Completed acquisition by GLO Dutch Bidco of Mallinckrodt Nuclear Medicine and Mallinckrodt Netherlands Holdings

Decision on relevant merger situation and substantial lessening of competition

ME/6689/17

The CMA's decision on reference under section 22(1) of the Enterprise Act 2002 given on 26 June 2017. Full text of the decision published on 7 July 2017.

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

SUMMARY

1. On 27 January 2017, GLO Dutch Bidco B.V. (**GLO Dutch**)[1] acquired the global nuclear imaging business of Mallinckrodt Nuclear Medicine LLC and Mallinckrodt Netherlands Holdings B.V. (together **Mallinckrodt**) (the **Merger**). GLO Dutch was a subsidiary of GLO BidCo S.à.r.l., which also controlled IBA Pharma SA (**IBA**).[2] **IBA** and **Mallinckrodt** 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, as extended, 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 overlap in the supply of single photon emission computed tomography (**SPECT**) radiopharmaceuticals in the UK. These SPECT radiopharmaceuticals include different products, such as technetium-99m

[1] Following a series of post-Merger intergroup corporate transactions, GLO Dutch has been integrated into Mallinckrodt Medical B.V.
[2] GLO BidCo S.à.r.l. (and thus IBA) is indirectly owned and controlled by funds advised by CapVest Partners LLP.

(**^{99m}Tc**) generators (**Generators**), non-radioactive kits (**Cold Kits**) and other radionuclides (**Hot Kits**). The CMA has assessed the impact of the Merger in the supply of each of Generators, Cold Kits and Hot Kits in the UK. With regard to Cold Kits and Hot Kits, the CMA has considered separately each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

4. In relation to the supply of Cold Kits and Hot Kits in the UK, the CMA 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 effects. The available evidence shows that sufficient competitive constraints will remain post-Merger in all plausible frames of reference in these products.

5. In relation to the supply of Generators in the UK, the CMA believes that the Merger does give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects. The Merger has resulted in a reduction in the number of suppliers providing Generators to UK customers from three to two and the evidence indicates that the competitive constraints remaining post-Merger may not be sufficient to constrain the Parties.

6. The CMA has, however, decided to exercise its discretion under section 22(2)(a) of the Act not to refer the Merger to a Phase 2 investigation on grounds of *de minimis*.[3] The CMA has considered carefully the size of the Generator market, the strength of any competition concerns, the magnitude of the likely harm, replicability and other factors and concluded that, overall the Merger does not justify making a reference.

7. The Merger will therefore **not be referred** to a Phase 2 investigation under section 22(1) of the Enterprise Act 2002 (the **Act**).

ASSESSMENT

Parties

8. IBA, is a developer, manufacturer and distributor of SPECT, positron emission tomography (**PET**), other radiopharmaceuticals and related products. The turnover of IBA in 2016 was approximately £[✂] worldwide. In the UK, IBA's

[3] '*De minimis*' is shorthand for the CMA's exception to refer on the basis of the market being of insufficient importance. Please see: *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 5.

products are distributed exclusively by Alliance Medical Limited (**Alliance**).[4] IBA had sales of approximately £[✂] to Alliance in 2016.

9. The target is the global nuclear imaging business of Mallinckrodt. It develops, manufactures and supplies SPECT radiopharmaceuticals worldwide, including in the UK.[5] The global turnover of Mallinckrodt in 2016 was approximately £[✂], of which £[✂] was attributable to the UK.

Transaction

10. IBA acquired Mallinckrodt on 27 January 2017.[6] On 6 April 2017, the Parties announced that IBA and Mallinckrodt will trade under the 'Curium' brand.

Jurisdiction

Enterprises ceasing to be distinct

11. As a result of the Merger, the enterprises of IBA and Mallinckrodt have ceased to be distinct for the purposes of section 23 of the Act.

Share of supply test

12. The CMA believes that the share of supply test, as defined in section 23 of the Act, is satisfied. Pre-Merger, the Parties overlapped in the supply of SPECT products in the UK, with a combined share of supply of Generators of 60-70% (increment 30-40%) based on revenues (see paragraph 54 below).

13. IBA submitted that the share of supply test has not been met as IBA is not directly active in the UK. It explained to the CMA that, in the UK, IBA's products are distributed by Alliance, (see paragraphs 29 to 33 below). IBA manufactures its products in France and sells these 'ex-works' to Alliance, which then sells the products in the UK. IBA submitted that IBA is a distinct enterprise to Alliance and has no influence over Alliance.

14. The CMA has a wide discretion in applying the share of supply test under section 26(4) of the Act. The CMA notes that section 23(6) of the Act makes it clear that, where goods or services are the subject of different forms of supply, the share of supply test may be assessed by considering all forms of supply taken together, separately or in groups, whichever the decision-making

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[4] Alliance is a separate enterprise to IBA. See further paragraphs 29-33 below.

[5] It also operates the radiopharmay based at University College Hospital London and supplies unit doses to nuclear medicine clinics in the Greater London area. In addition, it operates a molybdenum processing facility (see further paragraph 24 below).

[6] See press release: http://www.prnewswire.com/news-releases/mallinckrodt-completes-sale-of-its-nuclear-imaging-business-to-iba-molecular-for-approximately-690-million-300398172.html

authority considers appropriate. In this case, the CMA has found that IBA is involved in the strategic and operational management of the supply of IBA products into the UK by Alliance. In particular, under the contractual arrangements between IBA and Alliance, [✂][7] [✂]. On the basis of this evidence, the CMA believes that it is appropriate to include Alliance's sales of IBA products in the UK in its consideration of the Parties' share of supply.

Timing

15. The Merger completed on 27 January 2017 and was first made public on 24 August 2016. The four month deadline for a decision under section 24 of the Act, as extended, is 7 July 2017.

Conclusion on jurisdiction

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

Process

17. The CMA identified this transaction as warranting an investigation through its mergers intelligence function[8], and opened an own-initiative investigation into the Merger by sending an Enquiry Letter to IBA on 17 March 2017.

18. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 8 May 2017 and the statutory 40 working day deadline for a decision is therefore 4 July 2017.

19. Given the CMA's decision on the application of the *de minimis* exception, the Parties agreed to waive their procedural rights to a full phase 1 investigation, including the receipt of an issues letter and an issues meeting.[9]

Counterfactual

20. 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

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[7] [✂].
[8] See *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, paragraphs 6.9-6.19 and 6.59-60.
[9] The CMA also undertook its assessment in relation to Cold Kits and Hot Kits taking into account the relative size of those potentially affected markets (amounting to less than £[✂]).

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.[10]

21. In this case, there is no evidence supporting a different counterfactual. IBA submitted that, if the Merger had not taken place, Mallinckrodt would likely have been sold to a different party but it would have continued to operate in a similar way to its operation now. Third parties did not put forward arguments in this respect. Therefore, the CMA believes the pre-Merger conditions of competition to be the relevant counterfactual.

Background

SPECT

22. Nuclear medicine uses radioactive isotopes, referred to as radionuclides, for the diagnosis and treatment of disease. SPECT is one type of imaging method whereby radionuclides that emit gamma rays are used to generate images of tissues and organs. The most commonly used radionuclide for SPECT is ^{99m}Tc. This radionuclide is commonly combined with a non-radioactive Cold Kit to prepare a finished radiopharmaceutical that is then introduced into the body by injection, swallowing or inhalation. The properties of different Cold Kits allow for the finished radiopharmaceutical to be carried and bound to specific parts of the body, ie to certain tissues or organs. The radiation emitted from the radionuclide can then be seen by a gamma camera. Almost all of the ^{99m}Tc used in nuclear medicine is produced by radioactive decay of Molybdenum-99 (**^{99}Mo**).

[10] *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).

Supply chain for ^{99m}Tc Generators

23. The supply chain for the ^{99m}Tc Generator production process is illustrated graphically in **Figure 1**.

Figure 1: Supply chain overview

Source: mallinckrodt.com/nuclear_imaging/Global_Mo-99_Supply_Chain.aspx (retrieved 12/05/2017)

24. ^{99}Mo is produced in nuclear reactors from the decay of uranium. Currently there are six medical isotope-producing reactors worldwide which provide the vast majority of the world's ^{99}Mo needs.[11] When fission has produced ^{99}Mo in the reactor, it is then removed and transferred to a molybdenum processing facility. There are currently four ^{99}Mo processing facilities in the world, one of which is owned and operated by Mallinckrodt. Next, the isolated ^{99}Mo is transferred to a manufacturing facility to make Generators. Generators are systems that store ^{99}Mo and allow its decay product, ^{99m}Tc, to be recovered for use.[12] Generators can be loaded with different amounts of radioactivity, depending on shipping periods and the requirements of the radiopharmacy or hospital. Customers commonly order Generators by specifying the required radioactivity level (ie in becquerel).

Customers

25. ^{99m}Tc Generators are shipped to radiopharmacies and hospitals. Radiopharmacies prepare unit doses of ^{99m}Tc-labelled radiopharmaceuticals for administration to patients. First, ^{99m}Tc is obtained from a Generator on site, this process is referred to as 'elution'. The ^{99m}Tc is then typically added to a non-radioactive Cold Kit. All procedures are carried out in a clean room or isolator to provide radiation shielding and sterile conditions. Customers told the CMA that they typically receive one or two deliveries of Generators per week and elute these once or twice per day.

[11] There was a shortage of ^{99}Mo in 2009 due to unforeseen closures of reactors. See for instance https://www.oecd-nea.org/cen/docs/2017/sen-hlgmr2017-2.pdf.
[12] The CMA understands that Alliance intends to manufacture [✂] ^{99m}Tc from its own cyclotrons based in the UK. It is technically viable to produce ^{99m}Tc through this alternative method, though the commercial viability of this alternative method of production is less certain.

26. Due to the short half-lives of ^{99}Mo and ^{99m}Tc (around 66 hours and 6 hours, respectively), they cannot be stockpiled and the supply chain operates to deliver ^{99m}Tc to hospitals within tight time scales to minimise decay losses.

27. There are also other radionuclides used for SPECT imaging some of which have longer average half-lives than ^{99m}Tc. These are sometimes referred to as Hot Kits. Some of these Hot Kits do not rely on the supply of uranium and can be produced in accelerators, therefore not relying on the supply chain described above. Depending on the product, these are produced either directly by the supplier or in the radiopharmacy, using a (different type of) generator.

28. Customers told the CMA that they would commonly request quotes or tender for a range of SPECT products comprising, amongst other products[13], Generators, Cold and Hot Kits. Most customers told the CMA that their SPECT purchases fall under the EU rules and guidelines on public procurement. Tenders are therefore widely advertised and the processes are open, competitive and suppliers are treated according to these rules. Customers also told the CMA that suppliers can bid for any of the lots that form part of a tender so that no single supplier is required to bid for all products.

Alliance

29. On 14 May 2014, IBA appointed Alliance as exclusive distributor of its products in the UK. The distribution agreement is for a duration of [✂] and, since [✂], the agreement has specified that [✂]. IBA told the CMA that it is not an agency relationship, but an arm's length supplier/distributor relationship. In accordance with this agreement, IBA supplies product 'ex-works' from its Saclay facility to Alliance, which resells them to UK-based customers at prices set by Alliance. IBA does not make any specifications with regards to the contracts entered into between Alliance and its customers in the UK and it does not see the individual customer prices set by Alliance. However, Alliance provides IBA with its average prices from time to time, and IBA told the CMA that it generally assumed there is an average uplift from cost of [✂]%.

30. Payments to IBA under the distribution agreement are made [✂], with IBA entitled to a minimum payment of £[✂] annually. Alliance told the CMA that [✂].

[13] Eg consumables and sundries.

31. The distribution agreement between IBA and Alliance [✂]. The agreement does, however, permit Alliance to [✂]. Alliance is currently expanding its UK manufacturing facilities (which are currently dedicated to PET) so that it will have two facilities with this capability in the future. IBA submitted that [✂].

32. The distribution agreement also requires Alliance to [✂], and to [✂]. Alliance is required to be [✂]. [✂]. Alliance is also [✂].

33. As Alliance sets or negotiates terms with customers of IBA's products in the UK, the CMA considered whether the merged entity would have the ability and incentive to alter these terms. Given the [✂] within which IBA could terminate its agreement with Alliance, and its control over the product being supplied to Alliance for onward supply to customers in the UK, the CMA believes that there is a realistic prospect that the merged entity would have the ability and incentive to influence the terms on which its products are supplied through Alliance to UK customers.

Frame of reference

34. 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.[14]

35. Pre-Merger the Parties overlapped in the supply of Generators, Cold Kits and Hot Kits to radiopharmacies in the UK. The Parties also have an indirect vertical relationship. Mallinckrodt also produces ^{99}Mo. However, it it does not supply ^{99}Mo to any other suppliers of Generators in the UK.

Product scope

36. IBA said that the relevant market was the industrial SPECT market, which it said comprised two segments: non-specific SPECT (Generators, which did not have an application to a particular organ) and specific SPECT (products used for detecting a particular disease or with a specific use, such as bone imaging, ie Cold and Hot Kits). IBA added that non-specific and specific SPECT products could not be substituted for one another.

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

Demand-side factors

37. In relation to Generators, the information received from customers suggested that, despite certain differences between suppliers, eg in delivery schedules and laboratory equipment specific to a certain Generator type, the products currently sold in the UK are largely substitutable. The CMA notes that all current suppliers in the UK supply roughly similar activity ranges of Generators.

38. With respect to Hot and Cold Kits, customers told the CMA that doctors have very little effective choice as radiopharmaceuticals are developed specifically to target a certain organ, tissue, or type of medical condition. Customers said that there is sometimes more than one radiopharmaceutical for a specific organ or tissue, but this is often because different agents may be more suitable for the imaging of different parts or functions of the relevant organ or tissue. Customers said that, where there are different Cold Kits for a particular type of SPECT imaging procedure of a particular organ, tissue, function or medical condition, they are often chemically or functionally different,[15] and clinicians may have different preferences for different products.

39. Clinicians told the CMA that they follow best clinical practice when they decide which SPECT product to use and this is not driven by price considerations. However, this choice can be limited as only certain products or procedures are reimbursed by the NHS for NHS-funded patients. Clinicians also told the CMA that best practice may evolve over time with one product being replaced by a new or improved product for a particular application.

40. On the basis of this evidence, the CMA believes that switching is unlikely to occur between different Cold and Hot Kits that do not fulfil the same purpose.

Supply-side factors

41. The boundaries of the relevant product market are generally determined by reference to demand-side substitution alone. The CMA may nevertheless aggregate narrow relevant markets into one broader market on the basis of supply-side factors when:

    (a) Firms have the ability and incentive quickly to shift capacity between different products; and

[15] Differences may also lie in aspects such as shelf-life, package size, or suppliers' delivery schedule.

(b) The same firms compete to supply these different products and the conditions of competition between the firms are the same for each product.[16]

42. Third Parties told the CMA that, although some Cold Kits' formulae are in the public domain, manufacturers of one type may not necessarily have the ability to shift capacity between different types. They said that, for some types, the raw materials may not be easily obtainable or producible; and products, processes, and facilities are highly regulated and require approval from a number of organisations, including from authorities at the manufacturing location and at the point of delivery. Third parties also said that the set of competitors differs between different types of Cold Kit, with some manufacturers specialising in specific branches of medicine.

43. On the basis of this evidence, the CMA does not believe it appropriate to aggregate all Cold and/or Hot Kits into a broader frame of reference. However, this point was not crucial since, as set out below, no competition concerns arise in Cold or Hot Kits on any plausible basis.

Conclusion on product scope

44. For the reasons set out above, the CMA has assessed the impact of the Merger in the following product frames of reference:

(a) The supply of Generators;

(b) The supply of Cold Kits separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition; and

(c) The supply of Hot Kits separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

Geographic scope

45. IBA told the CMA that its SPECT products are supplied across the UK to NHS or private radiopharmacies and hospitals. Current competitors active in the UK also told the CMA that they deliver across the UK.

[16] See *Merger Assessment Guidelines* (OFT1254/CC2), September 2010, paragraph 5.2.17.

46. IBA said that there is a UK-wide price for the relevant products [✂].[17] This was confirmed by the Department of Health. Customers commonly pay lower prices because they tender or request quotes.

47. Generator suppliers currently competing in the UK explained that the supply chain and logistic arrangements are in place to supply all parts of the UK given the importance of the perishability of the product.[18]

48. The Parties' customers told the CMA that suppliers commonly have at least a sales representative in the UK and that the sales, advertising and marketing strategies are the same across the UK.

Conclusion on geographic scope

49. For the reasons set out above, the CMA has assessed the impact of the Merger on a national, ie UK-wide, geographic frame of reference.

Conclusion on frame of reference

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

    (a) The supply of Generators in the UK;

    (b) The supply of Cold Kits in the UK separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition; and

    (c) The supply of Hot Kits in the UK separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

Competitive assessment

Horizontal unilateral effects

51. 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.[19] Horizontal unilateral effects are more likely when the merging parties are close competitors.

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[17] See also the 'competitive assessment' section below for how prices are determined.
[18] It represents the largest share of outlay for SPECT products in the UK and has one of the shortest half-lives of these products.
[19] *Merger Assessment Guidelines*, from paragraph 5.4.1.

52. 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 supply Generators in the UK and the supply of Cold Kits and Hot Kits in the UK separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

Generators

Shares of supply

53. IBA told the CMA that there are currently three main suppliers of Generators in the UK: Mallinckrodt, Alliance (IBA), and General Electric Healthcare (**GE**).

54. Mallinckrodt, Alliance and GE provided their sales revenues for Generators in 2016, as shown in Table 1.

Table 1: CMA's market share estimates for generators (UK, 2016)

	Turnover £ million	Share %
IBA (Alliance)	[✂]	[30-40]
Mallinckrodt	[✂]	[30-40]
Sum	[✂]	[60-70]
GE	[✂]	[30-40]
Polatom (IEL)	[✂]	[0-5]
Total	£4,61	100

Source: Parties ([✂])

and GE.

55. Polatom is a supplier of Generators in some European countries. However, it told the CMA that it had [✂] sales of Generators in the UK in 2016. This was confirmed by Imaging Equipment Limited (**IEL**)[20] and ROTOP.[21]

56. The Parties told the CMA that the three current suppliers of Generators in the UK can all supply the range of Generator products, their Generators are interchangeable despite certain differences (eg wet and dry Generators) and all three suppliers' offer Generators with roughly similar ranges of radioactivity. This was confirmed by GE. Therefore, it appears that there are three close competitors. The Merger results in a reduction from three to two suppliers of Generators in the UK.

[20] IEL is the distributor of ROTOP/Polatom in the UK.
[21] ROTOP, a company based in Germany, is the marketing authorisation holder for Polatom Generators in the UK.

Third-party views

57. The majority of customers (21 of 29 respondents) were concerned about the horizontal effects of the Merger. Most of them told the CMA that they were concerned about the impact of the Merger on the supply of Generators, in particular the reduction in the number of suppliers and the effect this may have on the security of supply of radioisotopes in the UK. The concerns were partly based on previous experiences of supply disruptions.

58. Some customers also thought that the merged entity may discontinue one of the two Generator products and that this would lead to switching costs for customers as they would have to make changes to their laboratory equipment in order to accommodate a different manufacturer's Generators. Conversely, some customers considered, in line with submissions from the Parties, that the merged entity may benefit from a greater security of supply in raw materials and therefore offer greater security of supply in Generators.

59. Only a minority of customers raised concerns about possible effects on prices. However, the CMA notes that most respondents were users of the products (ie clinicians) and not purchasers of the product (ie NHS procurement). The CMA also notes the relatively small share that SPECT products represent in the overall budgets of the NHS entities making the purchase. The CMA therefore considers that an absence of customer concerns about the price effect of the Merger is in this case not a meaningful indication of the likelihood or magnitude of price increases.

60. Some customers told the CMA that the merged entity would offer the lowest prices for Generators. However, another customer provided an example of Mallinckrodt's attempt to increase the price of its Generators approximately six weeks after completion of the Merger from between 9% and 23% (depending on the Generator model).

61. Several customers told the CMA that, whilst Generators may be a relatively standardised product, the quality of service is very important and a reduced choice of suppliers might result in a reduced quality of service.

62. ROTOP told the CMA that it hoped the Merger would lead to a situation in which suppliers can pass on increased raw material costs to customers which they were previously unable to do.

63. Polatom raised concerns about the Merger, saying that it would lead to a 'monopolisation' of the market. It confirmed that it had no sales of Generators in the UK but said that it is willing to grow its business (including in the UK).

Competitive constraints

64. The merged entity will continue to face competition in the supply of Generators in the UK from GE. The CMA therefore considered whether this would be sufficient to prevent adverse effects from the Merger.

65. The circumstances where two suppliers are sufficient to deliver competitive outcomes are highly restrictive and somewhat idealised.[22] On the current evidence available, the CMA is not satisfied that these conditions exist in the supply of Generators in the UK, in particular because evidence from customers suggests that they do not necessarily consider all suppliers as perfect substitutes for each other, and individual tenders are not necessarily large relative to a supplier's total sales.

66. The CMA investigated other potential suppliers of Generators in the UK. IBA said that IEL/Polatom had recently entered the market and it expected Polatom to win market share at the expense of the three existing suppliers. However, as discussed below (see paragraphs 93 to 94), the CMA believes that IEL/Polatom and other potential suppliers of Generators do not currently pose a competitive constraint on the Parties, and it has found insufficient evidence to believe that they are likely to do so in the foreseeable future. IBA also said that it anticipates that Alliance will enter the production of ^{99m}Tc with its own cyclotrons from about 2020. However, the CMA notes that any effect on the market from such entry is more than two years away and therefore would not represent a timely constraint on the merged entity.

Conclusion on Generators

67. For the reasons set out above, the CMA believes that the Merger has resulted in a reduction in the number of suppliers providing Generators to UK customers from three to two and the evidence indicates that the competitive constraints remaining post-Merger may not be sufficient to constrain the Parties. The CMA therefore believes that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of Generators in the UK.

Cold and Hot kits

68. The CMA considered Cold Kits and Hot Kits separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

[22] See Bidding Markets, Paul Klemperer, Competition Commission, June 2005.

Parties' views

69. In total, IBA listed over 25 different types of Cold Kits and a number of Hot Kits produced or supplied by the Parties. Of these products, there are no apparent overlaps with respect to eight products. However, some of the remaining products can be used for similar indications. For these products, the CMA considered the constraints conferred by other manufacturers' products or procedures, depending on the particular organ, tissue, function and/or medical condition for which the Parties' products could be used.

70. The Parties' submitted that some of their overlapping products are no longer in use due to clinicians' preferences and the existence of newer products or procedures.

71. With respect to bone scintigraphy, lung perfusion scintigraphy and Thallium the Parties submitted that their products were similar and were used for similar indications, although there were differences in activity strength, expiry dates and stability after labelling.[23]

Third-party views

72. Only a minority of customers (three out of 29 respondents) were concerned about the horizontal unilateral effects of the Merger in the supply of Cold or Hot Kits. The majority of customers considered that the Parties offer different types of Cold and Hot Kits such that there would be little merger effect.

73. The CMA consulted with several clinicians to assess each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition where the Parties' Cold Kits or Hot Kits overlap. The clinicians told the CMA that the application and use of Cold Kits evolves over time with new and improved products leading sometimes to changes in the set of interchangeable products for a specific application.

74. No concerns were raised by clinicians in relation to the following Kits: Gallium, Iodium and Yttrium and the Parties' products used for angiocardioscintigraphy, myocardial perfusion, renal cortex and renal filtration.

75. In three areas – bone scintigraphy, lung perfusion scintigraphy and Thallium – at least one customer or one clinician identified that there would be three or fewer suppliers post-Merger. Therefore, the CMA assessed these areas in more detail, as set out below.

[23] A period of time during which a multidose product can be used whilst retaining quality within an accepted specification once the container is opened.

CMA's assessment

76. The CMA considered whether supply conditions might vary for different customers, in particular on the basis of customer size. All competitors told the CMA that they typically compete for all contracts across the UK, regardless of contract value. The CMA has also found that customers sometimes buy SPECT products jointly. The CMA therefore believes that the following findings (in particular the availability of alternative products) can be applied to all customers in the UK.

- *Bone scintigraphy*

77. Skeletal (bone) scintigraphy is a nuclear medicine procedure used to diagnose and assess the severity of a variety of bone diseases and conditions, including fractures, infection and cancer.

78. The Parties submitted that pre-Merger they each supplied one product in this segment: Mallinckrodt supplied HDP and IBA supplied OSTEOSIS. The Parties provided evidence[24] to the CMA which suggested that other modalities may be used for bone scintigraphy such as radiography, computerised tomography (**CT**) and magnetic resonance imaging (**MRI**). They also submitted that MDP (produced by GE) and various generic MDP medicines supplied and/or produced by Diagnostic Imaging Ltd, Medi Radiopharma and Polatom compete with the Parties' products in the bone scintigraphy segment.

79. Clinicians and NHS procurement teams told the CMA that bone scans are one of the most important and frequent procedures in nuclear medicine. One clinician told the CMA that an insufficient number of suppliers would remain post-Merger. However, other clinicians told the CMA that there are several suppliers of generic alternatives with UK marketing authorisations successfully competing in the UK and they did not have any concerns in relation to this category.

80. The CMA believes that the existence of possible alternatives (as listed by recognised clinicians) would limit any impact on competition resulting from the Merger in this segment.

- *Lung perfusion scintigraphy*

81. The most common indication for lung scintigraphy is to determine the likelihood of pulmonary embolism. Other less common indications include:

[24] The Parties listed Cold and Hot kits by indication, for example 'bone' or 'lung', alongside the name of the Parties' products for the indication, other modalities which may be used and competitors' products for that indication.

evaluation of lung transplantation, pre-operative evaluation and right-to-left shunt evaluation.

82. The Parties submitted that they each supplied one product in this segment; Mallinckrodt supplied LyoMAA and IBA supplied PULMOCIS. The Parties said that other modalities may be used including multidetector CT, echography and biology and that two other products supplied by GE and Medi Radiopharma compete with the Parties' products in this segment.

83. Clinicians told the CMA that lung perfusion scans are important and frequent procedures. Clinicians said that lung agents are similar and can all be used interchangeably but they differ in shelf life and in radioactivity levels. One clinician raised concerns as he was only familiar with the Parties' products and considered them to be the only available alternatives. However, other clinicians said that no concerns arise in this frame of reference. One mentioned that DTPA (a renal agent) can be used to produce an aerosol for an alternative way to image lung perfusion.

84. The CMA believes that the existence of possible alternatives (as listed by recognised clinicians) would limit any impact on competition resulting from the Merger in this segment.

- *Thallium (diagnostic)*

85. The Parties told the CMA that thallium-201 (**^{201}Tl**) is a Hot Kit which is used as a radioisotope for myocardial, parathyroid and neoplastic scintigraphy and that they each supply one product in this segment. Other modalities which may be used include multidetector CT, echography and biology and that two PET products can be considered to be in competition with the Parties' products in this segment.

86. All clinicians told the CMA that ^{201}Tl is not commonly used anymore in myocardial and parathyroid imaging, where it has been superseded by ^{99m}Tc-labelled Cold Kits. One clinician, however, said that it is still used in neoplastic scintigraphy where it is the agent of choice. The clinician raised concerns about a possible reduction from two to one supplier post-Merger as no alternative suppliers exist. The other clinicians did not raise concerns in this area, explaining that other products are now used.

87. In view of the above feedback, the CMA believes that the use of ^{201}Tl has now become relatively obsolete. This minimises the impact on competition of the Merger in relation to this product.

Conclusion

88. On the basis of the evidence set out above from clinicians, the CMA believes that alternative products exist and sufficient competitive constraints will remain post-Merger in all plausible frames of reference for Cold Kit and Hot Kit products where the Parties overlap. The CMA therefore believes that the Merger does not give rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to Cold Kits or Hot Kits separately for each type of SPECT imaging procedure depending on the organ, tissue, function, and/or medical condition.

Barriers to entry and expansion

89. Entry, or the 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.[25] Since the CMA considers that the Merger does not give rise to a realistic prospect of an SLC in relation to Cold Kits and Hot Kits, it has considered entry, or the expansion of existing firms, only with respect to Generators.

90. Customers told the CMA that they prefer Generator products with a UK marketing authorisation over products with an EU marketing authorisation, although there is mutual recognition between them.[26] The Medicines and Healthcare Products Regulatory Agency (**MHRA**) and competitors told the CMA that the difficulty of obtaining a marketing authorisation depended on several factors, with it costing between £10,000 and £100,000 and taking up to 10 years.[i]

91. Customers and competitors told the CMA that, even when the formulation of certain radiopharmaceuticals are in the public domain, access to the necessary raw materials needs to be obtained and a manufacturing process needs to be developed, both requiring regulatory approval by the local authorities. Moreover, there is a world-wide shortage of ^{99}Mo and established Generator manufacturers have longstanding commercial relationships with upstream suppliers.

92. Competitors also told the CMA that economies of scale are important in the supply of Generator products. Third parties suggested that set-up costs are very high, mainly consisting of sunk costs; and distributors said that significant economies of scale can be achieved in relation to logistics and transportation

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[25] *Merger Assessment Guidelines*, from paragraph 5.8.1.
[26] There is no mutual recognition of extra-Community authorisations.

costs. There are also sunk costs in relation to competing for contracts as competitors told the CMA that they have dedicated staff in the UK, usually with a regional focus.

93. Based on the information the CMA has obtained from potential suppliers of Generators in the UK, the CMA believes that these suppliers do not currently pose any competitive constraint on the Parties and they are very unlikely to do so in the foreseeable future. IEL told the CMA that it had competed to supply Generators into the UK in the past but it had found that it was not in a position to offer competitive prices. IEL said that it had since decided not to compete for the supply of Generators in the UK. It said that it was not bidding for any Generator tenders in the UK and it had no intention to begin doing so.

94. Polatom and ROTOP told the CMA that they have UK marketing authorisations for Generators but that the Generators they supply are not competitive in the UK as they are more expensive than competing products. One customer told the CMA that Polatom does not manufacture Generators of higher activities (greater than 100 GBq) which are required by larger hospitals in the UK.

95. IBA also named Monrol, a Turkish/U.A.E. manufacturer of SPECT and PET products as a potential supplier into the UK. However, based on the information received from third parties,[27] Monrol does not have a EU or UK marketing authorisation for Generators.

96. No third party considered that entry or expansion in the manufacture of Generators would be possible within the timeframe and on the scale necessary to mitigate the effects of the Merger.[28]

97. For the reasons set out above, the CMA believes that entry or expansion would not be sufficiently timely or likely to prevent a realistic prospect of an SLC as a result of the Merger.

Conclusion on substantial lessening of competition

98. Based on the evidence set out above, the CMA believes that it is or may be the case that the Merger has resulted, or may be expected to result in a realistic prospect of an SLC as a result of horizontal unilateral effects in relation to the supply of Generators in the UK.

[27] This information was provided by other third parties and not by Monrol.
[28] *Merger Assessment Guidelines*, paragraph 5.8.1 *et seq*.

Exceptions to the duty to refer

99. Where the CMA's duty to refer is engaged, the CMA may, pursuant to section 22(2)(a) of the Act, decide not to refer the merger under investigation for a phase 2 investigation on the basis that the market(s) concerned is/are not of sufficient importance to justify the making of a reference (the ***de minimis* exception**). The primary purpose of the *de minimis* exception is to avoid references being made where the costs involved would be disproportionate to the size of the market(s) concerned.[29] The CMA has considered below whether it is appropriate to apply the *de minimis* exception to the present case.

100. The Parties submitted that, given the estimated value of the market raising competition concerns as a result of the Merger is below £5 million, if the CMA were to conclude that the Merger gives rise to a realistic prospect of an SLC, it should apply its *de minimis* discretion and not refer the Merger for an in-depth phase 2 investigation.

Markets of insufficient importance

101. In considering whether to apply the *de minimis* exception, the CMA will consider, in broad terms, whether the costs involved in a reference would be disproportionate to the size of the market(s) concerned, taking into account also the likelihood that harm will arise, the magnitude of competition that would be lost by the merger and the duration of such effects. The CMA will also have regard to the wider implications for future cases of any decision that it takes to exercise its *de minimis* discretion. [30]

102. The CMA takes into account the above factors in its judgment as to whether or not to exercise its discretion in each particular case. However, recognising the value of predictability, the CMA has provided some guidelines on the availability of 'de minimis' by setting some indicative thresholds. Those guidelines state that, where the annual value in the UK of the market(s) concerned is, in aggregated terms, less than £5 million (and where the CMA considers there are no clear-cut undertakings in lieu available in-principle), a reference to phase 2 will generally not be justified. The CMA would expect to refer a merger where the value of the market(s) concerned is less than £5 million only exceptionally, and where the direct impact of the merger in terms of customer harm is particularly significant and/or where the merger is one of

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[29] See *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 8.
[30] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 12.

a potentially large number of similar mergers that could be replicated across the sector in question.[31]

'In principle' availability of undertakings in lieu

103. The CMA's general policy, regardless of the size of the affected market, is not to apply the *de minimis* exception where clear-cut undertakings in lieu of a reference could, in principle, be offered by the parties to resolve the concerns identified.[32] In most cases, a clear-cut undertaking in lieu will involve a structural divestment.

104. The CMA considered whether the Parties could offer a suitable package of assets, know-how, manufacturing facilities, staff and other necessary accessory services to replicate the production and distribution of Generators to UK customers to an extent which would restore the competitive constraint that the Parties currently impose on each other in relation to the supply of Generators in the UK.

105. The CMA concluded that, while it might be theoretically possible to assemble such a remedy package, there would be several substantial practical difficulties, in particular due to the Parties' production of Generators taking place in two facilities located in the Netherlands and France, both of which supply to many other geographic markets. The CMA noted that any remedy which significantly affected the Parties' activities in other markets might not be proportionate to remedy the concerns identified in the UK.

106. The CMA takes a conservative approach to assessing whether undertakings in lieu are in principle available. To the extent that there is any doubt as to whether undertakings in lieu would meet the 'clear-cut' standard, those undertakings cannot be deemed to exist 'in principle'.[33]

107. In view of the doubts and challenges set out above, the CMA does not believe that an 'in principle' clear-cut undertaking in lieu is available in this case.

Relevant factors

108. The CMA will consider the likely level of consumer harm by reference to a number of factors when deciding whether or not to apply the *de minimis*

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[31] *Mergers: Exception to the duty to refer in markets of insufficient importance,(*CMA 64), 16 June 2017, paragraph 15.
[32] *Mergers: Exceptions to the duty to refer and undertakings in lieu of reference guidance*, paragraphs 2.2 and 2.18-27.
[33] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 22-27.

exception: the size of the market, the strength of the CMA's concerns that harm will occur as a result of the merger, the magnitude of competition that would be lost by the merger, and the likely duration of the SLC.[34] The CMA will also consider the wider implications of a *de minimis* decision.[35] Each of these factors is discussed in turn below.

Market size[36]

109. The Parties submitted that the size of the Generator market in the UK was approximately £4.6m (based on the Parties' and GE's sales revenues in 2016). The CMA confirmed these figures.

110. The fact that the size of this market is below £5 million is a strong factor in favour of applying the *de minimis* exception.[37]

Strength of the CMA's concerns

111. The CMA takes into account the strength of its belief regarding the likelihood that the merger will have an anticompetitive effect when deciding whether to exercise the *de minimis* exception.[38]

112. In this case, as stated above,[39] the CMA believes that the Merger might give rise to a realistic prospect of an SLC in the supply of Generators in the UK. However, the CMA notes that GE, which was the largest supplier of Generators in the UK pre-Merger, will continue to provide some competitive constraint on the merged entity. The CMA also notes that there are alternative providers which could enter the UK market (eg Polatom), particularly in the event of significant adverse merger effects which might make the UK a more attractive market to enter. The CMA also notes the development of new technology (cyclotrons) which market participants expect to provide an alternative to the Parties' products in the future.

113. These factors lead the CMA to conclude that the strength of its concerns is not an aggravating factor for the purposes of its *de minimis* assessment.

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[34] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 28-29.
[35] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 12.
[36] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 30.
[37] See paragraph 102 above.
[38] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 31-33.
[39] See paragraph 67 above.

Magnitude of competition lost[40]

114. The Merger leads to a reduction in the number of competitors in the supply of Generators in the UK from three to two. This reduction in the level of competition might typically (absent countervailing competitive constraints) be expected to lead to large price increases and/or a degradation in quality and/or reduced innovation.

115. A customer told the CMA that, following the Merger, it was quoted prices around 9% to 23% higher. The CMA did not assess whether these price increases were due to factors other than the impact of the Merger as external factors, such as exchange rate fluctuations or other input cost changes, may also influence prices. Nevertheless, this evidence, in isolation, would point against the application of the *de minimis* exception.

Durability

116. The CMA assesses the likely durability of the merger effect as part of its assessment of the suitability of the application of the *de minimis* exception. The CMA may consider whether any barriers to entry into the concerned market(s) are substantial and durable. For example, the CMA may not be sufficiently confident that entry would be timely, likely and sufficient to prevent competition concerns from arising but may believe that entry or expansion is ultimately likely to occur. Equally, the CMA may consider that the durability of a merger's impact will be limited because technological advancements or market transformation will render merger effects relatively short-lived.[41]

117. In this case, the CMA is aware that Polatom[42] is a licensed supplier of Generators in the UK and supplies in many other countries. Polatom is also building a new facility which it expects will strengthen its competitive offering in the UK. Polatom told the CMA that it expects its new facility to address many of the issues which are currently preventing it from competing effectively with the Parties and GE in the UK. It expects the new production facility to be completed by the end of 2017/early 2018. Therefore, effective new entry may occur in the medium to long term.

118. The CMA is also aware that the development of cyclotrons might provide an alternative to the Parties' products in the future. Alliance envisages to enter

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[40] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 34-37.
[41] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 38-39.
[42] ROTOP, a company based in Germany, is the marketing authorisation holder for Polatom Generators in the UK.

the supply of Generators in the UK with its cyclotron-produced ^{99m}Tc around 2020.

119. These factors lead the CMA to conclude that the durability of harm is not an aggravating factor for the purposes of its *de minimis* assessment.

Wider implications of a 'de minimis' decision[43]

120. The CMA will be less likely to apply the *de minimis* exception where it believes that the merger is one of a large number of similar mergers that could be replicated across the sector.[44]

121. In the present case, the CMA has seen no evidence of similar mergers taking place or being in contemplation. The CMA also notes that the Merger is in a sector (the production and supply of Generators) with limited scope for analogous future transactions under comparable competitive conditions.

122. Internal documents submitted by IBA suggest that [✂]. IBA and some customers also indicated that the Merger might improve the Parties' service quality and the reliability of supply for customers.

123. These factors lead the CMA to conclude that the wider implications of a *de minimis* decision is not an aggravating factor for the purposes of its *de minimis* assessment.

Conclusion on the application of the de minimis exception

124. Taking all the above factors into consideration, the CMA believes that the size of the market concerned in this case is not of sufficient importance to justify the making of a reference. As such, the CMA believes that it is appropriate for it to exercise its discretion to apply the *de minimis* exception.

125. Given the CMA's decision on the application of the *de minimis* exception, the Parties agreed to waive their procedural rights to a full phase 1 investigation, including the receipt of an issues letter and an issues meeting.

DECISION

126. Consequently, the CMA believes that it is or may be the case that (i) a relevant merger situation has been created; and (ii) the creation of that situation has resulted, or may be expected to result, in an SLC within a market

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[43] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraphs 40-44.
[44] *Mergers: Exception to the duty to refer in markets of insufficient importance*, (CMA 64), 16 June 2017, paragraph 41.

or markets in the UK. However, pursuant to section 22(2)(a) of the Act, the CMA believes that the market concerned is not of sufficient importance to justify the making of a reference.

Andrew Wright
Director of Mergers
Competition and Markets Authority
26 June 2017

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[i] The MHRA told the CMA that there are different types of marketing authorisations and that the time to develop a product and the cost of development of a product vary. The MHRA stated that The Association of British Pharmaceutical Industries has reported that it takes approximately 12 years to research and develop a medicine containing a new active substance and typical costs are of the order £1.15bn. The CMA does not believe that this correction alters its overall reasoning or the substance of its decision.