EN

Case No COMP/M.4207 - CAMPINA / FONTERRA CO-OPERATIVE GROUP / JV

Only the English text is available and authentic.

REGULATION (EC) No 139/2004
MERGER PROCEDURE

Article 6(1)(b) NON-OPPOSITION
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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02/06/2006

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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 Where possible the information omitted has been replaced by ranges of figures or a general description.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 parties

Dear Sir/Madam,

Subject: Case No. COMP/M.4207 - CAMPINA / FONTERRA CO-OPERATIVE GROUP / JV
Notification of 24.4.2006 pursuant to Article 4 of Council Regulation No 139/2004[1]

1. On 24 April 2006, the Commission received a notification of a proposed concentration by which Campina B.V. ("Campina", The Netherlands) and Fonterra Co-operative Group Limited ("Fonterra", New Zealand) create a jointly controlled full-function joint venture (the "Joint Venture") in the field of pharmaceutical excipients and lactose for fine chemical manufacture.

2. After examination of the notification, the Commission has concluded that the notified operation falls within the scope of Council Regulation (EC) No 139/2004 ("the Merger Regulation"), and does not raise serious doubts as to its compatibility with the common market and with the functioning of the EEA Agreement.

I. THE PARTIES

3. **Campina** is a Netherlands-based co-operative, internationally active in the development, production, sale and distribution of dairy and dairy related consumer products. In the production and supply of food and pharmaceutical ingredients, Campina acts through its wholly owned subsidiaries DMV International GmbH and

[1] OJ L 24, 29.1.2004 p. 1.

DMV International B.V. (together "DMV"). DMV develops and produces functional and nutritional ingredients for the food, nutrition and pharmaceutical industry.

4. **Fonterra** is a New Zealand based dairy group, co-operatively owned by over 11,000 New Zealand dairy farmers. Fonterra's principal activities are the production of dairy-based branded consumer and food products and the supply of dairy-based ingredients for the food manufacturing industry. Its other operations comprise the provision of agricultural and technological support to farmers and biotechnological research and development focused on the diary industry.

5. Both the notifying parties manufacture and supply pharmaceutical grade lactose that can be used as an excipient in pharmaceuticals. Campina is also active in producing excipients that are based on other substances than lactose. Excipients are inactive substances used as carriers or diluting agents in active drug formulations, or to aid the process by which a pharmaceutical product is manufactured. Both Campina and Fonterra are also active in manufacturing lactose for fine chemical manufacture. ("Lactulose" and "Lactitol", used in human medicine, nutrition and in livestock breeding).

II. THE OPERATION

6. The proposed joint venture of Campina/DMV and Fonterra will be formed by the creation of a limited partnership under German law (DMV-Fonterra Excipients GmbH & Co. KG). Both Fonterra and Campina will be limited partners and a new German limited company (DMV Verwaltungs GmbH) which will be owned in equal proportion by Campina and Fonterra will be the general partner. The head office of the Joint Venture will be located in Goch, Germany.

7. Campina and Fonterra will contribute to the Joint Venture their respective pharmaceutical grade lactose businesses together with their business that supplies lactose for fine chemical manufacturers. Campina will also contribute to the Joint Venture its manufacture of excipients that are based on other substances than lactose. Further Campina and Fonterra will transfer to the Joint Venture all employees currently specifically working in the field of pharmaceutical excipients. This also includes Campina's and Fonterra's dedicated R&D and process development team for pharmaceutical excipients.

8. Campina currently has over 100 agents and distributors and Fonterra approximately 30-40 agents and distributors which are almost exclusively acting in the field of pharmaceutical grade lactose, excipients and lactose for fine chemical manufacture. The relationships with these agents and distributors will be transferred to and will be solely under the control of the Joint Venture. Also all direct sales contracts with end customers (i.e. pharmaceutical and fine chemical companies) will be transferred to the Joint Venture.

9. Furthermore, Campina and Fronterra will also transfer to the Joint Venture all the trade and brand names and domain names specific to the pharmaceutical grade lactose and excipient businesses. All existing property rights of Campina and Fronterra in the pharmaceutical grade lactose and excipients businesses will be licensed to the Joint Venture; any further intellectual property developed by the joint venture in the field of pharmaceutical grade lactose and excipients will be owned by the Joint Venture.

10. In addition, Campina will transfer to the Joint Venture the following production facilities: (i) a plant (and its personnel) located in Noerten-Hardenberg, Germany (the "Noerten-Hardenberg plant") which is used for the production of pharmaceutical grade lactose suitable for direct compression (DC) of tablets ("DC-lactose") and (ii) a plant located in Foxhol, The Netherlands (the "Foxhol plant") which is used for the production of sodium starch glycolate and croscarmellose sodium. Fonterra will contribute to the Joint Venture its Kapuni IGL plant, New Zealand (the "Kapuni II plant") that will produce pharmaceutical grade lactose suitable for applications in direct powder inhalation ("DPI-lactose").

11. The Kapuni-II plant, which will be contributed to the Joint Venture, will sell exclusively to one large purchaser of pharmaceutical grade lactose for the use in respiratory products for a period of […][2]. Therefore, sales of these products will not be made to the market until the conclusion of the exclusivity period. Supply from the Kapuni-II facility has not yet commenced, since the relevant facilities still need the necessary regulatory approvals.

12. Two other plants, Campina's plant at Veghel, The Netherlands (the "Veghel plant") and Fonterra's general plant located in Kapuni, New Zealand (the "Kapuni-I plant") will not be transferred to the Joint Venture. These plants are partly also used for the production of some of the products directly sold or further processed by the Joint Venture. Accordingly, the Veghel plant and the Kapuni-I plant manufacture products to be supplied to the Joint Venture (for direct resale and for further processing) but these plants will also continue to manufacture products which are outside of the scope of the Joint Venture. According to the parties' submission, 80% of the output of Campina's Veghel plant is dedicated to other products than pharmaceutical grade lactose, with the balance of 20% of the output being supplied to the Joint Venture for direct sale or further processing. Fonterra currently runs four plants which produce lactose with the Kapuni-I plant being the only plant supplying the Joint Venture. The volume of milled and sieved lactose to be supplied to the Joint Venture for further processing amounts to […] of the Kapuni-I plant.

13. With regard to the lactose products which are not subject to further physical processing, the Joint Venture will provide the following benefits: branding, quality assurance, after sales services and technical sales support (including "customisation" of the products for customer-specific pharmaceutical formulations).

14. In addition, Campina/DMV will transfer to the joint venture the following third party distribution and manufacturing agreements: (i) a distribution agreement with the co-operative Verkoop- en Productievereniging van Aardappelmeel en Derivaten ("Avebe") which grants DMV the exclusive distribution rights for the sale and marketing of starch-based excipient products manufactured by Avebe, and (ii) a tolling agreement with Ming Tai Chemical Co. Ltd. ("Ming Tai") for spray dried microcrystalline cellulose (MCC), a cellulose-based pharmaceutical excipient. DMV currently resells the spray dried MMC manufactured by Ming Tai under its own brand name "Pharmacel" which – together with all the other brands of Campina/DMV regarding pharmaceutical excipients – will also be transferred to the joint venture.

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2 […] indicates deleted business secrets.

III. CONCENTRATION

15. The transaction concerns the creation of an autonomous, jointly controlled full-function joint venture within the meaning of Article 3(4) of the Merger Regulation. The Joint Venture will perform on a lasting basis, all the functions of an autonomous economic entity manufacturing and supplying pharmaceutical grade lactose, excipients and lactose for fine chemical application.

16. The Joint Venture will perform substantially all the functions of a manufacturer and supplier of pharmaceutical grade lactose, excipients and lactose for fine chemical manufacture, including research and development, manufacturing as well as sales and marketing activities. The Joint venture will have a dedicated management team and sufficient dedicated own staff to perform all the functions of a pharmaceutical grade lactose, excipients and fine chemical lactose manufacturer. Furthermore, the Joint Venture will own all the brand names and will have access to all the relevant intellectual property rights necessary to produce its products. Finally, all the relationships that the Parties have directly with end-customers and with dedicated distributors and agents will be transferred to and solely under control of the Joint Venture.

17. On the basis of the above mentioned the Commission concludes that the proposed transaction constitutes a concentration within the meaning of Article 3(4) of the Merger Regulation.

IV. COMMUNITY DIMENSION

18. The concentration has a Community dimension within the meaning of Article 1 of the Merger Regulation. The thresholds set out in Article 1(2) of the Merger Regulation are met. The undertakings concerned have a combined group aggregate worldwide turnover of more than 5 billion Euros. The Campina and Fonterra groups each have a Community wide turnover in excess of 250 million Euros and both do not achieve more than two-thirds of their Community wide turnover within one and the same Member State.

V. COMPETITIVE ASSESSMENT

A. Relevant product markets

19. The Joint Venture will be active in the manufacture and sale of (i.) pharmaceutical grade lactose and (ii.) non-lactose-based pharmaceutical excipients. The horizontal overlap of the proposed concentration occurs for lactose. Therefore, for the purpose of this decision, the precise definition of the relevant markets for non-lactose based excipients can be left open.

20. Lactose - also known as *milk-sugar* - is a sugar mainly derived from milk products. Lactose is less sweet than other sugars like sacharose and glucose. Cow milk contains 4% to 5% lactose. Whey, a by-product of the cheese production, is most commonly used as the major input and starting point of the lactose production.

21. Lactose is derived by a crystallization process applied to the whey which is followed by washing and drying of the lactose crystals. In principle, the resulting product is an “edible” form of lactose. As pure lactose forms big hard crystals that do not dissolve easily, secondary steps of processing are applied to reach more homogeneous sizes of

lactose crystals. According to the subsequent processes applied, the following forms of lactose can be distinguished: milled lactose, sieved lactose, roller dried lactose, spray dried lactose and agglomerated lactose.

22. Each of the different processes creates a number of different qualities of the product. For example, the process of milling and sieving separates the lactose particles into different size-groupings and the resulting product are referred to according to the (maximum) particle size (e.g. “Milled lactose with mesh size 150”). Milled and sieved lactose then constitute the starting point for further secondary processing (such as spray drying, roller drying, agglomeration) which lead to even purer and more homogeneous qualities of lactose.

23. Lactose principally comprises two grades: pharmaceutical grade lactose and edible grade lactose. Pharmaceutical grade lactose is used as a pharmaceutical excipient. In principle, all the different forms of lactose (i.e. sieved, milled, spray dried, roller dried and agglomerated lactose) are suitable for pharmaceutical application. Edible grade lactose is used in fine chemical applications, the manufacture of infant formulae and is added to food and confectionery products. Fine chemicals that use edible lactose as a starting material include the production of the synthetic sugars Lactulose and Lactitol that have uses in human medicine as laxatives, as nutritional supplements and in livestock breeding.

1. Definitions submitted by the parties

24. The parties submitted that there are two relevant product markets involved. The parties distinguish (i) a distinct and indivisible market for all pharmaceutical excipients on the one hand and (ii) the product market for all lactose, edible and pharmaceutical grades, on the other hand.

Pharmaceutical excipients

25. Pharmaceutical excipients are the non-active ingredients which are included in the drug manufacturing process or are contained in a finished pharmaceutical product dosage form. There are hundreds of different pharmaceutical excipients differing in chemical composition, basic substance and functionality.

26. As regards the functionalities, pharmaceutical excipients can serve a number of different purposes in a drug formulation. Excipients can be used to transport the active ingredients to the right part of the body, prevent the active ingredients from being released too early, ensure disintegration of the drug, protect the drugs’ stability, improve the look and taste of the drug or assist in the identification of a drug product. As a rule, most of the excipients provide several different functionalities for the finished product (i.e. the pharmaceutical).

27. As regards the basic substance used, the following substances, sometimes after further processing, may be used as pharmaceutical excipients amongst others: lactose, starch, cellulose, magnesium, stearic acid, gelatine, sucrose, talc or sodium. Due to the multi-functionality of most of the pharmaceutical excipients, a pharmaceutical company may in some cases even combine several excipients based on different basic substances in the same drug.

28. According to the parties, all pharmaceutical excipients have to be considered to belong to the same indivisible relevant market for pharmaceutical excipients for the following

reasons: Because there is almost an infinite number of ways in which a pharmaceutical drug can be formulated, there is also similar freedom of pharmaceutical companies in choosing between the different types or combinations of excipients at the pre-formulation / development stage of a drug. Although not all excipients are perfect substitutes for each other, in the parties' opinion there is a wide scope of substitutability at the point that a drug is being developed / formulated.

29. In addition, the parties provided the view that due to the multi-functionality of the different excipients, any sub-division of the excipient market would be inherently imperfect. Many excipients are currently used across the common dosage forms and categorization of functionalities. Furthermore, it should also be taken into account that different formulations of the same drug very often also use different excipients.

30. The parties further submitted that the only factors constraining a customer's choice of excipients at the formulation / development stage of a drug are: (i) pharmacopoeial minimum standards applicable to the dosage form in question (i.e. there are technical limitation for the interchangeability of several excipients depending on the dosage form of the drug), (ii) the chemical stability of the excipients and possible reactions with the active ingredient of a pharmaceutical and (iii) self imposed preferences of the pharmaceutical company as regards the dosage form, the look or the functionalities of the pharmaceutical.

Lactose

31. In addition, the parties submitted that the proposed transaction may also affect the (alternative) relevant product market for (edible and pharmaceutical grade) lactose which only partly overlaps with the market for pharmaceutical excipients.

32. As mentioned above, lactose principally comprises two grades: pharmaceutical grade lactose and edible grade lactose. Pharmaceutical grade lactose is used as a pharmaceutical excipient, mostly in solid dosage forms. Edible grade lactose is used in fine chemical applications (i.e. for example the production of the synthetic sugars Lactulose and Lactitol) and the manufacture of infant formulae. Edible lactose is also added to a wide range of different food and confectionery products.

33. As regards demand-side substitutability, the parties concede that in drug manufacture most countries do not allow edible grade lactose to be used because it has not been gone through the same testing and certification processes as pharmaceutical grade lactose. However, according to the parties, all the non-pharmaceutical customers can use both grades of lactose. The parties submitted that in particular fine chemical manufacturers generally have a preference for edible grade lactose that has been manufactured in the same environment and using the same processes as pharmaceutical grade lactose.

34. As regards supply-side substitutability, the parties submitted that pharmaceutical grade lactose and edible grade lactose are inherently the same product. The only difference between the two grades of lactose, according to the parties, stem from the fact that pharmaceutical grade lactose is tested and certified to higher standards and sometimes further processed to more sophisticated grades of lactose.

2. Outcome of the Commission's market investigation

35. Both product market definitions provided by the notifying parties have not been confirmed by the Commission's market investigation. On the contrary, the market investigation provided strong indications that pharmaceutical grade lactose and edible grade lactose constitute distinct relevant product markets. Furthermore, the results of the market investigation also indicate that pharmaceutical grade lactose ("lactose-based excipients") cannot be considered to belong to a very broad product market which includes all the different types of pharmaceutical excipients based on very different substances (like lactose, starch, cellulose, gelatine etc.) and destined for very different pharmaceutical applications and dosage forms.

On the substitutability between pharmaceutical and edible grade lactose

36. As regards the substitutability between edible and pharmaceutical grade lactose, the Commission preliminarily takes note of the parties submission that most countries do not allow edible grade lactose to be used in the manufacture of pharmaceuticals because it has not been gone through the same testing and certification processes as pharmaceutical grade lactose. This has been confirmed by the Commission's market investigation. The use of edible grade lactose for the use as an excipient in pharmaceuticals is prohibited in almost every part of the world (including Europe). Health regulations and health related risks for applying edible grade lactose in medicines force the pharmaceutical industry to rely on pharmaceutical grades of lactose.

37. In addition, the customers currently using pharmaceutical grade lactose indicated that they need an approved and certified quality, documentation and traceability of the lactose used in pharmaceutical formulation. For some manufacturing processes customers even indicated that the usually higher protein content in edible grade lactose may disturb the manufacturing process of a pharmaceutical. Accordingly, virtually all the customers currently using pharmaceutical grade lactose indicated that they would not switch from pharmaceutical grade lactose to edible grade lactose upon a small but significant non transitory price increase. .

38. Contrary to what the parties claim, also the fact that edible and pharmaceutical grade lactose are in some way identical from a chemical point of view is in itself not indicative for a high supply-side substitutability between the two grades of lactose for the following reasons: Firstly, as indicated above, there are several secondary steps of processing the basic edible lactose derived from the crystallisation of whey (milling, sieving, spray drying, roller drying, agglomeration) which lead to different qualities of lactose as regards particle size and product homogeneity. Whereas milling and sieving are standard processes which are also applied for edible lactose, the other processes (spray drying, roller drying, agglomeration) produce higher qualities of lactose which are required for specific pharmaceutical applications (e.g. lactose suitable for "direct compression" of tablets = Direct Compression (DC) lactose). Secondly, according to the parties' own submission, the supply of pharmaceutical grade lactose additionally requires the establishment and maintenance of the relevant testing, certification, traceability and quality assurance procedures.

39. Furthermore, according to the parties own submission, there is a significant price difference between edible grade and pharmaceutical grade lactose, with the latter being significantly more expensive. Prices for pharmaceutical grade lactose are generally at least three times higher than for edible grade lactose. Accordingly, there is no

economic incentive to use pharmaceutical grade lactose for purposes for which edible grade of lactose could be or is allowed to be used.

40. Based on these elements, the Commission concludes that there are strong indications that pharmaceutical grade lactose and edible grade lactose have to be analysed as distinct relevant product markets.

On the substitutability between lactose and other pharmaceutical excipients

41. The results of the market investigation also indicate that pharmaceutical grade lactose (lactose-based pharmaceutical excipients) cannot be considered to form part of a very broad product market which includes all types of pharmaceutical excipients based on very different basic substances (like lactose, starch, cellulose, gelatine etc.) and destined for very different pharmaceutical applications and dosage forms.

42. Preliminarily, it has to be noted that the parties almost exclusively refer to the pre-formulation and development stage of a pharmaceutical to substantiate the view that all pharmaceutical excipients are substitutable from a demand-side perspective. Because at this stage of a life cycle of a drug almost an infinite number of ways exist in which a drug can be formulated, there is – in the parties opinion – also similar freedom of pharmaceutical companies in choosing between the different types of excipients.

43. As regards the commercial stage of a drug, the parties concede that once a drug is registered with agencies such as the European Medicines Agency (EMEA) or the U.S. Food and Drug Agency (FDA) there is only limited scope for switching the excipient and the excipients are purchased only within the registered category. This view has been confirmed by the Commission's market investigation. The vast majority of customers involved in the investigation indicated that they would not switch to another type of excipient during the commercial period of a drug even in case of a small but significant non-transitory price increase. This is mainly due to the additional costs imposed by any change of the formulation of a drug which – among other things – also include additional costs for testing and necessary administrative procedures (approval, registration). Since excipients only represent a rather small share of the total cost of the production of a drug (according to the estimates provided by the vast majority of customers around 5-10%), pharmaceutical companies are very reluctant to change the exipients chosen in the formulation stage during the commercial stage of a drug.

44. Additionally, contrary to the submission of the parties, even during the formulation and development stage of a pharmaceutical drug the substitutability between different types of excipients based on different basic substances is rather limited. According to the results of the market investigation, in this regard in particular the following aspects have to be taken into account:

45. First of all, it has to be noted that there is a wide variety of different dosage forms of a drug for very different forms of administering the active substance to the body, i.e. liquids (injections, syrup), semi-solid dosages (ointments, gels), solid dosages (tablets, capsules) or drugs for inhalation. Because of these different methods of administering the active substance to the body, pharmaceutical excipients specifically used in one specific dosage form (e.g. tablets) cannot be used in another dosage form (injections). Therefore pharmaceutical excipients specifically used in one specific dosage form cannot be considered to be a suitable substitute for those drug formulations which are intended to be used in other dosage forms (e.g. tablets, capsules).

46. Pharmaceutical grade lactose is mainly used as a filler and binder in solid dose pharmaceuticals. Pharmaceutical grade lactose is mainly used as filler and binder in tablet dosages and it may also be used in pharmaceuticals in powder sachets. In syrup lactose is only used as a sweetener. Pharmaceutical grade lactose is not commonly used, if at all, as an excipient in injection pharmaceuticals, ointments and gels.

47. This assessment is ultimately also confirmed by the notifying parties which indicated that pharmaceutical grade lactose is mainly used as an excipient for pharmaceutical drugs in solid dosage form (i.e. tablets, capsules) and – to a very limited extent – for drugs using the technique of dry powder inhalation. According to the parties own submission, the differentiation between the different dosage forms should not be relevant for the assessment of the current transaction since "*[the Joint Venture] will only be active in excipients that are currently used for solid dose forms*"[3].

48. In addition, even considering one and the same dosage form (e.g. solid dose), different excipients provide very different functionalities which can not be provided by other excipients based on different basic substances. According to the overview of the functionalities of different excipients submitted by the parties[4], lactose can be used as filler in solid dosage forms of drugs (e.g. tablets). On the one hand, the same function can also be provided by other excipients such as starch or cellulose. But on the other hand, these alternative excipients also provide additional functionalities that are not always provided by lactose. For example, lactose on the one hand may be used as a binder in solid dosage forms of pharmaceuticals. But on the other hand, most of the excipients which – like lactose – provide the filler-function cannot provide the additional function of a binder.

49. Accordingly, to approximately 15% of the market participants involved in the Commission's market investigation even indicated that the differentiation of different sub-markets for pharmaceutical lactose would be necessary. In particular, a distinction of separate product markets along the lines of the different applications for pharmaceutical lactose was considered to be appropriate.

50. Essentially, there are three different technologies to use lactose as an excipient in a pharmaceutical drug: (i) wet granulation, (ii) direct compression (DC), and (iii) dry powder inhalation (DPI). Wet granulation and direct compression are different methods used in the manufacture of tablets. Whereas the direct compression process enables the pharmaceutical company to combine the lactose without any further processing with the active substance of the drug and produce ("compress") the tablets, the wet granulation process leaves it to the pharmaceutical company to produce in subsequent moistening and drying processes the quality of the lactose excipient needed for the tablet. Dry powder inhalation is a specific application of a very fine lactose powder in drug formulations destined to be inhaled by the patient.

51. However, according to the parties, the different application technologies cannot be considered to constitute separate relevant product markets for the following reason. As indicated above, there are mainly five different forms of pharmaceutical lactose which mainly differ in the size and homogeneity of the lactose crystals: milled lactose, sieved

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3 Parties reply to the Commission's request for information, response dated 22 May 2006, p. 4.

4 Form CO, Annex 16.

lactose, spray dried lactose, roller dried lactose, and agglomerates lactose. According to the parties, the same type of lactose may be used for different lactose applications in a pharmaceutical drug. For example, both the wet granulation process as well as the dry powder inhalation process use milled lactose as an input. Further spray dried, roller dried and agglomerated lactose are currently the most suitable types of lactose used in for direct compression applications, but they also can be used for the dry powder inhalation process.

3. Conclusion

52. Based on the elements discussed, the Commission concludes that, contrary to the view provided by the parties in the notification, pharmaceutical grade lactose cannot be considered either to belong to the broader market for lactose (including also edible grade lactose) or to be part of the very broad market for pharmaceutical excipients (including all excipient based on different basic substances and for all dosage forms). According to the results of the market investigation, the relevant product market is significantly narrower, probably even being limited to several sub-markets for pharmaceutical grade lactose, defined according to the different applications of lactose.

53. However, due to the fact that even with the narrowest possible relevant product market (i.e. the different applications of lactose) the concentration will not result in a significant impediment of effective competition, the precise product market definition can be left open for the purpose of this decision.

B. Relevant geographical market

54. According to the view provided by the parties, the markets for pharmaceutical excipients and lactose are global or at least EEA-wide in scope. Notwithstanding the fact that the exact delineantion of the relevant product market(s) ultimately does not need to be determined, the Commission's market investigation provided strong indications that such market(s) in the present case would be at least EEA-wide in scope.

55. The main excipients and lactose suppliers sell at least EEA-wide or world-wide and end-users of excipients often buy on an at least EEA-wide or even world-wide scale. Purchasers that normally source from suppliers located in the EEA, generally indicated that they would source from another region if a small but significant non transitory price increase would appear.. Furthermore, a majority of the purchasers is sourcing from different regions in order to be less exposed to the risk of health safety related supply problems, such as "mad cow"-disease.

56. In any event, considering that neither with the geographical market definition defined as comprising the EEA-,market nor with the geographical market definition defined as comprising the world-wide-,market the concentration would result in a significant impediment of effective competition in the common market or in a substantial part of it, the precise definition of the relevant geographical market can be left open for the purpose of this decision.

C. Impact of the transaction

57. According to the estimates provided by the parties which were confirmed by the Commission's market investigation, the supply for pharmaceutical grade lactose world-wide and in the EEA shows the following structure (see table below):

Structure of the supply for pharmaceutical grade lactose (2005)

Company	Worldwide	EEA
Campina/DMV	[30-40]%[5]	[35-45]%
Fonterra	[5-15]%	[0-5]%
Campina-Fonterra-JV	**[45-55]%**	**[40-50]%**
Meggle	[15-25%]	[25-35%]
Friesland-Domo	[10-20%]	[15-25%]
Foremost	[0-10%]	[0-10%]
Kerry Quest	[0-10%]	[0-10%]
Others	[5-15]%	[5-15]%

58. Campina/DMV currently is the strongest supplier world-wide and in the EEA, holding a share of [30-40]% worldwide and [35-45]% in the EEA. With significantly less than 5% of the total European supply of pharmaceutical grade lactose, Fonterra's presence in the EEA is currently rather limited. The main regional focus of Fonterra's customer base for pharmaceutical grade lactose lies in the Asian-Pacific region as well as Latin America. On a worldwide scale, Fonterra currently reaches a share of the total supply for pharmaceutical grade lactose of [5-15]%.

59. The second largest supplier of pharmaceutical grade lactose world-wide and in the EEA is the German-based Molkerei Meggle Wasserburg GmbH & Co. KG ("Meggle"). As is shown by the significantly weaker position in the worldwide supply of pharmaceutical grade lactose [(15-25%)], Meggle – compared to Campina/DMV – is currently much more focused on the European market reaching a share of the total supply for pharmaceutical grade lactose in the EEA of [25-35%]. Number 3 in the European as well as the worldwide supply of pharmaceutical grade lactose is the Dutch-based company Friesland Foods Domo ("Domo") holding [15 – 25%].

60. Additionally, there are several smaller players active in the market currently holding a share of well below 10% of the total supply of pharmaceutical grade lactose. For example, the US-based supplier Foremost Farms USA Co-operative ("Foremost") – like Fonterra – is currently active in the EEA only to a limited extent. The main focus of Foremost's customer-bases lies in the US and Latin America. The group of smaller suppliers of pharmaceutical grade lactose furthermore includes the UK-based Kerry Group plc which – through its subsidiary Kerry Bio-Science – currently reaches

[5] Structure of supply is stated in ranges […] for confidentiality reasons.

roughly [0 to10%] of the world-wide total supply and roughly [0 to 10%] of the EEA-wide total supply of pharmaceutical grade lactose.

61. Due to fact that the regional focus of Fonterra's customer base is currently not in Europe, the proposed transaction only leads to a small horizontal overlap in the EEA. In addition, several further aspects show that the proposed transaction would not eliminate the closest competitor of Campina/DMV and will have only a very limited impact on the main competitive constraints currently exerted on Campina/DMV in the field of pharmaceutical grade lactose:

62. The Commission's market investigation has confirmed the parties' submission that pharmaceutical companies usually multi-source pharmaceutical grade lactose from different suppliers. Of the pharmaceutical companies involved in the Commission's market investigation 75% confirmed to be multi-sourcing.

63. In addition, the market investigation clearly indicates that Fonterra's products are currently not perceived to be the closest substitutes to the pharmaceutical grade lactose manufactured by Campina/DMV. The vast majority of customers involved in the Commission's market investigation indicated that the strongest competitive constraint currently stems from Meggle and Domo. According to these customers Meggle and Domo are more advanced producers of lactose. Both Meggle and Domo are capable of producing certain pharmaceutical grade lactose products for the use in inhalation end-products that the notifying parties cannot produce at the moment. Meggle and Domo are regarded as having particular strength in technical know-how in the production of lactose for wet granulation and direct compressed usage. Both Meggle and Domo have a wide range of products and are capable to sell these products globally.

64. Additionally, also the smaller suppliers of pharmaceutical grade lactose post merger will continue to exert a significant competitive constraint on the Joint Venture. One producer of edible grade of lactose is moving into producing pharmaceutical grade of lactose as well. According to the results of the market investigation, the Joint Venture will not have any significant advantage over its competitors as regards the technological know-how and the application knowledge needed for market success. The majority of customers indicated that all the suppliers of pharmaceutical lactose provide the product quality as well as the know-how needed for the "customisation" of pharmaceutical grade lactose for specific pharmaceutical applications. Accordingly, most of the customers indicated that they could easily switch to alternative suppliers of pharmaceutical grade lactose in case of a significant price increase of the merged entity.

65. Furthermore, the market investigation provided no indication that the competitors of the Joint Venture would face other barriers to increase of production and sales of pharmaceutical lactose in response to a price increase of the merged entity. All the major competitors of the Joint Venture (i.e. Meggle, Domo, Foremost) are – like Campina and Fonterra – vertically integrated in the relevant upstream markets, i.e. the production of dairy products (like milk, cheese etc.). Additionally, these companies are also active in the neighbouring market for edible grade lactose which – at least from a chemical point of view – is to a certain extent and for some forms (i.e. milled and sieved lactose) the same product as pharmaceutical grade lactose. According to the parties' estimates, the total production capacity for lactose of the largest three suppliers in the EEA (Campina/DMV, Meggle, Domo) currently amounts to 180,000

metric tonnes from which currently approximately only 75,000 metric tonnes (42%) are sold as pharmaceutical grade lactose.

66. As regards the different pharmaceutical applications of pharmaceutical grade lactose, the market investigation has not provided a different picture. The vast majority of pharmaceutical grade lactose (more than 95%) is currently used in applications based on wet granulation and direct compression processes. All the major suppliers of pharmaceutical grade lactose provide the different types of lactose (milled, sieved, spray-dried, roller dried, agglomerated) which are needed for these applications. As regards dry powder inhalation (DPI) it has to be noted that this segment is still a niche (less than 5% of the total sales of pharmaceutical grade lactose). The market investigation furthermore confirmed that Friesland-Domo is currently by far the leading supplier of lactose suitable for DPI-applications.

67. Finally, it has to be noted that neither any customer nor any competitor involved in the Commission's market investigation has raised the concern that the proposed transaction may lead to a significant impediment of effective competition or an increased leeway of the merged entity to increase its prices.

68. On the basis of the above, the Commission has concluded that the concentration does not raise competitive doubts and that it would not significantly impede effective competition in the common market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position.

VI. CONCLUSION

69. For the above reasons, the Commission has decided not to oppose the notified operation and to declare it compatible with the common market and with the EEA Agreement. This decision is adopted in application of Articles 6(1)(b) of Council Regulation (EC) No 139/2004.

For the Commission
signed
Neelie KROES
Member of the Commission