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Case No COMP/M.6091 - GALENICA / FRESENIUS MEDICAL CARE / VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA JV

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REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
Date: 05/10/2011

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 Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE
ARTICLE 6(1)(b) DECISION

To the notifying party:

Dear Sir/Madam,

Subject: Case No COMP/M. 6091 - GALENICA / FRESENIUS MEDICAL CARE / VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA JV
Commission decision pursuant to Article 6(1)(b) of Council Regulation No 139/2004[1]

1. On 31 August 2011, the European Commission received a notification of a proposed concentration pursuant to Article 4 and following a referral pursuant to Article 4(5) of Council Regulation (EC) No 139/2004[2] by which the undertakings Galenica Ltd. ("Galenica", Switzerland) and Fresenius Medical Care AG & Co. KGaA ("FMC", Germany) acquire, within the meaning of Article 3(1)(b) of the Merger Regulation, joint control of Vifor Fresenius Medical Care Renal Pharma Ltd ("the JV", Switzerland) by way of a purchase of shares in a newly created company constituting a joint venture.

I. THE PARTIES AND THE OPERATION

2. Galenica, a publicly listed company based in Switzerland, is the parent company of the Galenica Group, an international group active in the provision of healthcare. Galenica develops, manufactures and sells pharmaceutical products worldwide and, in Switzerland, runs pharmacies, provides logistical and database services and sets up networks. Galenica's wholly owned subsidiary Vifor (International) Ltd. ("Vifor") is active in R&D, production and sale of pharmaceutical products against iron deficiency anaemia (iron preparations, such as *Venofer* and *Ferinject*). Vifor is also

1 OJ L 24, 29.1.2004, p. 1 ("the Merger Regulation"). With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this decision.

2 OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

currently developing a pharmaceutical product against hyperphosphataemia (a phosphate binder called *PA-21*), which it expects to launch in the […] at the earliest.

3. FMC, a publicly listed company based in Germany, belongs to the Fresenius Group, a global healthcare group. FMC is active in the renal field, in particular in R&D, production and sale of dialysis products (machinery, such as haemodialysis machines and dialysers, and related disposable products). FMC also provides dialysis services worldwide for patients suffering from chronic kidney disease ("CKD").[3] FMC distributes small volumes of phosphate binders (*PhosLo, Phosphosorb and OsvaRen*) (produced by another entity of the Fresenius Group).[4] It also acts as a distributor for Galenica's iron preparations (*Ferinject* and *Venofer*). FMC does not currently distribute iron preparations for other producers. Nonetheless, […], FMC concluded an agreement […] whereby FMC would have the right to market and distribute in the EEA *Ferrologic*,[…]).[5] Finally, FMC is currently developing an adapter piece, […], for the […] administration of a medicine […] to the extracorporeal circuit of a dialysis machine.

4. The JV, to be based in Switzerland, will be active in the renal field[6] and more precisely in R&D, marketing and distribution of:

   (i) pharmaceutical products against hyperphosphataemia (phosphate binders, in particular Galenica's *PA-21*),
   (ii) intravenous pharmaceutical products against iron deficiency anaemia prescribed by a renal specialist to a patient suffering from CKD stages III to V[7] (intravenous iron preparations, in particular Galenica's *Venofer* and *Ferinject*[8]), and
   (iii) medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system as part of a dialysis treatment (in particular FMC's *[…]*).

5. Following the proposed transaction, Galenica will retain the right to produce, market and distribute oral iron preparations as well as *Venofer* and *Ferinject* outside the renal field. FMC will remain active in the distribution of phosphate binders and the provision of dialysis services and will retain the right to produce *[…]* and to market and distribute it outside the renal field. […].

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3 In addition to FMC, another company of the Fresenius Group, Helios, provides dialysis services in Germany.

4 Fresenius Medical Care Deutschland GmbH.

5 However, […] FMC is unable to indicate a date for the launch of *Ferrologic* in the EEA.

6 Other fields where patients may require iron therapy are, e.g., gastroenterology, oncology, cardiology, and gynecology.

7 Patients with CKD stages I and II do not generally show symptoms and are not diagnosed or seen by a nephrologist. These patients do not require iron therapy.

8 […].

6. […], Galenica and FMC ("the Parties") entered into a […] “JV Agreements”). The JV Agreements provide that the Parties will establish a JV in which 55% of the shares will be held by Galenica and the remaining 45% will be held by FMC.

II. CONCENTRATION

Joint control

7. According to the Shareholders Agreement, […] the Parties will nominate […] Directors to the Board of Directors of the JV. The Chairman of the Board will be designated by Galenica and the Vice-Chairman by FMC.

8. The affirmative vote of at least […] is required for any resolution of the Board regarding strategic decisions affecting the JV's business policy, such as:.[…].

9. In view of the above, and in accordance with the Commission’s Jurisdictional Notice,[9] the Parties will exercise joint control over the JV.

Full functionality

10. In line with the criteria laid down in the Commission's Jurisdictional Notice[10], the JV will be full functional as it will possess sufficient resources to operate independently on the market; will carry out activities going beyond one specific function for the parents; will be economically autonomous with regard to sale and purchase relations with its parents and will operate on a lasting basis.

Conclusion

11. The proposed transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the EU Merger Regulation.

III. EU DIMENSION

12. The notified concentration does not have an EU dimension within the meaning of Article 1 of the Merger Regulation. However, on 23 June 2011, the notifying party informed the Commission in a reasoned submission pursuant to Article 4(5) of the Merger Regulation that the concentration was capable of being reviewed under the national competition laws of at least three Member States, namely Austria, the Czech Republic, Germany, Poland, Portugal, the Slovak Republic and Spain, and requested the Commission to examine it. None of the Member States competent to examine the concentration indicated its disagreement with the request for referral within the period laid down by the Merger Regulation.

13. Therefore, the concentration is deemed to have an EU dimension pursuant to Article 4(5) of the Merger Regulation and the Commission has jurisdiction to examine it.

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9 Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings, OJ C 95, 16.4.2008, p. 1, paragraphs 62-82.

10 Paragraphs 91-109.

IV. COMPETITIVE ASSESSMENT

14. The proposed transaction concerns the sale of pharmaceutical products, namely iron preparations and phosphate binders, the sale of medical devices and the provision of dialysis services in several EEA Member States for patients suffering from chronic kidney disease.

IV.1 MARKET DEFINITION

1. Relevant product market

(i) Introductory remarks on finished dose pharmaceuticals

15. The proposed transaction involves two […] pharmaceuticals. The activities of FMC and the JV potentially overlap in the distribution of phosphate binders whilst the JV's sales of iron products to FMC will be vertically linked.

ATC classification

16. In previous decisions[11], the Commission has noted that pharmaceuticals may be classified in therapeutic classes by reference to the "Anatomical Therapeutic Chemical" classification ("ATC"), devised by the European Pharmaceutical Marketing Research Association ("EphMRA") and maintained by EphMRA and Intercontinental Medical Statistics ("IMS"). The ATC has 16 categories (A, B, C, D, etc.), each with different levels[12]. At the third ATC level ("ATC3"), pharmaceuticals are grouped by their therapeutic indication, i.e. their intended use. This level has been in the past generally used as the starting point for investigating and defining relevant product markets in competition cases, in particular for competition between innovator companies.

17. However, analyses at other ATC levels, or a mixture thereof, may be warranted if the circumstances of the case show that sufficiently strong competitive constraints on the undertakings involved are situated at another ATC level and there are indications that the ATC3 class does not lead to a correct market definition.[13] The Commission has previously departed from the ATC3 class where the market investigation indicated that a market definition based on other elements was more appropriate, for example at the ATC4 level[14], on the basis of equivalent active pharmaceutical

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11 For example, M.5865 *Teva/Ratiopharm*; M.5661 *Abbott/Solvay*; M.5253 *Sanofi-Aventis/Zentiva*; M.5953 *Reckitt Benckiser/SSL International;* M.5999 *Sanofi-Aventis/Genzyme*.

12 The first level/category of the ATC indicates the anatomical main group. The second level indicates the main therapeutic group. The third level indicates the therapeutic/pharmacological subgroup while the fourth level indicates the chemical/therapeutic/pharmacological subgroup. The first level categories, ATC1, are subdivided into ATC2 categories, which are in turn sub-divided into ATC3 categories. Some ATC3 categories are sub-divided into ATC4 categories, whereas some others are not.

13 M.5502 *Merck/Schering Plough;* M.5253 *Sanofi-Aventis/Zentiva*.

14 M.5253 *Sanofi-Aventis/Zentiva.*

ingredients (molecule level)[15], or where several medicines were used for the treatment of a particular disease irrespective of their ATC classification[16].

Prescription pharmaceuticals and over-the-counter pharmaceuticals

18. In previous decisions, the Commission has considered that medicines available over-the-counter ("OTC"), that is, without a medical prescription, normally belong to a different product market than drugs available only on medical prescription ("Rx").[17]

Different pharmaceutical forms and routes of administration

19. Medicines are differentiated not only by their active ingredient(s) but also, in particular, as recognized by the European regulatory framework for medicines for human use, by their posology, pharmaceutical form and method and route of administration, which may limit their substitutability[18].

(ii) Phosphate binders

20. Phosphate binders are used to reduce phosphate levels in late-stage kidney failure.[19] They are always administered orally as their medical effect occurs in the gastrointestinal tract of the human body.

21. Phosphate binders are classified under ATC3 class V3G, which covers (i) products to treat excess phosphate (hyperphosphataemia) and (ii) products to treat excess potassium (hyperkalaemia).

22. The Commission noted in *Sanofi-Aventis/Genzyme* that the ATC classification is not a relevant basis for defining the markets for phosphate and potassium binders and that the starting point appears to be the type of substance targeted by the particular drug (phosphate and potassium).[20]

23. The Notifying Parties submit that the relevant product market should be defined as comprising all kinds of phosphate binders and as a separate market from potassium binders.

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15 M.5865 *Teva/Ratiopharm*; M.5295 *Teva/Barr*.

16 For example, "Multiple Sclerosis" in M.4049 *Novartis/Chiron.*

17 M.5502 *Merck/Schering Plough;* M.5253 *Sanofi-Aventis/Zentiva;* M.3544 *Bayer Healthcare/Roche*; M.3394 *Johnson & Johnson/Johnson & Johnson MSD Europe*.

18 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), Articles 9 and 11.

19 Phosphorus is contained in certain kinds of food. Healthy kidneys remove excess phosphorus from the body. One of the consequences of renal failure is inadequate removal of phosphorus, which results in increased serum phosphorus levels. This may lead to the calcification of blood vessels and is associated with cardiovascular mortality. In addition to dialysis therapy and dietary restrictions, a pharmaceutical therapy to lower phosphorus levels is required.

20 M.5999 *Sanofi-Aventis/Genzyme.*

24. Galenica's pipeline phosphate binder *PA-21*, which the JV will market and distribute, and the phosphate binders sold by FMC are only available on prescription (only one of the three FMC's products, *OsvaRen*, is available OTC in around 50% of the EU Member States).

25. In this case, the product market definition for phosphate binders can be left open as no serious doubts arise whether phosphate binders are regarded as a separate market from potassium binders or as part of an overall market for all kinds of phosphate binders.

(iii) Iron preparations

26. Iron preparations are indicated for the treatment of iron deficiencies, in particular anaemia. They are classified under ATC3 class B3A, which covers "haematinics, iron and all combinations". ATC4 levels B3A1 and B3A2 further distinguish between "plain iron" and "iron combination products" respectively. Both *Venofer* and *Ferinject*, the products produced and sold by Galenica, are classified under ATC4 class B3A1.[21]

27. With regard to the molecule (or active pharmaceutical ingredient - "API") on which Galenica's products are based, *Venofer* is based on iron sucrose whilst *Ferinject* is based on feric carboxymaltose, that is, on two different molecules.[22] However, as both products are used in the downstream market for dialysis services, in this case a market definition based on the product's molecule is not appropriate.

28. Iron preparations can be delivered on prescription or OTC, and can be administered in oral or intravenous form. Intravenous iron preparations are always subject to medical prescription and their prices are normally regulated, whilst oral iron preparations are available OTC, although they can be reimbursed if prescribed by a doctor.

29. The Commission has examined iron preparations in previous decisions but finally left the product market definition open.[23]

30. The Notifying Parties submit that the product market definition should cover all iron preparations used in the treatment of iron deficiencies classified under ATC3 class B3A, without distinguishing between intravenous and oral iron preparations or between OTC and prescription iron preparations.

31. However, both *Venofer* and *Ferinject* are plain iron intravenous preparations, classified in ATC4 group B3A1, subject to prescription for the treatment of iron deficiencies in a number of medical areas.[24]

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21 *Ferrologic*, […] which is not yet marketed, is also classified under ATC4 class B3A1.

22 *Ferrologic*, […] is also based on iron sucrose.

23 M.2312 *Abbott/BASF*; M.4402 *UCB/Schwarz Pharma*; M.5253 *Sanofi-Aventis/Zentiva*.

24 This is also the case of *Ferrologic.*

32. Galenica will transfer to the JV the right to conduct R&D, marketing and distribution of *Venofer* and *Ferinject*[25] only in the renal field. These intravenous iron preparations in the renal field are prescribed by a renal specialist to patients suffering from chronic kidney disease stages III to V. Nonetheless, intravenous iron preparations are also used in other fields such as, for example, gastroenterology, oncology and cardiology.[26]

33. The market investigation examined whether the product market definition for iron preparations should be segmented into oral and intravenous iron preparations. A majority of respondents expressed the view that oral and intravenous iron preparations should be regarded as separate product markets.

34. However, in this case, the product market definition for iron preparations can be left open as no serious doubts arise under any plausible market definition, in particular under the narrowest product market definition covering plain iron intravenous preparations classified under ATC4 class B3A1.

(iv) Medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system

35. The Commission has not defined in previous decisions the product market for medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system.

36. The Notifying Parties submit that these devices could be considered to be part of an overall product market covering dialysis products, given that FMC's pipeline *[…]* is being developed as an adapter piece for dialysis machines, that is, as a non-consumable piece that will be […] connected to a dialysis machine. Alternatively, *[…]* could be considered to be part of a narrower product market covering adapter pieces for the […] administration of a medicament […] to the extracorporeal circuit of a dialysis machine. The Notifying Parties, however, argue that this narrower market definition would not be adequate as it is envisaged that *[…]* will be developed in a way that it can be used outside the treatment of dialysis patients, that is, as an adapter piece for machines other than dialysis machines. A third possibility would thus be a broader product market definition covering all medical devices for the purpose of administering […] pharmaceutical substances into a patient's blood system.

37. In this case, the product market definition can be left open as no serious doubts arise under any plausible market definition.

(v) Dialysis services

38. Dialysis is the life-saving replacement of the blood cleansing function of kidneys in patients with acute or chronic kidney failure. There are two types of dialysis

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26 In the field of gynecology, most patients respond well to oral iron preparations and only severe cases of iron deficiency anaemia require intravenous iron therapy.

treatments: hemodialysis ("HD") and peritoneal dialysis ("PD"). Both HD and PD treatments remove waste and excess water from the blood. HD removes waste and water by circulating blood outside the body through an external filter called a dialyzer. An HD treatment typically lasts 3 to 5 hours and is provided in a dialysis centre three times per week. In PD, waste and water are removed from the blood inside the body using the peritoneal membrane of the peritoneum as a natural semipermeable membrane. PD is carried out at home by the patient and is normally repeated 4-5 times per day. PD is less efficient than HD, but because it is carried out for a longer period of time, the result in terms of removal of waste and water is similar to HD. PD frees patients from having to go to a dialysis clinic on a fixed schedule several times per week.

39. On the demand side, generally a patient and his/her physician decide before beginning the dialysis treatment which treatment will be most convenient. Once the dialysis treatment has been initiated, patients are still able to switch. Sometimes patients change from PD to HD if the patient's medical condition deteriorates. Vice versa, a change from HD to PD is possible although rather rare.

40. On the supply side, both HD and PD treatments are prescribed and monitored by nephrologists and medical personnel specifically trained who can service HD and PD patients alike.

41. The Commission has not defined in previous decisions the product market for dialysis services.

42. The Notifying Parties submit that the product market definition for dialysis services should cover all medical services regarding HD and PD treatments given that, from the demand side, PD and HD are generally substitutable as both treatments serve the same purpose and, from the supply side, dialysis centres and hospitals generally offer services for both kinds of treatments.

43. In this case, the product market definition for dialysis services can be left open as no serious doubts arise whether HD and PD are regarded separately or the product market is defined as including FMC's activities in both HD and PD.

2. Relevant geographic market

(i) Phosphate binders and iron preparations

44. The Commission has in previous decisions defined the geographic market for pharmaceutical products as national in scope on the basis of, inter alia, different national regulatory frameworks, price setting and reimbursement rules.[27]

45. This definition also appears appropriate in the circumstances of this case and the Notifying Parties agree with it.

(ii) Medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system

27 M.5253 *Sanofi-Aventis/Zentiva*; M.5295 *Teva/Barr*; M.5953 *Reckitt Benckiser/SSL International*.

46. The Commission found in *J&J/Guidant* and *Abbott/Guidant* that the relevant geographic market for medical devices is national, essentially because of differences in reimbursement schemes, procurement processes, prices and market shares across countries in the EEA, as well as the fact that most customers consider a local sales office a necessity and do not source from abroad.[28]

47. The Notifying Parties submit that the geographic market for adapter pieces such as *[…]* should be defined at least as national in scope.

48. In this case, the geographic market definition for adapter pieces such as *[…]* can be left open as no serious doubts arise whether the market is defined as national or broader.

(iii) Dialysis services

49. In previous decisions the Commission has left open whether the relevant geographic market for hospital services should be considered to be national or rather regional/local.[29]

50. The Notifying Parties submit that the geographic market for dialysis services should be defined as national because, although, from a patient's (demand) perspective, markets tend to be regional as most dialysis patients are not willing to travel more than necessary to obtain treatment, the market for the provision (supply) of dialysis services is subject to national regulation, the contracts for the provision of dialysis services are often subject to nationwide tender proceedings, and there are no regional differences in the prices charged to patients as prices are regulated at a national level.

51. The results of the market investigation with regard to the geographic scope of the market for dialysis services were inconclusive. However, many respondents considered unlikely a regional scope of the market.

52. In this case, the geographic market definition for dialysis services can be left open as serious doubts can be excluded whether the market is defined as regional/local or national.

IV.2 COMPETITIVE ASSESSMENT

53. The Notifying Parties confirmed that the activities of the Galenica Group and the Fresenius Group outside the scope of the JV do not overlap and are not vertically linked.

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28 M.3687 *Johnson & Johnson/Guidant*; M.4150 *Abbott/Guidant*.

29 M.4367 *APW/APSA/Nordic Capital/Capio*; M.5805 *3i/Vedici Groupe*; M.4229 *APHL/L&R/Netcare General Healthcare Group*; M.5548 *Barclays /RBS /Hillary*.

1. Horizontal overlaps

(i) Phosphate binders

54. FMC is active in the distribution of phosphate binders (*OsvaRen, Phosphosorb* and *PhosLo*) produced by another entity of the Fresenius Group (Fresenius Medical Care Deutschland GmbH). Galenica has a pipeline phosphate binder called *PA-21* […] and which it expects to launch in […]. Galenica will transfer to the JV the right to market and distribute *PA-21*. In previous decisions[30] relating to originator pipelines, the Commission considered a pipeline in a sufficiently advanced stage of development as a possible competitive constraint.

55. In 2010, FMC's market shares in the narrowest market definition for phosphate binders (that is, excluding potassium binders) in each of the EEA Member States where it is active (Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy, the Netherlands, Norway, Slovakia, Slovenia, Spain, Sweden and the UK) were <5%. The Notifying Parties estimate that the JV's sales of *PA-21* during the first two years after launch in each of the EEA Member States where sales are initially planned (UK, Germany, France, Italy and Spain) will not exceed 10%.

56. The proposed transaction does not therefore give rise to horizontally affected markets in respect of phosphate binders.

57. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to phosphate binders.

(ii) Iron preparations

58. Galenica is active in the production and distribution of oral and intravenous iron preparations in a number of medical fields. Galenica will transfer to the JV the right to conduct R&D, market and distribute its intravenous iron preparations *Ferinject* and *Venofer* only in the renal field. Galenica will keep the right to produce, market and distribute its own oral iron preparations as well as its intravenous iron preparations *Ferinject* and *Venofer* in fields other than the renal field.

59. Galenica and the JV will therefore be active in the marketing and distribution of intravenous iron preparations although in different medical fields. If, however, it is considered that the activities of Galenica and the JV would overlap horizontally in the marketing and distribution of intravenous iron preparations, the proposed transaction would not lead to an increment in the overall market share for intravenous iron preparations but rather to a redistribution of Galenica's existing total market share between, on the one hand, Galenica in respect of intravenous iron preparations in the non-renal field and, on the other hand, the JV in respect of intravenous iron preparations in the renal field.

60. FMC is not active in the production of iron preparations but currently acts as a distributor for Galenica in Belgium.[31] FMC will transfer to the JV its marketing and

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30 M.5502 *Merck/Schering Plough;* M.5476 *Pfizer/Wyeth;* M.5999 *Sanofi-Aventis/Genzyme.*

31 According to the market share data provided by the Parties, FMC distributed Galenica's *Venofer* in Belgium in 2010 with a market share of [70-80%]

distribution rights related to Galenica's intravenous products. FMC has no other marketing or distribution activities with regard to iron preparations from other suppliers. Nonetheless, as mentioned above, […] FMC concluded an agreement with […] for an initial duration of […] years whereby FMC has the right to market and distribute in the EEA *Ferrologic,* […] *Ferrologic* has not yet been launched and FMC is unable to indicate when this will occur.[32]

61. The proposed transaction does not therefore give rise to horizontally affected markets in respect of intravenous iron preparations.

62. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to intravenous iron preparations.

2. Vertical links

63. The proposed transaction results in the establishment of vertical links between upstream markets where the JV will be active (namely the distribution of phosphate binders, intravenous iron preparations and *[…]*) and the downstream market for the provision of dialysis services where FMC is active.

64. The proposed transaction also raises the question whether distributors of intravenous iron preparations will face input foreclosure as a result of the transfer of the distribution of intravenous iron preparations from Galenica to the JV.

(i) Phosphate binders and dialysis services

65. Galenica is developing a phosphate binder called *PA-21* which it expects to launch in […]. Galenica will transfer the right to market and distribute *PA-21* to the JV.

66. As indicated, phosphate binders (which are prescribed and supplied independently of dialysis services) are always administered in oral form. The phosphate binders supplied by the JV and the dialysis services provided by FMC will thus not be vertically linked as patients purchase phosphate binders directly from pharmacies.

67. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to a possible vertical link between phosphate binders and dialysis services.

(ii) Iron preparations and dialysis services

68. Following the proposed transaction, the JV will be granted the right to distribute Galenica's intravenous iron preparations in the renal field. FMC will remain active in the provision of dialysis services. Intravenous iron preparations are used during the dialysis procedure to treat patients' iron deficiency. This vertical link results in a number of vertically affected markets.

69. The following table shows, for 2010: (i) Galenica's market shares on an overall market for oral and intravenous plain iron preparations and a market for only intravenous plain iron preparations (Galenica’s oral and intravenous iron

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preparations are both classified under ATC4 class B3A1), and (ii) FMC's market shares[33] on an overall market for dialysis services (including both hemodialysis and peritoneal dialysis) at national and regional levels, for the EEA Member States where the two Parties are active in their respective markets and at least one of them has a market share of 25% or more.

	Galenica's market share (%) in value for all iron preparations	**Galenica's market share (%) in value for IV iron preparations[34]**	**FMC's market share (%) national**	**FMC's market share (%) regional[35]**
Czech Republic	[10-20]	[5-10]	[20-30]	[50-60] [90-100]
Estonia	[50-60]	[90-100]	[30-40]	[30-40]
France	[0-5]	[50-60]	[0-5]	[30-40]
Germany	[20-30]	[50-60]	[0-5]	All < [20-30]
Hungary	[30-40]	[0-5]	[30-40]	[30-40] -[90-100]
Poland	[20-30]	[70-80]	[20-30]	[20-30] [40-50]
Portugal	[30-40]	[90-100]	[40-50]	[30-40] [80-90]
Romania	[80-90]	[90-100]	[40-50]	[20-30] [60-70]
Slovakia	[60-70]	[90-100]	[50-60]	[30-40] [90-100]
Slovenia	[60-70]	[90-100]	[20-30]	[30-40]
Spain	[10-20]	[60-70]	[20-30]	[20-30] [90-100]
Sweden	[50-60]	[90-100]	[0-5]	All < [20-30]
United Kingdom	[20-30]	[80-90]	[10-20]	[20-30] [90-100]

70. The Notifying Parties provided an overview of national legislation and professional codes of conduct of the relevant EEA Member States governing the choice of the pharmaceutical product to be prescribed by a doctor to a patient, which thus apply to the choice of intravenous iron preparation to be prescribed by a nephrologist for the provision of dialysis treatment. The national legislations of all EEA Member States concerned, except the Czech Republic and Poland, provide that doctors are free to choose the pharmaceutical product to be prescribed to a patient and that this decision will only be driven by reasons related to the patient's health and well-being or by Good Medical Practice principles. In line with these national legislations, and given that intravenous iron preparations are prescribed separately and in addition to dialysis services, following the proposed transaction doctors will continue to choose

33 FMC's market share data includes sales by Helios, another entity of the Fresenius Group that provides dialysis services in Germany.

34 This market share data includes intravenous iron preparations for all fields, that is, renal and non-renal (for example, oncology, cardiology, gastroenterology and gynecology).

35 Indicates the lowest and highest values above 25%.

the intravenous iron preparation that they deem most appropriate for their patients regardless of the entity that provides the dialysis treatment downstream.

71. The Notifying Parties submit that, irrespective of the doctors' freedom of choice, even if FMC's doctors chose to always prescribe intravenous iron preparations supplied by the JV, and despite the significant market shares held by Galenica on the most narrowly defined market for *intravenous* iron preparations and by FMC on the most narrowly defined market for *regional* dialysis services, the JV would have no incentive to engage in an input foreclose strategy towards FMC's rivals on the downstream market for dialysis services and that a customer foreclosure strategy towards the JV's upstream rivals would have no significant detrimental effect on patients of dialysis treatment.

72. With regard to input foreclosure, the Notifying Parties claim that, even in a situation where no competitor is present on the upstream market for intravenous iron preparations, the JV will have no economic incentive to refuse supplying intravenous iron preparations to competitors of FMC. Indeed, such a strategy would seriously endanger the JV's profits given that credible competitors of FMC currently purchase Galenica's intravenous iron preparations. For example, as indicated in the table above, where Galenica has a monopoly or near monopoly on the upstream market for intravenous iron preparations, namely [90-100%] in Sweden, [90-100%] in Slovenia and [90-100%] in Estonia, Portugal, Romania and Slovakia, FMC's competitors on the downstream market for dialysis services that buy Galenica's intravenous iron preparations collectively still hold, on a national level, very large or significant market shares, namely [90-100%] in Sweden, [80-90%] in Slovenia, [60-70%] in Estonia, [50-60%] in Portugal, [50-60%] in Romania and [40-50%] in Slovakia. Therefore, whilst any profit lost with an input foreclosure strategy would likely be significant, it is uncertain that it would bring about any additional profit for FMC in the downstream market. The Notifying Parties note that Galenica, as a JV's jointly controlling parent, has a strong economic interest in the JV being as successful and profitable as possible, and that it can be excluded that Galenica would have any interest in agreeing to a strategy which would limit sales and profits of the JV.

73. Moreover, a number of credible competitors are present on the national markets for intravenous iron preparations, such as Sanofi-Aventis and Novartis, as follows: Czech Republic (Sanofi-Aventis: [90-100%]), France (Pierre-Fabre: [40-50%]), Germany (Sanofi-Aventis: [30-40%], others: [5-10%]), Hungary (Sanofi-Aventis: [90-100%]), Poland (Pharmacosmos, a new entrant:[10-20%], Novartis: [10-20%]), Spain (five competitors collectively hold [30-40%]), Sweden (Pharmacosmos: [0-5%]), UK (Pharmacosmos: [10-20%]). The presence of several competitors on these markets also indicates that barriers to entry into this market, where generic products are also present (for example, Galenica's *Venofer* and […] *Ferrologic*), are not high.

74. Finally, new companies have recently entered or are expected to enter the market for intravenous iron preparations. For example, in 2010, Pharmacosmos received marketing authorisations for its product *Monofer* in Sweden, Denmark, Iceland, the Netherlands, Belgium, Portugal, Estonia, Bulgaria, Norway, Poland, Ireland, Latvia, Lithuania and the UK. Also, AMAG Pharmaceutical has licensed its product *Feraheme* to Takeda and the latter is seeking an EEA-wide approval through the centralised procedure. Launch of *Feraheme* is expected in 2011/ 2012.

75. As to customer foreclosure, FMC's market shares on a national level range, as indicated in the table above, from [0-5%] (Sweden) to [50-60%] (Slovakia). In the Member States where Galenica has a monopoly on the upstream market for intravenous iron preparations, namely Estonia, Portugal, Romania and Slovakia, no customer foreclosure concerns arise as Galenica supplies, already prior to the proposed transaction, all intravenous iron preparation requirements on the dialysis services market. With regard to Member States where competitors of Galenica remain on the upstream market for intravenous iron preparations, no customer foreclosure concerns arise as Galenica's competitors will continue to be able to supply intravenous iron preparations to FMC's competing dialysis service providers given that, collectively, FMC's rivals still hold at least 60% of the relevant national markets ([70-80%] in the Czech Republic, [90-100%] in France, [90-100%] in Germany, [60-70%] in Hungary, [70-80%] in Poland, [80-90%] in Slovenia, [70-80%] in Spain, [90-100%] in Sweden and [80-90%] in the UK).

76. With regard to customer foreclosure in hypothetical regional markets for dialysis services (which, as indicated, the results of the market investigation did not support in a conclusive manner), only in a few regions of four Member States does FMC have market shares above 50% on the downstream market for dialysis services where competitors of Galenica are present on the upstream market for intravenous iron preparations.[36]

77. In these cases, a customer foreclosure strategy would not result in a significant detrimental effect on patients of dialysis treatment because, as the market for intravenous iron preparations is of a national scope and thus dialysis service providers purchase intravenous iron preparations on a national basis, Galenica's competitors in the market for intravenous iron preparations could turn to other regions to find a customer base. In addition, as shown by the data submitted by the Notifying Parties, the number of patients that receive dialysis services from FMC in the regions concerned is less than 25% of the overall number of patients on a national basis (Czech Republic: [20-30%]; Hungary: [10-20%]; Spain: [5-10%]; UK: [1-5%]). Following the proposed transaction there will therefore remain sufficient demand for Galenica's competitors on the upstream national market for intravenous iron preparations. Likewise, if FMC's rival dialysis centres in a region where FMC has a market share above 50% were supplied under worse conditions post-merger, they could, given that purchases of intravenous iron preparations are made on a national level, turn to any other national supplier of iron preparations.

78. Slovakia is the only EEA Member State where, if downstream markets for dialysis services are defined on a regional basis, Galenica would have a monopoly on the upstream market for intravenous iron preparations and FMC on the downstream market in one region[37]. This situation, however, predates the proposed transaction and is not merger specific.

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36 Czech Republic: Praha [50-60%]; Severovýchod: [70-80%]; Severozápad: [80-90%]; Stredni Cechy: [90-100%]; Hungary: Észak-Magyarország: [90-100%]; Spain: Cantabria: [70-80%]; Ciudad Autónoma de Ceuta: [90-100%]; Extremadura: [60-70%], Región de Murcia: [80-90%]; UK: Cheshire: [90-100%]; East Yorkshire: [90-100%]; Herefordshire: [90-100%]; Lincolnshire: [60-70%].

37 Braislaský kraj.

79. Moreover, a number of competitors are present on the national markets for dialysis services,[38] as follows: Czech Republic (B. Brown: [10-20%]), Estonia (Lääne Tallinna: [30-40%], Pohja Eesti: [10-20%]), Germany (KfH: [20-30%], PHV: [5-10%] Hungary (Diaverum: [10-20%], B.Braun: [30-40%]), Poland (Diaverum: [10-20%], B.Braun: [5-10%]) Portugal (Diaverum: [20-30%], Euromedic: [5-10%]), Slovakia (B. Brown: [10-20%]), Slovenia (Splosna bolnisnica Celje: [5-10%], Splosna bolnisnica Novo Mesto: [5-10%], Univerzitetni klinicni center Maribor: [10-20%]) and Spain (Diaverum: [10-20%]). The presence of several competitors on these markets also indicates that barriers to entry are not high. In addition, as indicated in the table above, the Notifying Parties have market shares below 40% in the majority of national markets, namely the Czech Republic, Estonia, France, Germany, Hungary, Poland, Slovenia, Spain, Sweden and the UK and above 40% only in Portugal, Romania ands Slovakia.

80. The market investigation revealed no substantiated competition concerns from either customers or competitors regarding the vertical link between the supply of intravenous iron preparations by the JV and the provision of dialysis services by FMC. Only one respondent claimed, in particular, that the proposed transaction would lead to input and customer foreclosure as FMC would instruct all its dialysis centres to purchase all their intravenous iron preparation requirements from the JV. However, as indicated, under the legislation of all the Member States concerned except the Czech Republic and Poland (the respondent is not active in the Czech Republic), it is the doctor who freely chooses the pharmaceutical product to be prescribed to the patient and he/she does so separately and in addition to dialysis services. Further, neither Galenica nor the JV have an economic incentive to engage in a strategy of input foreclosure with regard to FMC's rivals downstream that would lead to reduced profits for the JV. Likewise, a customer foreclosure strategy on narrowly defined regional markets would not prevent nation-wide iron suppliers from finding customers in other regions (this would also be the case in Poland, where FMC would have market shares below 50% on all narrowly defined regional markets).

81. It is therefore considered that the proposed transaction will not lead to input or customer foreclosure in connection with intravenous iron preparations and dialysis services.

82. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to the vertical link between intravenous iron preparations and dialysis services.

(iii) Medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system and dialysis services

83. FMC is currently developing *[…]*, a medical device that it expects to launch […]. *[…]* is an adapter piece for the […] administration of a pharmaceutical […] into the extracorporeal circuit of a dialysis machine. FMC intends to develop *[…]* in a way that it can also be used with dialysis machines of third providers of such machines and outside the treatment of dialysis patients. FMC will transfer to the JV the right to market and distribute this product.

38 Competitors with market shares below 5% are not listed.

84. The Notifying Parties indicate that FMC has an interest to promote *[…]* as widely as possible and that, equally, the JV will have an interest in maximising the sales of this product.

85. In addition, *[…]* is a device that facilitates, for personnel in dialysis centres, the administration of an […] pharmaceutical into the extracorporeal dialysis treatment system. *[…]* cannot be used as a tool to foreclose FMC's competing dialysis centres from the pharmaceuticals […]as these […]can still be administered with a needle and syringe. […] is not therefore an indispensable or even important input for the provision of […] dialysis services. Moreover, as indicated, the JV intends to maximise sales of this product.

86. The market investigation revealed no substantiated competition concerns from either customers or competitors regarding input or customer foreclosure in connection with medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system and dialysis services.

87. In view of all of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to a possible vertical link between medical devices for the purpose of administering […] pharmaceutical substances into the patient's blood system and dialysis services.

(iv) Production and distribution of iron preparations

88. Following the proposed transaction, Galenica will remain active in the production of oral and intravenous iron preparations while the marketing and distribution of Galenica's intravenous iron preparations in the renal field will be entrusted to the JV. The question arises whether this vertical link between Galenica and the JV could lead to input foreclosure for distributors of intravenous iron preparations.

89. The Notifying Parties explain that the proposed transaction will have no impact on distributors of intravenous iron preparations in the Czech Republic, Germany, Slovakia, France, Romania, Sweden and the UK given that, in these Member States, Galenica distributes iron preparations through its own sales subsidiary.

90. In Poland, Portugal and Spain, Galenica currently distributes its intravenous iron preparations through third party distributors. The Notifying Parties indicate that, in conformity with the Shareholders Agreement, their intention is that the JV appoints in each Member State the most efficient sales force,[39] such that the JV may decide to maintain the distributors currently used by Galenica. In any event, in these Member States as well as in Estonia, Hungary and Slovenia, a number of new producers have

[39] […] Agreement states that the JV will "take into account the particular strengths of existing distribution organisations of the Parties in different countries as well as considerations of practicability with respect to the marketing and distribution of the Products and prior agreements with other third parties which may already exist (including but not limited to the fact that in some countries the marketing authorization holder has to be a local company and therefore a change might be too costly in view of the benefits)."

recently entered the market for the production of intravenous iron preparations that will compete with the JV in the renal field.[40]

91. The market investigation revealed no substantiated competition concerns from either customers or competitors regarding input foreclosure in connection with the distribution of iron preparations in the Member States concerned.

92. In view of the above, the proposed transaction does not raise serious doubts as to its compatibility with the internal market with regard to the vertical link between production and distribution of iron preparations.

V. CONCLUSION

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

For the European Commission,

(signed)
Joaquín ALMUNIA
Vice-President

40 For example, in Estonia, Galenica's market share for iron preparations (both intravenous and oral) decreased from [70-80%] in 2008 to [50-60%] in 2010, while a competitors'[…], increased from [20-30%] in 2008 to [40-50%] in 2010; in Slovenia, competing producers launched new products in 2009: […]; finally, in Spain, several undertakings entered the iron market over the last five years: […]