Completed acquisition by Tiancheng International Investment Limited (part of Creat Group Co., Ltd.) of Biotest AG

Decision on relevant merger situation and substantial lessening of competition

ME/6711/17

Please note that [✂] indicates figures or text which have been deleted or replaced in ranges for reasons of commercial confidentiality.

SUMMARY

1. On 31 January 2018, Tiancheng International Investment Limited (**Tiancheng International**), a subsidiary of Creat Group Co., Ltd (**Creat**), acquired Biotest AG (**Biotest**) (the **Merger**). Creat and Biotest are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) believes that it is or may be the case that the Parties' enterprises have ceased to be distinct and that the share of supply test is met. The four-month period for a decision has not yet expired. The CMA therefore believes that it is or may be the case that a relevant merger situation has been created.

3. The Parties (Creat through its indirect subsidiary Bio Products Laboratory Holdings Ltd. (**BPL**)) are both active in the production and supply of certain therapeutic products derived from blood plasma. This involves collecting blood from donors and using it to manufacture therapeutic products via a process called fractionation. The Parties both collect blood from locations outside the UK. After certain volumes are sold to third parties, the Parties process the rest of the blood[i] at their fractionation centres and sell the products worldwide.[1]

[1] Prior to the transaction, Biotest also sold plasma to other plasma therapeutic manufacturers in the US.

4. The CMA assessed the impact of the Merger within the following frames of reference:

   (a) Intravenous immunoglobulins (**intravenous IG**), on a UK-wide basis;

   (b) Anti-hepatitis B immunoglobulins (**anti-hepatitis B IG**), on a UK-wide basis;

   (c) Factor VIII, on a UK-wide basis;

   (d) Factor IX, on a UK-wide basis;

   (e) Albumin, on a UK-wide basis;

   (f) Upstream supply of source blood plasma, on a global basis; and

   (g) Upstream supply of specialty blood plasma, on a global basis.

5. The CMA considered the impact that the loss of competition between the Parties would have on the supply of intravenous IG, anti-hepatitis B IG, Factor VIII, Factor IX and albumin.

6. Within most frames of reference, the CMA found that the Parties would continue to be constrained by several competitors. In relation to the supply of anti-hepatitis B IG (a small segment in which fewer other suppliers are present), the CMA found that there is, in practice, no competitive interaction between the Parties' products (which have different uses and/or modes of administration) and therefore that the Merger would have no impact on the competition.

7. There is also a vertical dimension to the Merger, since the Parties supply source and speciality blood plasma to third parties for the manufacture of blood plasma therapies. However, the CMA was able to exclude an input foreclosure theory of harm on the basis that the Parties would not have the ability to pursue such a strategy (in particular because their share of supply in the upstream market is low and all key competitors are vertically integrated and self-source, as well as having access to a range of alternative sources of external supply).

8. The CMA therefore believes that the Merger does not give rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral or vertical effects.

9. The Merger will therefore **not be referred** under section 22(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

10. Creat is a Chinese investment group which is active globally, focusing on equity investments across biopharmaceuticals, financial services, agriculture, mining and other industries. Creat is active in the global supply of blood plasma through two indirect subsidiaries, Shanghai RAAS Blood Products Co., Ltd ([✂]) and BPL.

11. BPL, based in Elstree in the UK, was originally founded and owned by the UK Department of Health. It was taken under partial private ownership in 2013, and then under full private ownership when bought by Creat in 2016. It operates 34 plasma collection centres in the US, and either sells the plasma collected (mainly to biopharmaceutical companies in the US), or fractionates it at its facility in the UK. BPL sells its therapeutic products worldwide; its turnover was approximately £[✂] in 2016, of which around £[✂] was generated in the UK.

12. Biotest is an international supplier of plasma and plasma-derived substances based in Dreieich, Germany. Biotest owns eight collection sites in Germany and five in Hungary;[ii] it has agreed to sell its 22 US sites.[2] Like BPL, Biotest sells source and specialty plasma in the US, although it will cease to do so once the divestment of its US sites is complete. The remainder of the plasma Biotest collects is fractionated at its centre in [✂] or [✂].

13. Biotest's turnover in 2016 was approximately £404m worldwide and approximately £11m in the UK.

Transaction

14. The Merger completed on 31 January 2018, when Creat, through its indirect subsidiaries Tiancheng International and Tiancheng (Germany) Pharmaceutical Holdings AG, purchased the entire issued share capital of Biotest.

15. Creat informed the CMA that the Merger was reviewed, and cleared by, competition authorities in the US and Turkey.

[2] As a condition to the clearance of the acquisition by the Committee for Foreign Investment in the United States.

Jurisdiction

16. As a result of the Merger, the enterprises of Creat and Biotest have ceased to be distinct.

17. The Parties overlap in the supply of a number of blood plasma products, including albumin. In the 5% concentration of albumin, the Parties have a combined share of supply under the CMU framework of 40-50% by volume (with an increment of 0-5%), while in the 20% concentration of albumin, the Parties have a combined share of 50-60% by volume (with an increment of 0-5%).[3] The CMA therefore believes that the share of supply test in section 23 of the Act is met.

18. The Merger completed on 31 January 2018 and the CMA was informed about its completion on that day. The four-month deadline for a decision under section 24 of the Act is 31 May 2018.

19. The CMA therefore believes that it is or may be the case that a relevant merger situation has been created.

20. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 26 March 2018 and the statutory 40 working day deadline for a decision is 23 May 2018.

Counterfactual

21. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual). For completed mergers the CMA generally adopts the pre-merger conditions of competition as the counterfactual against which to assess the impact of the merger. However, the CMA will assess the merger against an alternative counterfactual where, based on the evidence available to it, it believes that, in the absence of the merger, the prospect of these conditions continuing is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than these conditions.[4]

22. In this case, there is no evidence supporting a different counterfactual, and neither Creat nor third parties have put forward arguments in this respect.

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[3] Source: data from Commercial Medicines Unit.
[4] *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, from paragraph 4.3.5. The *Merger Assessment Guidelines* have been adopted by the CMA (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, Annex D).

Therefore, the CMA believes the pre-Merger conditions of competition to be the relevant counterfactual.

Background

23. Blood plasma derivatives are proteins found in human plasma which, once isolated though the fractionation process, can have therapeutic value. The Parties and their competitors collect most of their blood plasma from their collection centres, fractionate it and use it to manufacture therapeutic products. Some of the main therapeutic products made by the Parties and their competitors are non-specific immunoglobulins (including intravenous IG), specific immunoglobulins (including anti-hepatitis B IG), clotting factors (including Factor VIII and Factor IX) and albumin.

Frame of reference

24. Market definition provides a framework for assessing the competitive effects of a merger and involves an element of judgement. The boundaries of the market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some constraints are more important than others. The CMA will take these factors into account in its competitive assessment.[5]

25. The Parties overlap in the supply of the following blood plasma products:

    (a) non-specific immunoglobulins;

    (b) anti-hepatitis B IGs;

    (c) factor XIII;

    (d) factor IX; and

    (e) albumin.

26. There is a further vertical link between the Parties' activities in:

    (a) the supply of source blood plasma; and

    (b) the supply of specialty blood plasma.

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[5] *Merger Assessment Guidelines*, paragraph 5.2.2.

Product scope

27. In previous decisions in the pharmaceutical sector, both the European Commission (**EC**) and the CMA (and its predecessor organisations) have referred to the "Anatomical Therapeutic Chemical" (**ATC**) classifications, both those devised by the European Pharmaceutical Marketing Research Association[6] and by the World Health Organisation.[7] The EC has indicated that the third ATC level (ATC3), which groups medicines according to their therapeutic properties, can generally be used as a starting point for market definition, although it may be appropriate to carry out analyses at other levels, for example at ATC4 or molecule level, or across classes, if the specific circumstances of a case indicate that the ATC3 level is not the most appropriate for the purposes of market definition.[8]

28. The pharmaceutical area affected by this transaction is the manufacture and sale of plasma derivatives. While the UK competition authorities have not previously considered the market, the EC has previously found that products derived from plasma are "*in a special domain in the pharmaceutical world*",[9] due to their reliance on donations of a natural bodily fluid,[10] as well as their particular characteristics in terms of production and use.[11] In these precedent cases, the EC identified albumin, intravenous IG, Factor XII and Factor IX as separate markets.

Non-specific immunoglobulins

29. The Parties overlap in the production and sale of non-specific immunoglobulins.

30. Immunoglobulins are protective antibodies produced by the body to fight against invading viruses or bacteria. Non-specific immunoglobulins contain a wide variety of antibodies and are given to patients who cannot make their

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[6] Decision of the Office of Fair Trading: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc (Decision No. CA98/02/2011) (2011); Completed acquisition by Shire plc of Viropharma Incorporated (2014) ME/6331/13; EC decision M.3751 – Novartis / Hexal (2005); EC decision M.5502 – Merck / Schering-Plough (2009); EC decision M.4049 – Novartis / Chiron (2006); EC decision M.5999 - Sanofi-Aventis / Genzyme (2011).
[7] Decision of the Office of Fair Trading: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc (Decision No. CA98/02/2011) (2011); Completed acquisition by Shire plc of Viropharma Incorporated (2014) ME/6331/13; EC decision M.495 – Behringwerke AG / Armour Pharmaceutical Co (1995); EC decision M.821 – Baxter / Immuno (1996).
[8] EC decision M.5661 – Abbott / Solvay (2010); Completed acquisition by Shire plc of Viropharma Incorporated (2014) ME/6331/13.
[9] EC decision M.495 Behringwerke AG / Armour Pharma Co, paragraph 15; EC decision M.821 – Baxter / Immuno (1996).
[10] Although in some parts of the world, notably the US, donors may legally be remunerated.
[11] EC decision M.821 – Baxter / Immuno (1996), paragraph 6.

own antibodies. They can be administered intravenously or subcutaneously, and in different concentrations:

(a) Biotest supplies one intravenous IG product in the UK, Intratect (available in 5% and 10% concentration).[12]

(b) BPL supplies two intravenous IG products in the UK, Gammaplex (5% concentration) and Vigam (5% concentration).

(c) BPL also sells a subcutaneous immunoglobulin (**subcutaneous IG**) in the UK, Subgam (16% concentration).

31. As noted above, the EC has considered intravenous IGs as a distinct product market, while the CMA (and its predecessor organisations) has not previously considered immunoglobulins.

32. Creat submitted that the Parties' immunoglobulin products should be distinguished by method of administration, with the only overlap arising in intravenous IGs, and BPL's subcutaneous IG being considered within a separate frame of reference. Creat submitted that intravenous IGs and subcutaneous IGs have limited demand- and supply-side substitutability in particular because:

(a) On the supply-side, subcutaneous IG uses more source plasma and is therefore more expensive, meaning that the competitive set is more limited; and

(b) On the demand-side, the differing cost of source plasma means subcutaneous IG is more expensive and there are some costs in switching from intravenous IG to subcutaneous IG because patients need to be trained to administer the product independently.

33. The evidence available to the CMA suggests that subcutaneous administration is easier, faster, has fewer side effects than intravenous IG,[13] and enables patients to be treated at home.

34. The CMA also considered whether the frame of reference should be narrowed by concentration of intravenous IG. Previous EC decisions did not make such

[12] Biotest also has a small volume of UK sales of a second product, Pentaglobin, which, however, is used to treat [another] type of immunoglobulin deficiency.
[13] See, for example, Great Ormond Street Hospital Clinical Guidelines at https://www.gosh.nhs.uk/health-professionals/clinical-guidelines/immunoglobulin-infusions-intravenous-and-subcutaneous.

a distinction[14] and Creat submitted that it would not be appropriate, as both concentrations are used for the same medical indications.

35. The CMA therefore analysed the merger by reference to a frame of reference for intravenous IG. The CMA has not needed to conclude on whether different levels of concentration form separate frames of reference as no competition issues arise on any plausible basis.

Anti-hepatitis B IG

36. The Parties both produce anti-hepatitis B IG, which is a type of specific immunoglobulin (ie an immunoglobulin containing high levels of antibodies that fight a certain illness). The Parties' products are:

    (a) BPL's anti-hepatitis B IG product (unbranded), which is administered intramuscularly. It is available in 200IU and 500IU vials (although BPL is not currently manufacturing 200IU vials).

    (b) Biotest's intravenous (Hepatect) and subcutaneous (Zutectra) products. Hepatect is available in 5000IU and 100IU vials.

37. Creat submitted that the Parties' products should be differentiated by their indications in particular because:

    (a) Biotest's Zutectra and its Hepatect in 5000iU vials are used for the prevention of hepatitis-B virus re-infection after liver transplantation for hepatitis-B induced liver failure; and

    (b) Biotest's Hepatect in 100IU vials and BPL's anti-hepatitis B IG in 200IU and 500IU vials overlap with respect to the following indications:

        (i) In case of accidental exposure to non-immunised subjects;

        (ii) In patients on kidney dialysis, until vaccination has become effective;

        (iii) In the new-born of a hepatitis-B virus carrier-mother; and/or

        (iv) In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination.

38. Consistent with its approach to non-specific immunoglobulins, Creat submitted that the Parties' products (specifically BPL's unbranded anti-hepatitis IG and Biotest's Hepatect in 100IU vials) should be further

[14] EC decision M.495 – Behringwerke AG / Armour Pharmaceutical Co (1995); EC decision M.821 – Baxter / Immuno (1996).

differentiated by mode of administration (i.e. intramuscular as opposed to intravenous administration). Creat submitted that intravenous administration allows for higher dosing and more rapid pharmacokinetics, making Biotest's Hepatect more appropriate for use in hospitals. Patients receiving an intravenous infusion must also be closely monitored for any symptoms throughout the infusion period, making Biotest's product less suitable for clinicians treating patients in a GP practice.

39. Third party responses on differentiating anti-hepatitis B IGs by use or administration method were mixed: some third parties considered that the products were completely different, but others suggested or implied that it could sometimes be possible to treat them as substitutes.

40. Decisional precedent suggests that it can be appropriate to distinguish between products on the basis of use and method of administration. However, as set out below at paragraphs 84-85 below, it was not necessary to conclude on the precise product frame of reference given that the available evidence indicated that there is no competitive interaction between the Parties' products.

Factor VIII

41. Factor VIII, a specific plasma protein that is missing in patients suffering from haemophilia, is a type of clotting factor. It enables the treatment of patients by substituting the missing factor into the patient's system. It is also used in the treatment of some patients with von Willebrand disease.

42. The Parties manufacture and sell Factor VIII derived from human blood plasma. Factor VIII can also be manufactured through genetic engineering (so called 'recombinant' preparations). Recombinant preparations, due to their artificially manufactured nature, reduce the risk of transmitting viruses to patients, and now account for over 90% of sales of Factor VIII in the UK.

43. In previous decisions, the EC considered Factor VIII to be a distinct product market containing both recombinant and blood plasma-based preparations. The CMA noted, however, that the EC last analysed Factor VIII for the merger control purposes in the 1990s, at which point recombinant products were comparatively new.[15]

44. Creat submitted that the EC's delineation was appropriate and that no further distinction should be made between plasma-derived and recombinant products, on the basis that the products are fully interchangeable on the

[15] EC decision M.495 – Behringwerke AG / Armour Pharmaceutical Co (1995); EC decision M.821 – Baxter / Immuno (1996).

demand-side. The Merger investigation found that third parties did not hold strong views on this point.

45. However, it was not necessary to reach a conclusion on the exact product frame of reference, as no competition concerns arise on any plausible basis.

Factor IX

46. Factor IX, another type of clotting factor, is used to treat patients with Haemophilia B. Like Factor VIII, it can be manufactured from human blood plasma or as a genetically engineered recombinant product. The vast majority of patients diagnosed with haemophilia B are treated with recombinant Factor IX.[16]

47. Creat submitted that, as for Factor VIII, the recombinant and plasma-based varieties should be considered as part of one market, in line with the EC's decisions. The Merger investigation found that third parties did not hold strong views on this point.

48. However, it was not necessary to reach a conclusion on the exact product frame of reference, since there were no competition issues even on the narrowest basis.

Albumin

49. Albumin is the most common protein in blood plasma and can be used to treat people with some types of liver or kidney disease and patients who have suffered burns or have lost a large quantity of blood in surgery.[17] Creat submitted, in line with EC precedent,[18] that albumin is a distinct product frame of reference. Albumin is a commodity product, and any brand can therefore be used to treat any patient. Responses to the Merger investigation supported this view.

50. Albumin is generally available in two concentrations, 5% and 20%, which may have different therapeutic uses. Creat submitted a distinction by concentration was not necessary, as more concentrated albumin solutions can be diluted to make them suitable for different medicinal applications.

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[16] See information from the United Kingdom Haemophilia Centres Doctors' Organisation (UKHDO) at http://www.ukhcdo.org/wp-content/uploads/2018/02/Bleeding-Disorder-Statistics-for-April-2016-to-March-2017-for-UKHCDO.pdf, p48.
[17] See information at https://www.blood.co.uk/why-give-blood/how-blood-is-used/blood-components/plasma/.
[18] EC decision M.495 – Behringwerke AG / Armour Pharmaceutical Co (1995); EC decision M.821 – Baxter / Immuno (1996).

51. The CMA therefore considered the impact of the Merger with respect to albumin.

Upstream supply of source and specialty blood plasma

52. The Parties are active in supplying source and speciality blood plasma to third parties for the manufacture of blood plasma therapies. Such supply often occurs on an ad hoc basis since manufacturers are vertically integrated and seek to self-supply the majority of their plasma. Previously, BPL has purchased small volumes of both source and specialty plasma from Biotest to supplement its own collection.

53. Source plasma differs from speciality plasma both on the supply-side (since it is donated by individuals without any specific characteristics) and on the demand-side (since they are used to manufacture different therapies).

54. The CMA considers that source and specialty plasma may represent distinct frames of reference. However, it was not necessary to reach a conclusion on the exact product frame of reference, since there were no competition issues on any plausible basis.

Conclusion on product scope

55. For the reasons set out above, on a cautious basis, the CMA has considered the impact of the Merger in the following product frames of reference:

(a) Intravenous IG;

(b) Anti-hepatitis B IG;

(c) Factor VIII;

(d) Factor IX;

(e) Albumin;

(f) Upstream supply of source blood plasma; and

(g) Upstream supply of speciality blood plasma.

Geographic scope

Intravenous IG, Anti-hepatitis B IG, Factor VIII, Factor IX and Albumin

56. Creat submitted that plasma-derived therapeutic products are highly transportable and are regularly shipped to locations around the world.

Furthermore, the fact that demand for these products generally outstrips supply means that supply decisions are inherently worldwide in nature. Creat submitted that the CMA should take into account the worldwide nature of supply for plasma-derived products, even if no worldwide frame of reference is defined.

57. In previous decisions, the OFT (while ultimately leaving the geographic scope open),[19] and the EC,[20] assessed the blood plasma product frames of reference on a national basis due to the existence of different registration systems, safety standards and social security and pricing policies within each member state.

58. On this basis, the CMA considers that the frame of reference should not be widened beyond the UK.

59. Within the UK, there are a number of factors that suggest a UK-wide frame of reference:

    (a) Products are licensed for the UK by the Medicines & Healthcare products Regulatory Agency;

    (b) List prices are set by the Department of Health and Social Care and apply across the UK; and

    (c) While different jurisdictions in the UK sometimes have separate framework agreements for these products, the tendering process and the set of suppliers are largely the same, meaning that competitive conditions are comparable.

60. The CMA therefore considered the impact of the Merger in the supply of intravenous IG, anti-hepatitis B IG, Factor VIII, Factor IX and albumin on the basis of a UK-wide frame of reference.

61. However, it was not necessary for the CMA to reach a conclusion on the geographic frame of reference, since, as set out below, no competition concerns arise on any plausible basis.

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[19] The OFT, in Shire / Virophama (Completed acquisition by Shire plc of Viropharma Incorporated (2014) ME/6331/13) left the geographic scope open, although it noted that its previous decisional practice was to assess the blood plasma product market on a UK-wide basis (see Decision of the Office of Fair Trading: Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc (Decision No. CA98/02/2011) (2011)).
[20] EC decision M.495 – Behringwerke AG / Armour Pharmaceutical Co (1995); EC decision M.821 – Baxter / Immuno (1996).

Upstream supply of source blood plasma and upstream supply of speciality blood plasma

62. There is a vertical relationship between the Parties' activities, with BPL currently purchasing small volumes of source blood plasma and specialty blood plasma from Biotest.

63. Creat submitted that the geographic scope for the supply of source blood plasma and speciality blood plasma is worldwide, as the location of the manufacturer has no impact on the customer's purchasing decisions. Creat submitted that the majority of blood collection centres are in the US and that distribution is international. Similarly, within the UK, Creat submitted that there are no limitations on the distances that blood plasma products can be transported.

64. The CMA considered the impact of the Merger for the supply of source and specialty plasma to other manufacturers of plasma therapies on a global basis. However, it was not necessary for the CMA to reach a conclusion on the geographic frame of reference, since, as set out below, no competition concerns arise on any plausible basis.

Conclusion on frame of reference

65. For the reasons set out above, the CMA has considered the impact of the Merger in the following frames of reference:

    (a) Intravenous IG, on a UK-wide basis;

    (b) Anti-hepatitis B IG, on a UK-wide basis;

    (c) Factor VIII, on a UK-wide basis;

    (d) Factor IX, on a UK-wide basis;

    (e) Albumin, on a UK-wide basis;

    (f) Upstream supply of source blood plasma, on a global basis; and

    (g) Upstream supply of speciality blood plasma, on a global basis.

Competitive assessment

Horizontal unilateral effects

66. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the

merged firm profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[21] Horizontal unilateral effects are more likely when the merging parties are close competitors. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC in relation to horizontal unilateral effects in the following frames of reference:

(a) Intravenous IG;

(b) Anti-hepatitis B IG;

(c) Factor VIII;

(d) Factor IX; and

(e) Albumin.

Intravenous IG

Shares of supply

67. The CMA used IMS data[22] on intravenous IG volumes, provided by the Parties, to estimate shares of supply from 2016:

Table 1 – Estimated shares of intravenous IG supply in the UK (2016)

Manufacturer	Products	Share by volume, 2016
CSL Behring	Privigen, 10%	50-60%
Octapharma	Octagam, 5% and 10% Panzyga, 10%	10-20%
Grifols	Flebogamma DIF, 5% and 10% Gamunex, 10%	10-20%
Baxalta/Shire	Gammagard, 5% and 10% Kiovig, 10%	10-20%
BPL	Gammaplex, 5% Vigam, 5%	5-10%
Biotest	Intratect, 5% and 10%	5-10%

Source: CMA calculations, based on IMS data on intravenous IG volumes by product, provided by the Parties

68. The shares of supply show a number of strong competitors to the Parties' intravenous IG offering that will remain in the market post-Merger. The largest supplier is CSL Behring with its Privigen 10% product. This is followed by a

[21] *Merger Assessment Guidelines*, from paragraph 5.4.1.
[22] IMS, now known as IQVIA, provides data on sales of pharmaceutical products in the UK. This information was provided by the Parties, which noted that the data was extracted from IMS National Sales Data for the UK for 2017.

number of suppliers with a smaller share, including Octapharma, Grifols and Baxalta/Shire. The Parties' combined share of supply (at around 10-20%) is comparable to the shares of these manufacturers.

69. These shares [✂] calculated from data collected from the Commercial Medicines Unit (**CMU**), a team working within the Department of Health and Social Services which tenders on behalf of hospitals and trusts in England and Northern Ireland. The CMU's data on shares of supply in England and Northern Ireland[23] shows [✂].

70. Historical data from the Immunoglobulin Database[24] shows that market shares have remained largely stable between 2012/2013 and 2016/2017, with the main change being a fall in market share for BPL and a gain for CSL Behring. The CMU indicated that [✂].

71. On the IMS and the CMU dataset, the increment from the transaction would be relatively small (0-5% on IMS data and [✂]% under the CMU data).

Closeness of competition

72. The Parties submitted that intravenous IG is a commodity product, meaning that it is capable of being supplied by all suppliers. Although this may be the case for new patients, third party responses indicated that clinical practice is to avoid switching long-term patients (approximately 63% of patients in 2016/17[25]) in order to minimise the risk of adverse reactions. In effect, this would mean that a more limited proportion of total demand (approximately 37% of patients) remains contestable at present.

73. Some third parties also indicated that different brands of IG may not be substitutable, as patients may be able to tolerate only a limited range of immunoglobulin products. These third parties reported that they would be reluctant to switch between immunoglobulin products as switches would expose the patient to a larger plasma donor pool and could risk an adverse reaction. Certain IG products may therefore not be substitutable at all, at least for some patients.

74. Competition for the supply for intravenous IG in the UK takes place mainly through public tender processes for inclusion on framework agreements.

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[23] Biotest and BPL are no longer supplying the Welsh Blood Service, so there will be no change to supply in Wales resulting from the Merger. BPL also did not bid for [✂], and so the Merger will again result in no change to most recent supply.
[24] Data from the Immunoglobulin Database Annual Report 2016/17, provided to the CMA by Medical Data Solutions and Services.
[25] See Figure 2.1.2, Immunoglobulin Database Annual Report 2016/17.

Creat submitted that bidders are ranked on a number of criteria, the most important of which is price.

75. Creat submitted that the price of intravenous IG is regulated and that, therefore, the Parties would be constrained by the statutory list price following the Merger. However, under the current CMU framework, [✂]. The CMU has also confirmed that [✂]. Evidence on pricing submitted to the CMA by third parties supported this position.

76. The CMA's analysis of the most recent CMU framework suggests that Biotest is pricing [✂] in the intravenous IG market, having ranked [✂] and [✂] of intravenous IG. In the 10% concentration, [✂], in the 5% concentration, [✂], [✂].

77. However, the [✂]. Accordingly, even though Biotest may be pricing [✂], its constraint on the market (including BPL) is limited because it [✂] has the capacity to supply [✂] of the market.

Third party concerns

78. Third parties raised concerns around the impact of the Merger on the security of supply of intravenous IG in the UK. In particular, they noted that the market is capacity-constrained and that global demand for intravenous IG outstrips supply. Suppliers are therefore incentivised to prioritise jurisdictions in which they can sell at the highest prices. Third parties were concerned that, post-merger, Creat would be likely to redirect supply of intravenous IG to these jurisdictions and that the UK market would become further capacity constrained as a result.

79. The available evidence (including the views of third parties and the Parties' internal documents) does not suggest, however, that the Merger would bring about any change in the Parties' incentives in relation to the prioritisation of their supplies of intravenous IG. The CMA therefore considers that the Merger does not materially change the Parties' ability and incentive to dedicate supplies to the UK market.

Conclusion on horizontal unilateral effects

80. For the reasons set out above, the CMA believes that Biotest was only providing a limited constraint on BPL pre-Merger and competitive conditions will remain largely the same post-Merger given the number of competitors that will still be active in the market.

81. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to intravenous IG.

Anti-hepatitis B IG

Shares of supply

82. The market for anti-hepatitis B IG products is relatively small (in financial terms), with total sales of £[✂] in 2016. As noted above, the Parties are the only manufacturers of blood plasma therapies with a licence to supply anti-hepatitis B IG in the UK.

Closeness of competition

83. As noted above, Creat submitted that none of the Parties' anti-hepatitis B IG products are substitutable as they are indicated for different uses and/or administered differently. The CMA notes that it would be consistent with decisional precedent to distinguish between products on the basis of use and method of administration.

84. In this respect, the CMA found that that there is no competitive interaction between the Parties:

(a) Biotest's Zutectra and Hepatect (5000IU vials) [26] do not compete with BPL's anti-hepatitis B IG, as they are anti-hepatitis B treatments designed to prevent hepatitis B virus reinfection after liver transplantation for hepatitis B induced liver failure. BPL's product is not indicated for this use.

(b) While both Hepatect (100IU vials) [27] and BPL's anti-hepatitis B IG (200IU and 500IU vials) products are indicated for the same uses, Hepatect is administered intravenously while BPL's product is administered intramuscularly. Furthermore, for the indication where the products overlap, neither product is a first line treatment.[28]

85. As noted above, Creat submitted that intravenous administration allows for higher dosing and more rapid pharmacokinetics, making Biotest's Hepatect more appropriate for use in hospitals. Patients receiving an intravenous infusion must also be closely monitored for any symptoms throughout the infusion period, making Biotest's product less suitable for clinicians treating

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[26] Also available in 2,000IU vial sizes, although Creat submitted that these were less commonly supplied.
[27] Also available in 500IU vial sizes, although Creat submitted that these were less commonly supplied.
[28] UK guidelines indicate that Hepatitis B vaccine is the first-line intervention when infection occurs (or is suspected), while anti-hepatitis B IG is only indicated "*in high-risk situations or in a known non-responder to vaccine*". See the Green Book (*Immunisation against infectious disease*), p.5.

patients in a GP practice. This suggests a lack of substitutability between the products.

86. The available evidence also indicates that there is limited competitive interaction between the two products in practice. In this respect, Creat submitted evidence that showed that previous requests for tender for anti-hepatitis B IGs could not be met by both Parties. In particular:

(a) In [✂], Biotest does not supply any anti-hepatitis B IG products;

(b) In [✂], Biotest only supplies Hepatect (5000IU vials);

(c) In [✂], only 200IU vials and 500IU vials were most recently tendered for, meaning that Biotest was unable to supply this tender; and

(d) In [✂], both an intravenous and an intramuscular anti-hepatitis B IG were tendered for, each of which could only be supplied by either Biotest or BPL. [✂].

87. In addition, few third parties commented on anti-hepatitis B IG in the CMA's market investigation and none raised any concerns. None of the respondents in the market investigation suggested that the Parties' products were wholly substitutable,[29] with many noting the different methods of administration.

88. As there appears to be very limited interaction in practice between the Parties' products within this frame of reference (consistent with a lack of third party concerns), the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to anti-hepatitis B IG.

Factor VIII

89. When taking into account all Factor VIII products (ie both plasma-derived and recombinant products), the Parties have a very low combined share of supply (0-5%) with an increment of 0-5%.[30] Within the narrower plasma-derived frame of reference, the Parties' combined share of supply is also low (5-10%) with an increment of 0-5%.[31]

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[29] Although one considered that they were "generally" substitutable, with some exceptions.
[30] Market share of factor VIII concentrates issued by UK Haemophilia Centres: see information from the UKHDO at http://www.ukhcdo.org/wp-content/uploads/2018/02/Bleeding-Disorder-Statistics-for-April-2016-to-March-2017-for-UKHCDO.pdf, p.30.
[31] CMA calculations based on Figure 13: Market share of factor VIII concentrates issued by UK Haemophilia Centres: see information from the UKHCDO http://www.ukhcdo.org/wp-content/uploads/2018/02/Bleeding-Disorder-Statistics-for-April-2016-to-March-2017-for-UKHCDO.pdf, p.30.

90. The Parties submitted that post-Merger, they will continue to face strong competition from a large number of alternative suppliers. One customer stated that switching between Factor VIII products was difficult due to the limited number of suppliers. However, the CMA found that a number of large providers will continue to supply plasma-derived Factor VIII products in the UK (eg Grifols (30-40% share of supply), CSL Behring (20-30% share of supply) and Octapharma (20-30% share of supply)), with additional large providers supplying recombinant Factor VIII products (eg Pfizer and Shire/Baxalta).

91. Taking into account the Parties' low shares of the supply, the low increment, the significant constraints imposed on the Parties by other competitors post-Merger, as well as the absence of third party concerns, the CMA does not believe that the Merger will result in a realistic prospect of an SLC in Factor VIII in the UK.

Factor IX

92. When taking into account all Factor IX products (ie both plasma-derived and recombinant products), the Parties have a very low combined share of supply (0-5%) with an increment of 0-5%. Within the narrower plasma-derived frame of reference, BPL has a share of supply of 20-30%. However, as Biotest only supplies Factor IX to [✂], the resulting increment will be negligible.

93. Regarding post-Merger constraints on the Parties, Pfizer is the largest provider of Factor IX in the UK (80-90% share of supply). Additional providers with market shares between 0-5% and 5-10% will also remain active post-Merger (eg Grifols (5-10% share of supply) and SOBI/Biogen (0-5% share of supply)).

94. Third parties did not raise any specific issues with respect to Factor IX.

95. Taking into account the Parties' shares of the supply, the low increment, the significant constraints imposed on the Parties by other competitors post-Merger, as well as the absence of third party concerns, the CMA does not believe that the Merger will result in a realistic prospect of an SLC in Factor IX in the UK.

Albumin

Shares of supply

96. The CMA used market share data provided by the CMU to estimate the Parties' shares of supply. These shares of supply are representative rather than exact, since the CMU framework for albumin only covers England.

Similar share of supply data was not available for Northern Ireland, Wales or Scotland, but the Parties estimate that 77% of albumin sales are covered by the CMU framework.

97. The CMU data shows that BPL has [✂] the increment from Biotest will be small at [✂]%. The data also shows that post-Merger, [✂].

98. While share of supply data was not available for the other UK jurisdictions, the observation that BPL is a significant supplier, with Biotest adding only a small increment, is borne out by available information on recent tenders, since:

(a) BPL is the only supplier in [✂];

(b) the suppliers in [✂] are BPL and Octapharma;

(c) BPL, Octapharma and Biotest were included on the [✂] framework but Biotest did not commit to supplying any volume.

Closeness of competition

99. As with intravenous IG, competition for the supply for albumin in the UK takes place mainly through public tender processes. In May 2017, the CMU introduced a new tender process for albumin where suppliers bid for a specific volume of annual demand: 40%, 30%, 15%, 5% and/or a residual 10% category. As such, the CMA considers that market shares are expected to be in line with these allocations.

100. An analysis of the Parties' bids for inclusion in various framework agreements suggests that Biotest is not a significant competitor of BPL in the supply of albumin:

(a) Biotest did not compete against BPL for any of [✂] nor did it bid in the most recent [✂] and [✂] tenders. BPL was the only bidder in [✂], after a bid from [✂] was found to be non-compliant. Bidders in [✂] were [✂] and [✂];

(b) Although both Parties bid for the [✂] tender and were included on the framework along with Octapharma, only BPL and Octapharma committed to particular volumes of supply.

101. In addition, internal documents submitted by Creat showed that BPL did not consider Biotest to be a competitive constraint in the CMU tender, instead evaluating its bid against those of other competitors (Octapharma, Shire and CSL).

Conclusion on horizontal unilateral effects

102. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to albumin.

Vertical effects

103. Vertical effects may arise when a merger involves firms at different levels of the supply chain, for example a merger between an upstream supplier and a downstream customer or a downstream competitor of the supplier's customers.

104. Vertical mergers may be competitively benign or even efficiency-enhancing, but in certain circumstances can weaken rivalry, for example when they result in foreclosure of the merged firm's competitors. The CMA only regards such foreclosure to be anticompetitive where it results in an SLC in the foreclosed market(s), not merely where it disadvantages one or more competitors.[32]

105. The CMA's approach to assessing vertical theories of harm is to analyse (a) the ability of the merged entity to foreclose competitors, (b) the incentive of it to do so, and (c) the overall effect of the strategy on competition.[33]

106. In the present case, the CMA considered an input foreclosure theory of harm in relation to the supply of blood plasma, which is an input into the therapeutic products that the Parties and their competitors supply.

107. The Parties are active at different levels of the supply chain. Upstream, they collect and supply blood plasma to other third parties with whom they compete downstream. There is therefore a vertical relationship between the Parties' activities, with BPL purchasing small volumes of source and specialty blood plasma from Biotest.

108. However, the CMA considers that Creat would not have the ability to pursue an input foreclosure strategy post-Merger with respect to these products in particular because:

(a) The Parties' combined share of global plasma collection[34] is low (around 10-20%);[35]

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[32] In relation to this theory of harm 'foreclosure' means either foreclosure of a rival or to substantially competitively weaken a rival.
[33] *Merger Assessment Guidelines*, paragraph 5.6.6.
[34] Both Parties have blood plasma divisions from which they supply source and specialty plasma to third parties but all sales are made outside of the UK.
[35] Based on data supplied by the Parties.

(b) All key competitors are vertically integrated and self-source the majority of their plasma requirements;

(c) All key competitors have access to a range of collection companies that only supply to third parties; and

(d) The Parties' supply of (i) source blood plasma and (ii) specialty blood plasma to third parties in each case will account for less than 1% of total worldwide source and specialty blood plasma collected post-Merger.[36]

109. Due to Creat's lack of ability to foreclose, there was no need for the CMA to assess the Parties' incentive to foreclose or the effects of this foreclosure strategy on competition.

Conclusion on vertical effects

110. Accordingly, the CMA found that the Merger does not give rise to a realistic prospect of an SLC as a result of vertical effects in relation to the supply of (i) source blood plasma and (ii) specialty blood plasma.

Barriers to entry and expansion

111. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. In assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[37]

112. However, the CMA has not had to conclude on barriers to entry or expansion as the Merger does not give rise to competition concerns on any basis.

Decision

113. Consequently, the CMA does not believe that it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC within a market or markets in the United Kingdom.

114. The Merger will therefore **not be referred** under section 22(1) of the Act.

Colin Raftery
Director

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[36] Based on data supplied by the Parties.
[37] *Merger Assessment Guidelines*, from paragraph 5.8.1.

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[i] Paragraph 3: This paragraph should describe the product collected and processed by the Parties as blood plasma, rather than simply blood.

[ii] Paragraph 12: The CMA notes that Biotest has subsequently acquired three additional blood plasma collection sites and in total, at time of publication, owns eight collection sites in Germany, eight in Hungary and two in the Czech Republic.