the period of three years from the Entry Into Force, the Monitoring Trustee shall also have access to Vifor Pharma's [✂] database and any other relevant Vifor Pharma database to undertake biannual[8] reviews of such documents or samples of documents as the Monitoring Trustee considers appropriate of (i) Vifor Pharma's External Promotional and External Medical materials in the UK, (ii) Vifor Pharma's Internal Training Materials used for training in the UK, and (iii) Vifor Pharma's AdBoard Materials related to safety statements about Monofer and/or Ferinject in the UK, 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 three years from the Entry into Force), the Monitoring Trustee shall have access to Vifor Pharma's [✂] database and any other relevant Vifor Pharma database to undertake annual reviews of a reasonable sample[9] of (i) Vifor Pharma's External Promotional and External Medical materials in the UK, (ii) Vifor Pharma's Internal Training Materials used for training in the UK, and (iii) Vifor Pharma's AdBoard Materials related to safety statements about Monofer and/or Ferinject in the UK, to continue to monitor and verify that Vifor Pharma'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 consult Pharmacosmos at least twice a year and, upon advance notice, Vifor Pharma's General Manager in the UK and if appropriate Vifor Pharma Sales Field Force and MSLs in the UK, as well as any HCP Stakeholders the Monitoring Trustee deems relevant, to monitor and verify that Vifor Pharma did not engage in the Prohibited Conduct in the UK.

The Monitoring Trustee shall also monitor and prepare a biannual report on Vifor Pharma's compliance with the measures set out in Sections IV and V of these Commitments. The reporting obligation is due for the duration of the Commitment Period, except in relation to measures contained in paragraphs 13(V.a) and 13(V.d) that are put in place for the period of three years from the Entry into Force.

30. The CMA may, on its own initiative or at the request of the Monitoring Trustee or Vifor Pharma, give any orders or instructions to the Monitoring Trustee in order to ensure

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8 Two times per year, starting from 15 January 2026.

9 Up to 5% of the average number of Ferinject or iron related materials approved in the UK per review period after the first three years from the Entry into Force. The exact content of the sample shall be identified by the Monitoring Trustee.

compliance with the conditions and obligations attached to the Commitments Decision. Vifor Pharma may not give instructions to the Monitoring Trustee.

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

31. The Monitoring Trustee shall:

i) on 30 June 2025, or at a later date agreed in good faith between the CMA, the Monitoring Trustee, and Vifor Pharma, provide the CMA (sending Vifor Pharma 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 Commitments Decision; and assessing Vifor Pharma's compliance with the Commitments in relation to the First Communication Campaign;

ii) propose to Vifor Pharma such measures as the Monitoring Trustee considers necessary to ensure Vifor Pharma's compliance with the Commitments and the Monitoring Trustee shall propose measures to the CMA in the event that Vifor Pharma does not comply with the Monitoring Trustee's proposal within the timeframe set by the Monitoring Trustee;[10]

iii) act as a contact point for any requests by Pharmacosmos and other third parties in relation to the Commitments;

iv) on 30 October 2025, or at a later date agreed in good faith between the CMA, the Monitoring Trustee, provide the CMA (sending Vifor Pharma a non-confidential copy at the same time) a report of any issues or problems which may have risen in the execution of the Monitoring Trustee's obligations, in particular any issues of non-compliance by Vifor Pharma with the Commitments, including notably with respect to the Second and Third Communication Campaigns;

v) provide the CMA (sending Vifor Pharma a non-confidential copy at the same time) bi-annual written reports (with the first report delivered no later than 30 November 2025 or at a later date agreed in good faith between the CMA, the Monitoring Trustee) covering the Monitoring Trustee's fulfilment of its obligations and Vifor Pharma'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 Vifor Pharma with the Commitments.

32. At any time, the Monitoring Trustee will provide to the CMA, 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 CMA (sending Vifor Pharma a non-confidential version at the same time) if it concludes on reasonable grounds that Vifor Pharma is failing to comply

[10] In case of disagreement between the Monitoring Trustee and Vifor Pharma, the matter shall be escalated to the CMA.

with these Commitments in the UK. The Monitoring Trustee shall inform Vifor Pharma promptly of the content of any oral reports to the CMA.

33. At the expense of Vifor Pharma, the Monitoring Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to Vifor Pharma'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 Vifor Pharma refuse to approve the advisors proposed by the Monitoring Trustee the CMA may approve the appointment of such advisors instead, after having heard Vifor Pharma. Vifor Pharma is not entitled to issue instructions to the advisors. Such additional advisors must not have any conflict of interest with Vifor Pharma.

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

34. Vifor Pharma shall provide and shall cause its advisors 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 Vifor Pharma, as far as reasonably possible, in the context of the commercialisation of Ferinject in the UK, management and other personnel, and facilities, except information protected under legal privilege rules.

35. All confidential information is provided by Vifor Pharma to the Monitoring Trustee subject to due respect by the Monitoring Trustee of the confidentiality of such information.

36. On reasonable request and notice, Vifor Pharma shall make available to the Monitoring Trustee appropriate offices on their premises. Vifor Pharma shall be available for meetings in order to provide the Monitoring Trustee with all information necessary for the performance of the mandate.

37. Vifor Pharma 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 Vifor Pharma 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.

38. Vifor Pharma agrees that the CMA may share confidential information which is proprietary to Vifor Pharma with the Monitoring Trustee. The Monitoring Trustee shall not disclose such information.

39. Vifor Pharma agrees that the contact details of the Monitoring Trustee are published on the CMA's website and shall inform interested third parties of the identity and the tasks of the Monitoring Trustee.

40. Without prejudice to the CMA's other statutory powers of investigation, for the Commitment Period, the CMA may request all information from Vifor Pharma that is reasonably necessary to monitor the effective implementation of these Commitments.

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

41. 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 Vifor Pharma and to the CMA without delay:

    i) the CMA may, after hearing the Monitoring Trustee, require Vifor Pharma to replace the Monitoring Trustee; or

    ii) Vifor Pharma may, with the prior approval of the CMA, replace the Monitoring Trustee. If the Monitoring Trustee is discharged according to paragraph 41, 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 23-28 (inclusive).

42. Unless removed in accordance with paragraph 41, the Monitoring Trustee shall cease to act as Monitoring Trustee only after the CMA has discharged it from the mandate at the end of the Commitment Period and after all the Commitments have been implemented. The CMA may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies have not been fully and properly implemented.

IX. Review

43. Vifor Pharma may request that the CMA modify these Commitments where there has been a material change in any of the facts on which the Commitment Decision was based, including if Chapter 2 of the Act is no longer applicable to Vifor Pharma or if significant changes in the regulatory or legislative framework support the generation

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

X. Commitment Period

44. Unless provided otherwise, the term of these Commitments will be the period from the Entry into Force until 22 July 2034.

May 19, 2025

Duly authorized for and on behalf of Vifor Pharma

[✂]

Appendix 1 – Stakeholder Communication

Subject: Clarifications in Relation to Vifor Pharma's Communications about Monofer in the United Kingdom

"*Dear Sir/Madam,*

As you may know, the CMA has been investigating Vifor Pharma in relation to potentially misleading communications comparing Ferinject (ferric carboxymaltose) to Monofer (ferric derisomaltose) in the United Kingdom. This investigation has been concluded without an infringement finding against Vifor Pharma or admission of liability from Vifor Pharma. However, Vifor Pharma has agreed to a number of commitments including that Vifor Pharma disseminates this communication to you.

In the context of its investigation, the CMA raised preliminary concerns that Vifor Pharma has been disseminating potentially misleading information regarding the safety of Monofer. In this regard, Vifor Pharma 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 summary of product characteristics (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 hypersensitivity reactions (HSR) compared to Ferinject.*

We hope that this letter clarifies any potentially misleading past communications about Monofer in the United Kingdom.

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

Sincerely,

Vifor Pharma"

[✂]

Appendix 2 – Q&A

1. What were the exact allegations against Vifor Pharma?

The CMA raised preliminary concerns that Vifor Pharma has been disseminating potentially misleading information regarding the safety of Monofer, particularly in relation to whether Monofer is a dextran or dextran-derived/dextran-based product, whether it has increased risk of hypersensitivity reactions compared to Ferinject, and whether its safety profile is inferior to Ferinject.

The CMA investigation has been concluded without an infringement finding against Vifor Pharma or admission of liability from Vifor Pharma. Vifor Pharma has nevertheless agreed to a number of legally-binding commitments, including disseminating the clarification letter you have received, in order to remove and correct any possible confusion caused by our past communications about Monofer's safety.

As explained in our clarification letter, according to Monofer's SmPC, which was approved by the competent regulatory authorities, Monofer (i) is not a dextran, dextran-derived, or dextran-based product and (ii) is not associated with an increased risk of hypersensitivity reactions compared to Ferinject. It has not been scientifically established that Ferinject has a superior safety profile compared to Monofer, which was also confirmed by the European Medicine Agency through its successive reviews of intravenous iron medicines. We hope that this clarifies any potentially misleading past communications about Monofer's safety.

2. What has Vifor Pharma been communicating about Monofer?

In essence, the CMA was concerned that Vifor Pharma's past communications on Monofer's relation to dextran and risk of hypersensitivity reactions compared to Ferinject have been potentially misleading as they included statements that may not have been sufficiently accurate, balanced, comprehensive, and reflective of the information in Monofer's SmPC. Vifor Pharma therefore committed (i) to disseminate the clarifications you have received to clarify any potentially misleading past communications, and (ii) to refrain from making comparative claims about Monofer that are not based on information included in Monofer's SmPC or on clinical head-to-head trial between Ferinject and Monofer.

3. Why would Vifor Pharma agree to send those clarifications if there are no findings against you?

The CMA's investigation has been closed without an infringement finding and admission of liability, but subject to legally-binding commitments that remedy the CMA's preliminary concerns that Vifor Pharma's past communications on Monofer's safety have been potentially misleading, such as sending the present clarification letter to relevant healthcare professionals. Vifor Pharma committed that (i) it would remove any potential doubts caused by our past communications about Monofer's safety profile and relation to dextran by sending the clarification letter you have received, and (ii) it would not make comparative claims on Monofer's safety that are not based on

information included in Monofer's SmPC or on clinical head-to-head trial between Ferinject and Monofer.

For further information relating to the CMA's investigation and the commitments of Vifor Pharma, please refer to the CMA website at: https://www.gov.uk/cma-cases/investigation-into-suspected-anti-competitive-conduct-by-vifor-pharma-in-relation-to-intravenous-iron-treatments.

4. In your clarification letter you first state that no infringement has been found against you and then state that there are potential misunderstandings regarding your past communications about Monofer's safety. How is this consistent?

In the context of its investigation, the CMA raised preliminary concerns that Vifor Pharma's past communications to healthcare professionals about Monofer's safety have been potentially misleading as they included statements that may not have been sufficiently accurate, balanced, comprehensive and reflective of the information contained in Monofer's SmPC. Accordingly, the purpose of this clarification letter is to clarify any potentially misleading past communications about Monofer's safety. Doing so does not mean that Vifor Pharma has infringed the law. For further information relating to the safety profile of Ferinject and Monofer, please refer to their respective SmPCs. For further information relating to the CMA's investigation and to the commitments, please refer to the CMA's website, which has a specific case page relating to this matter.

5. Are you stating that Monofer has a better safety profile than Ferinject?

No. We are stating that the available head-to-head trials comparing Ferinject and Monofer neither suggest nor demonstrate that Ferinject has a superior safety profile compared to Monofer. For further information relating to the safety profiles of Ferinject and Monofer, please refer to their respective SmPCs.

6. Why should we be involved in this process?

As part of its investigation, the CMA was concerned that Vifor Pharma's past communications to healthcare professionals about Monofer's safety have been potentially misleading as they included statements that may not have been sufficiently accurate, balanced, comprehensive and reflective of the information contained in Monofer's SmPC. Accordingly, the purpose of the clarification letter you have received is to clarify any potentially misleading past communications about Monofer's safety. For further information relating to the safety profile of Ferinject and Monofer, please refer to their respective SmPCs.

7. What type of materials would have contained insufficiently balanced, comprehensive, and accurate information?

Vifor Pharma's communications related to Monofer were included in external promotional and medical materials that may have been presented to you or shared with you (orally or in writing). In essence, Vifor Pharma communicated that Monofer was a dextran or dextran-derived/dextran-based product and that it was associated with an increased risk of hypersensitivity reactions compared to Ferinject. Such communications have been potentially misleading, as they were not sufficiently

balanced, comprehensive, accurate and reflective of the information in Monofer's SmPC. Vifor Pharma committed to refrain from making comparative claims about Monofer's safety that are not derived from the SmPC or from head-to-head trials between Ferinject and Monofer.

As explained in the clarification letter you have received, according to Monofer's SmPC, Monofer is not a dextran, dextran-derived, or dextran-based product and does not have increased risk of hypersensitivity reaction compared to Ferinject. According to the class label on hypersensitivity reaction for IV iron products, the risk of hypersensitivity reactions for IV iron products is considered "uncommon" for all IV iron products currently available on the market, including Monofer and Ferinject. The available head-to-head trials comparing Ferinject and Monofer do no suggest that Ferinject has a superior safety profile compared to Monofer. We hope that this letter clarifies any potentially misleading past communications about Monofer.

8. Is there any material that you have communicated to me that was incorrect? Have you ever misrepresented data?

As part of its investigation, the CMA was concerned that Vifor Pharma's past communications to healthcare professionals about Monofer's safety have been potentially misleading as they included statements that may not have been sufficiently accurate, balanced, comprehensive and reflective of the information contained in Monofer's SmPC by suggesting that Monofer was a dextran or dextran-derived/dextran-based product and that it was associated with an increased risk of hypersensitivity reactions compared to Ferinject.

As explained in the clarification letter you have received, according to Monofer's SmPC, Monofer is not a dextran, dextran-derived, or dextran-based product and does not have increased risk of hypersensitivity reaction compared to Ferinject. There is a class label on hypersensitivity reaction for IV iron products, and the risk for HSRs is considered "uncommon" for all IV iron products currently available on the market, including Monofer and Ferinject. Based on the information included in Ferinject's and Monofer's respective SmPCs and absent head-to-head clinical trials on hypersensitivity reactions comparing Ferinject and Monofer, it is not appropriate to infer Ferinject to have a superior safety profile compared to Monofer. We hope that this letter clarifies any potentially misleading past communications about Monofer's safety.

9. Do you have to retract any material?

No, it is not possible to retract our past communications, but the aim of our clarification letter is to clarify any potentially misleading past communications on Monofer's safety. As explained in that clarification letter, Monofer does not have a limited evidence base that would call into question its safety and, according to Monofer's SmPC, which was approved by the competent regulatory authorities, Monofer is not a dextran, dextran-derived, or dextran-based product and does not have increased risk of hypersensitivity reaction compared to Ferinject. It is therefore not appropriate to infer Ferinject to have a superior safety profile compared to Monofer.

10. If my patients request Ferinject instead of Monofer, should I share the information contained in your clarification letter with them?

The clarification letter is addressed to all relevant healthcare professionals in order to clarify any potentially misleading past communications about Monofer's safety. Vifor Pharma is not in a position to direct or advise on prescribing decisions nor interfere with physician-to-patient communication. Nothing prevents you from sharing the information contained in our clarification letter.

Appendix 3 – Categories of Healthcare Professionals

Prescribers	
Medical Advisor	[✂]
Nurse	[✂]
Physician	[✂]
Sub-total	[✂]
Non-Prescribers	
Administrators	[✂]
Allied Health Professionals	[✂]
Medical Administration & Medical Assistant	[✂]
Midwife	[✂]
Pharmaceutical Advisor	[✂]
Pharmacists	[✂]
Pharmacist Assistant / Technician	[✂]
Pharmacy Administration	[✂]
Physical Therapist	[✂]
Researcher/Scientist	[✂]
Technician/Technologist	[✂]
Sub-total	[✂]
TOTAL	[✂]

Appendix 4 – NHS Trusts

NHS Trusts	
AIREDALE NHS FOUNDATION TRUST	
ALDER HEY CHILDREN'S NHS FOUNDATION TRUST	NORTH TEES AND HARTLEPOOL NHS FOUNDATION TRUST
ASHFORD AND ST PETER'S HOSPITALS NHS FOUNDATION TRUST	NORTH WEST ANGLIA NHS FOUNDATION TRUST
BARKING, HAVERING AND REDBRIDGE UNIVERSITY HOSPITALS NHS TRUST	NORTH WEST BOROUGHS HEALTHCARE NHS FOUNDATION TRUST
BARNSLEY HOSPITAL NHS FOUNDATION TRUST	NORTHAMPTON GENERAL HOSPITAL NHS TRUST
BARTS HEALTH NHS TRUST	NORTHERN CARE ALLIANCE NHS FOUNDATION TRUST
BEDFORDSHIRE HOSPITALS NHS FOUNDATION TRUST	NORTHERN DEVON HEALTHCARE NHS TRUST
BERKSHIRE HEALTHCARE NHS FOUNDATION TRUST	NORTHERN LINCOLNSHIRE AND GOOLE NHS FOUNDATION TRUST
BLACKPOOL TEACHING HOSPITALS NHS FOUNDATION TRUST	NORTHUMBRIA HEALTHCARE NHS FOUNDATION TRUST
BOLTON NHS FOUNDATION TRUST	NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST
BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST	OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
BUCKINGHAMSHIRE HEALTHCARE NHS TRUST	OXLEAS NHS FOUNDATION TRUST
CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST	PENNINE ACUTE HOSPITALS NHS TRUST
CAMBRIDGE UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	POOLE HOSPITAL NHS FOUNDATION TRUST
CAMBRIDGESHIRE AND PETERBOROUGH NHS FOUNDATION TRUST	PORTSMOUTH HOSPITALS UNIVERSITY NATIONAL HEALTH SERVICE TRUST
CENTRAL AND NORTH WEST LONDON NHS FOUNDATION TRUST	PUBLIC HEALTH WALES NHS TRUST
CHELSEA AND WESTMINSTER HOSPITAL NHS FOUNDATION TRUST	QUEEN VICTORIA HOSPITAL NHS FOUNDATION TRUST
CHESHIRE AND WIRRAL PARTNERSHIP NHS FOUNDATION TRUST	ROTHERHAM DONCASTER AND SOUTH HUMBER NHS FOUNDATION TRUST
CHESTERFIELD ROYAL HOSPITAL NHS FOUNDATION TRUST	ROYAL BERKSHIRE NHS FOUNDATION TRUST

NHS Trusts	
CORNWALL PARTNERSHIP NHS FOUNDATION TRUST	ROYAL BROMPTON & HAREFIELD NHS FOUNDATION TRUST
COUNTESS OF CHESTER HOSPITAL NHS FOUNDATION TRUST	ROYAL CORNWALL HOSPITALS NHS TRUST
COUNTY DURHAM AND DARLINGTON NHS FOUNDATION TRUST	ROYAL DEVON UNIVERSITY HEALTHCARE NHS FOUNDATION TRUST
COVENTRY AND WARWICKSHIRE PARTNERSHIP NHS TRUST	ROYAL FREE LONDON NHS FOUNDATION TRUST
CROYDON HEALTH SERVICES NHS TRUST	ROYAL NATIONAL ORTHOPAEDIC HOSPITAL NHS TRUST
CUMBRIA, NORTHUMBERLAND, TYNE AND WEAR NHS FOUNDATION TRUST	ROYAL PAPWORTH HOSPITAL NHS FOUNDATION TRUST
DARTFORD AND GRAVESHAM NHS TRUST	ROYAL SURREY COUNTY HOSPITAL NHS FOUNDATION TRUST
DERBYSHIRE HEALTHCARE NHS FOUNDATION TRUST	ROYAL UNITED HOSPITALS BATH NHS FOUNDATION TRUST
DEVON PARTNERSHIP NHS TRUST	SALISBURY NHS FOUNDATION TRUST
DONCASTER AND BASSETLAW TEACHING HOSPITALS NHS FOUNDATION TRUST	SANDWELL AND WEST BIRMINGHAM HOSPITALS NHS TRUST
DORSET COUNTY HOSPITAL NHS FOUNDATION TRUST	SHEFFIELD CHILDREN'S NHS FOUNDATION TRUST
DUDLEY INTEGRATED HEALTH AND CARE NHS TRUST	SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST
EAST AND NORTH HERTFORDSHIRE NHS TRUST	SHERWOOD FOREST HOSPITALS NHS FOUNDATION TRUST
EAST CHESHIRE NHS TRUST	SOMERSET NHS FOUNDATION TRUST
EAST KENT HOSPITALS UNIVERSITY NHS FOUNDATION TRUST	SOUTH LONDON AND MAUDSLEY NHS FOUNDATION TRUST
EAST LANCASHIRE HOSPITALS NHS TRUST	SOUTH TEES HOSPITALS NHS FOUNDATION TRUST
EAST LONDON NHS FOUNDATION TRUST	SOUTH TYNESIDE AND SUNDERLAND NHS FOUNDATION TRUST
EAST SUFFOLK AND NORTH ESSEX NHS FOUNDATION TRUST	SOUTH WARWICKSHIRE UNIVERSITY NHS FOUNDATION TRUST
EAST SUSSEX HEALTHCARE NHS TRUST	SOUTH WEST YORKSHIRE PARTNERSHIP NHS FOUNDATION TRUST
EPSOM AND ST HELIER UNIVERSITY HOSPITALS NHS TRUST	SOUTHPORT AND ORMSKIRK HOSPITAL NHS TRUST

NHS Trusts	
ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST	ST GEORGE'S UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
FRIMLEY HEALTH NHS FOUNDATION TRUST	STOCKPORT NHS FOUNDATION TRUST
GATESHEAD HEALTH NHS FOUNDATION TRUST	SURREY AND BORDERS PARTNERSHIP NHS FOUNDATION TRUST
GEORGE ELIOT HOSPITAL NHS TRUST	SURREY AND SUSSEX HEALTHCARE NHS TRUST
GLOUCESTERSHIRE HEALTH AND CARE NHS FOUNDATION TRUST	TAMESIDE AND GLOSSOP INTEGRATED CARE NHS FOUNDATION TRUST
GLOUCESTERSHIRE HOSPITALS NHS FOUNDATION TRUST	TAVISTOCK AND PORTMAN NHS FOUNDATION TRUST
GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS FOUNDATION TRUST	TEES, ESK AND WEAR VALLEYS NHS FOUNDATION TRUST
GREAT WESTERN HOSPITALS NHS FOUNDATION TRUST	THE CHRISTIE NHS FOUNDATION TRUST
GUY'S AND ST THOMAS' NHS FOUNDATION TRUST	THE CLATTERBRIDGE CANCER CENTRE NHS FOUNDATION TRUST
HAMPSHIRE HOSPITALS NHS FOUNDATION TRUST	THE DUDLEY GROUP NHS FOUNDATION TRUST
HARROGATE AND DISTRICT NHS FOUNDATION TRUST	THE HILLINGDON HOSPITALS NHS FOUNDATION TRUST
HEREFORDSHIRE AND WORCESTERSHIRE HEALTH AND CARE NHS TRUST	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
HERTFORDSHIRE PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST	THE PRINCESS ALEXANDRA HOSPITAL NHS TRUST
HOMERTON HEALTHCARE NHS FOUNDATION TRUST	THE QUEEN ELIZABETH HOSPITAL, KING'S LYNN, NHS FOUNDATION TRUST
HULL UNIVERSITY TEACHING HOSPITALS NHS TRUST	THE ROBERT JONES AND AGNES HUNT ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST
HUMBER TEACHING NHS FOUNDATION TRUST	THE ROTHERHAM NHS FOUNDATION TRUST
IMPERIAL COLLEGE HEALTHCARE NHS TRUST	THE ROYAL BOURNEMOUTH AND CHRISTCHURCH HOSPITALS NHS FOUNDATION TRUST
ISLE OF WIGHT NHS TRUST	THE ROYAL MARSDEN NHS FOUNDATION TRUST
JAMES PAGET UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	THE ROYAL ORTHOPAEDIC HOSPITAL NHS FOUNDATION TRUST

NHS Trusts	
KETTERING GENERAL HOSPITAL NHS FOUNDATION TRUST	THE ROYAL WOLVERHAMPTON NHS TRUST
KING'S COLLEGE HOSPITAL NHS FOUNDATION TRUST	THE SHREWSBURY AND TELFORD HOSPITAL NHS TRUST
KINGSTON AND RICHMOND NHS FOUNDATION TRUST	THE WALTON CENTRE NHS FOUNDATION TRUST
LANCASHIRE & SOUTH CUMBRIA NHS FOUNDATION TRUST	TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST
LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST	UNITED LINCOLNSHIRE TEACHING HOSPITALS NHS TRUST
LEEDS AND YORK PARTNERSHIP NHS FOUNDATION TRUST	UNIVERSITY COLLEGE LONDON HOSPITALS NHS FOUNDATION TRUST
LEEDS TEACHING HOSPITALS NHS TRUST	UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST
LEICESTERSHIRE PARTNERSHIP NHS TRUST	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST
LEWISHAM AND GREENWICH NHS TRUST	UNIVERSITY HOSPITALS BRISTOL AND WESTON NHS FOUNDATION TRUST
LINCOLNSHIRE PARTNERSHIP NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST
LIVERPOOL HEART AND CHEST HOSPITAL NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS DORSET NHS FOUNDATION TRUST
LIVERPOOL UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS OF DERBY AND BURTON NHS FOUNDATION TRUST
LIVERPOOL WOMEN'S NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
LONDON NORTH WEST UNIVERSITY HEALTHCARE NHS TRUST	UNIVERSITY HOSPITALS OF MORECAMBE BAY NHS FOUNDATION TRUST
MAIDSTONE AND TUNBRIDGE WELLS NHS TRUST	UNIVERSITY HOSPITALS OF NORTH MIDLANDS NHS TRUST
MANCHESTER UNIVERSITY NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS PLYMOUTH NHS TRUST
MEDWAY NHS FOUNDATION TRUST	UNIVERSITY HOSPITALS SUSSEX NHS FOUNDATION TRUST
MERSEY AND WEST LANCASHIRE TEACHING HOSPITALS NHS TRUST	VELINDRE NHS TRUST
MID AND SOUTH ESSEX NHS FOUNDATION TRUST	WALSALL HEALTHCARE NHS TRUST

NHS Trusts	
MID CHESHIRE HOSPITALS NHS FOUNDATION TRUST	WARRINGTON AND HALTON TEACHING HOSPITALS NHS FOUNDATION TRUST
MID YORKSHIRE TEACHING NHS TRUST	WEST HERTFORDSHIRE TEACHING HOSPITALS NHS TRUST
MIDLANDS PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST	WEST SUFFOLK NHS FOUNDATION TRUST
MILTON KEYNES UNIVERSITY HOSPITAL NHS FOUNDATION TRUST	WHITTINGTON HEALTH NHS TRUST
NORFOLK AND NORWICH UNIVERSITY HOSPITALS NHS FOUNDATION TRUST	WIRRAL UNIVERSITY TEACHING HOSPITAL NHS FOUNDATION TRUST
NORFOLK AND SUFFOLK NHS FOUNDATION TRUST	WORCESTERSHIRE ACUTE HOSPITALS NHS TRUST
NORTH BRISTOL NHS TRUST	WRIGHTINGTON, WIGAN AND LEIGH NHS FOUNDATION TRUST
NORTH CUMBRIA INTEGRATED CARE NHS FOUNDATION TRUST	WYE VALLEY NHS TRUST
NORTH MIDDLESEX UNIVERSITY HOSPITAL NHS TRUST	YEOVIL DISTRICT HOSPITAL NHS FOUNDATION TRUST
NORTH STAFFORDSHIRE COMBINED HEALTHCARE NHS TRUST	YORK AND SCARBOROUGH TEACHING HOSPITALS NHS FOUNDATION TRUST
Northern Ireland, Scotland and Wales	
NHS AYRSHIRE & ARRAN	NHS ORKNEY
NHS BORDERS	ANEURIN BEVAN UNIVERSITY HB
NHS DUMFRIES & GALLOWAY	CARDIFF & VALE UNIVERSITY HB
NHS FIFE	CWM TAF MORGANNWG UNIVERSITY HB
NHS FORTH VALLEY	HYWEL DDA UNIVERSITY HB
NHS GRAMPIAN	SWANSEA BAY UNIVERSITY HB
NHS GREATER GLASGOW & CLYDE	BETSI CADWALADR UNIVERSITY HB
NHS HIGHLAND	POWYS TEACHING HEALTH BOARD
NHS LANARKSHIRE	BELFAST HEALTH & SC TRUST
NHS LOTHIAN	NORTHERN HEALTH & SC TRUST
NHS SHETLAND	SOUTH EASTERN HEALTH & SC TRUST
NHS TAYSIDE	SOUTHERN HEALTH & SC TRUST
NHS WESTERN ISLES	WESTERN HEALTH & SC TRUST