Completed acquisition by Medtronic plc of certain assets of Animas Corporation

Decision on relevant merger situation and substantial lessening of competition

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 19 December 2017 Medtronic plc (**Medtronic**) acquired certain assets (the **Target Assets**) from Animas Corporation (**Animas**), a subsidiary of Johnson & Johnson (**J&J**) (the **Merger**). Medtronic and the Target Assets are together referred to as the **Parties**.

2. The Competition and Markets Authority (**CMA**) notes that the Merger does not involve an extensive transfer of assets. For example, it does not provide for the transfer of any physical assets (eg insulin pumps or consumables), fixed assets (eg manufacturing facilities), intellectual property, R&D assets and information, or employees.

3. The CMA notes, however, that the customer and patient records being transferred through the Merger appear to be of significant value and that the combination of these assets with the other transferred assets appears to support a degree of 'economic continuity' that may enable Medtronic to carry on the business previously supported by these assets.

4. The CMA therefore believes that the Target Assets may be an enterprise, and that as a result of the Merger, the enterprises of Medtronic and the Target Assets have ceased to be distinct.

5. 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.

6. The CMA considered whether the Merger should be assessed against a counterfactual other than the pre-Merger conditions of competition; in particular, whether the conditions for adopting the exiting firm counterfactual were met.

7. The CMA concluded that it was satisfied that J&J had taken the decision, for strategic reasons, to exit the market (ie that limb 1 of the exiting firm counterfactual was met). However, the CMA could not be confident that there was no substantially less anti-competitive purchaser for the Target Assets (limb 2 of the exiting firm counterfactual) for two main reasons. Firstly, J&J did not approach any other potential buyers at the time of the Merger. Secondly, certain other market players indicated to the CMA during the market investigation that they would have been interested in such an acquisition, and the available evidence did not enable the CMA to conclude that these suppliers would not have had a realistic prospect of proceeding with a bid. Accordingly, the CMA did not find that the conditions for an exiting firm counterfactual were met.

8. Nevertheless, having satisfied itself on the basis of compelling evidence that Animas would have inevitably exited the market absent the Merger, the CMA concluded that the pre-Merger conditions of competition was not a realistic counterfactual. Taking into account the nature of the Target Assets and that only certain purchasers could have purchased those assets, the CMA adopted a counterfactual in which the Target Assets were acquired by another existing supplier of tethered insulin pumps in the UK.

9. Given that the Target Assets would have transferred to an existing supplier of insulin pumps in the UK under both the Merger conditions and the counterfactual, the CMA's assessment focused on whether the acquisition of the Target Assets (and thereby Animas' patients) by Medtronic, rather than another existing UK market participant, would have any material effect on competition in the supply of tethered insulin pumps in the UK. The CMA did not consider it appropriate to further widen this frame of reference to all insulin pumps, or wider still to all insulin delivery systems, on the basis that the CMA found that patients may have a preference for tethered insulin pumps in particular, and further that some NHS trusts tender for these devices separately to other devices.

10. The CMA identified two broad approaches to procurement of tethered insulin pumps in the UK, and assessed the impact of the Merger under either approach (whilst acknowledging that variants or combinations of the two approaches are sometimes used by different NHS trusts):

(a) First, a ‘procurement-led approach’, under which the NHS Trust invites insulin suppliers to bid, in a single-bid, first-price auction. The NHS trust will then prioritise purchases to that supplier, although other suppliers may also be appointed to the framework and receive purchases; and

(b) Second, a ‘patient-led’ approach’, under which the patient is the key decision-maker in relation to the pump and is presented with a range of pump options, from a range of suppliers, from which he or she will choose (in conjunction with his or her medical advisor) the one which he or she prefers, which the NHS trust will then procure.

11. Under both approaches, the CMA found that the Merger will not result in any material change to competitive dynamics in relation to the supply of tethered insulin pumps in the UK (whether under a ‘procurement-led approach,’ a ‘patient-led approach,’ or variations or combinations of the two). This is because:

(a) there would be no reduction in the number of insulin pump suppliers from which NHS customers could solicit bids, or from which patients could choose their preferred pump; and

(b) there would be no material change in competitive strength of each bidder (in terms of their ability to compete within future framework contracts) is unchanged, including in relation to the quality of the products and services that suppliers offer.

12. The CMA therefore found that there would be no material change in competitive dynamics in relation to the supply of tethered insulin pumps in the UK. Accordingly, the CMA found 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 in relation to the supply of tethered insulin pumps in the UK.

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

ASSESSMENT

Parties

14. Medtronic is a developer of medical technology and a supplier of products, therapies and services treating a variety of medical conditions. Within its diabetes business, Medtronic is active in the manufacture and supply of insulin pumps and glucose management systems.

15. Animas is a wholly owned subsidiary of J&J. Animas is active in the manufacture and supply of insulin pumps and glucose management systems. The UK turnover of Animas in 2017 was approximately £[✂].

16. The Target Assets, transferred to Medtronic under the Merger, comprise:

(a) the right to purchase consumables[1] from Animas during a [✂] transitional period (the **Transitional Period**), on a purchase order basis,[2] for onward sale by Medtronic Limited to customers;

(b) customer/patient records, including the contact details, pump support history, purchasing history, patient payor details of Animas patients;

(c) service materials on the Animas *Vibe* pump (eg educational material, such as scripts for helpline staff or technical consultants); and

(d) trouble-shooting guides, call scripts, standard operating procedures and complaint identification guidance.

Transaction

17. In October 2017, a global asset purchase agreement (**APA**) was entered into between Animas and Medtronic MiniMed Inc, a subsidiary of Medtronic. The global APA was implemented in the UK in December 2017 through an ancillary agreement (the UK Country Transfer Agreement) between Johnson & Johnson Medical Limited (**J&J Medical UK**, a wholly-owned subsidiary of J&J and an affiliate of Animas), and Medtronic MiniMed Inc.

18. The APA and UK Country Transfer Agreement provides for the transfer of the Target Assets from J&J Medical UK to Medtronic Limited (the Medtronic entity which implements the agreement in the UK and which is the beneficiary of the UK assets).

19. The Merger follows a decision by J&J, further described in paragraphs 44 to 48 below, to exit from the supply of insulin pumps. The Parties submit that the purpose of the Merger is to ensure ongoing support for existing Animas patients during the Transitional Period, and to provide a smooth transition of

[1] 'Consumables' include a) the insulin reservoir, which houses the insulin and b) the infusion set, which connects the pump to the patient's body using flexible tubing are together known as consumables.

[2] Medtronic is able to make formal requests to Animas for consumables indicating types, quantities and agreed prices.

patients from Animas pumps to alternative Medtronic or other third-party pumps as Animas leaves the market.

Procedure

20. The CMA's mergers intelligence function identified the Merger as warranting an investigation.[3]

Background

21. The Merger concerns insulin pumps and associated consumables.

22. Insulin pumps are small portable devices which are attached to the body and mimic the human pancreas by delivering small doses of insulin when needed via a catheter placed under the patient's skin. Other methods of administering insulin include insulin pens and syringes.

23. There are two main types of insulin pump available in the UK: tethered pumps and untethered (or patch) pumps. Tethered pumps connect the pump to the patient's body using flexible tubing. Untethered pumps sit on the patient's skin and connect to the body with a needle at the infusion site. Medtronic and Animas have historically both supplied tethered pumps (although J&J has taken the decision to exit the supply of insulin pumps, and Animas is not entering into new supply arrangements for these products).

24. A tethered insulin pump consists of three main components: the main pump unit (which allows the user to control the delivery of insulin), the insulin reservoir (which houses the insulin) and the infusion set (which connects the pump to the patient's body using flexible tubing). Together, the insulin reservoir and infusion set are referred to as 'consumables'. Both Medtronic and Animas supply consumables for their own tethered pumps. By virtue of the Merger, Medtronic will take over supply of Animas' consumables during the Transitional Period, to the extent that Animas customers agree to this arrangement.

Jurisdiction

25. In the context of a completed transaction, a relevant merger situation exists where the following conditions are satisfied:[4]

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[3] See *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, paragraphs 6.9-6.19 and 6.59-60.
[4] Section 23 of the Act.

(1) two or more enterprises have ceased to be distinct; and

(2) either:

(i) the value of the target enterprise's UK turnover exceeded £70 million in its last fiscal year (the turnover test); or

(ii) the enterprises ceasing to be distinct have a share of supply in the UK, or in a substantial part of the UK, of 25% or more in relation to goods or services of any description (the share of supply test); and

26. The enterprises must not have ceased to be distinct more than four months before the date of any reference to phase 2.[5]

Enterprises ceasing to be distinct

27. The Parties submitted that the assets concerning the Animas business transferred to Medtronic under the Merger do not amount to an 'enterprise' within the meaning of the Act.

28. The Parties submitted that the Target Assets only enable Medtronic to provide consumables and support services to Animas' in-warranty patients (where the NHS Trusts consent to transfer),[6] during the Transitional Period, to ensure compliance by Animas with its warranty and service obligations. On this basis, the Parties suggested that the relationship between Animas and Medtronic should be considered more like that of a contractor and sub-contractor. The Parties also submitted that the assets transferred should be distinguished from those transferred (and considered to constitute an enterprise) in the *Eurotunnel* case,[7] given that they are narrower in scope and that the transitional arrangement is time-limited.

29. The CMA's assessment of whether assets being acquired amount to an enterprise depends on the specific facts and circumstances of each case (an assessment which can be, as the Supreme Court noted in *Eurotunnel*, finely balanced). In *Eurotunnel*, the Supreme Court noted that the question of

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[5] Section 24(1) of the Act. This four-month period starts from the earlier of the date when either 'material facts' about the transaction have been made public, or from the date that the CMA is provided with 'material facts' concerning the merger. The Act does not define 'material facts' but the CMA interprets these to be the information that is relevant to its determination of jurisdiction (see *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, paragraph 4.14). For the facts to have been 'made public', they must have been 'so publicised as to be generally known or readily ascertainable' (section 24(3) of the Act).

[6] The Parties submitted that the provision of transitional services by Medtronic (and the transfer of the Animas patients' data to Medtronic) is subject to the consent of Animas' customers (ie NHS trusts or health boards) and Animas' patients must be notified of the change. The CMA understands that 14 NHS Trusts have given consent.

[7] *Société Cooperative De Production Seafrance SA (Respondent) v The Competition and Markets Authority and another (Appellants)*, [2015] UKSC 75.

whether a given set of assets form an enterprise ultimately turns on 'economic continuity.' The CMA notes that this question is likely to be informed by the substance and not the form of a transaction.

30. The CMA notes that the APA does not provide for an extensive transfer of assets. For example, it does not provide for the transfer of any physical assets (eg insulin pumps or consumables), fixed assets (eg manufacturing facilities), intellectual property, R&D assets and information, or employees.

31. The CMA notes, however, that the customer and patient records being transferred under the APA appear to be of significant value and that the combination of these assets with the other transferred assets appears to support a degree of 'economic continuity' that may enable Medtronic to carry on the business previously supported by these assets. More specifically:

(a) As set out in the CMA's Guidance, '*the transfer of customer records is likely to be important in assessing whether an enterprise has been transferred*.'[8] In this case, the Merger provides Medtronic with customer/patient records without any access or use restrictions (other than the ordinary restrictions on use provided for by law). Medtronic will be able to use this information not only to supply consumables and support services during the Transitional Period, but also to seek to transfer Animas patients to a Medtronic pump – both during and beyond the Transitional Period.

(b) The available evidence indicates that an ability to establish a direct relationship with customers is a strategically important asset within the context of the market at issue. The available evidence also indicates that insulin pump patients tend to have significant loyalty to their existing supplier. In particular, third parties consistently told the CMA that there is a tendency for patients to remain with their existing insulin pump supplier on a long-term basis. Similarly, NHS trusts consistently identified that a large proportion of patients stay with the same manufacturer when they receive a new pump, while competitors told the CMA that existing pump patients rarely switch to a different pump supplier at the end of the warranty period (and only in very exceptional circumstances during the warranty period).

(c) The CMA therefore believes that access to Animas patients during the Transitional Period (through supplying consumables and support services to Animas' customers and patients during that period) may provide an

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[8] *Mergers: Guidance on the CMA's jurisdiction and procedure* (CMA2), January 2014, paragraph 4.8.

important basis for Medtronic to transition those patients to the supply of Medtronic pumps on a lasting basis.

(d) This is consistent with the views expressed by third parties, which told the CMA that customer contact details will give Medtronic additional access points to these customers and therefore give them an advantage in transferring such patients to a Medtronic pump.

(e) This position is also consistent with Medtronic's rationale for the Merger. Medtronic submitted evidence in relation to its valuation of the Target Assets, which suggested that it had valued the UK element of the transaction [✂]. The CMA noted, at that time, that the value of the projected consumables revenues in the UK [✂] (which would suggest that Medtronic attached little value to the customer and patient records being transferred). However, upon further investigation (intended to inform the CMA's understanding of the commercial drivers of the transaction), the CMA found evidence suggesting that the value attached to the UK part of the transaction may have been higher than the [✂] estimate previously provided [✂]. In particular [✂][9] [✂].[10] The CMA therefore believes that the consideration paid by Medtronic, which exceeds the projected consumables revenue, shows that there is likely to be additional value (beyond the projected consumables revenues) attached to the transferred assets and, in particular, that Medtronic appears to attach value to the customer and patient records being transferred through the Merger.

(f) Finally, certain provisions in the APA appear to be intended to facilitate the transfer of Animas patients to a Medtronic pump. Clause 4.2 of the APA [✂]. Clause 6.6(b) of the APA [✂].

32. Accordingly, the CMA believes, for the reasons set out above, that the Target Assets may be an enterprise within the meaning of section 129 of the Act and as a result of the Merger, the enterprises of Medtronic and the Target Assets have ceased to be distinct.

Share of supply test

33. The CMA estimates, based on third party data collected during the investigation, that the Parties supply insulin pumps and consumables to

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[9] [✂]
[10] [✂]

patients representing [50-60]% of the total UK patient base, with the Merger resulting in an [10-20]% increment in the share of supply.[11]

34. The Parties submitted that the share of supply test is not met because there is no 'guaranteed' increment to Medtronic, on the basis that customers must consent for their details to transfer to Medtronic and customers remain free to switch to other suppliers. The CMA notes, in this regard, that a 'guaranteed' increment in share is not an accurate characterisation of the statutory test (in particular because there is often some uncertainty that all customers of the target company will remain with the acquirer post-merger).

35. The CMA therefore considers that the share of supply test is met.

Time period

36. The Merger completed on 19 December 2017 and the CMA was first informed about it on 8 January 2018. The four-month deadline for a decision under section 24 of the Act is 18 June 2018, following extension under section 25(2) of the Act.

Conclusion on jurisdiction

37. On the basis of the above, the CMA believes that it is or may be the case that a relevant merger situation has been created.

38. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 10 April 2018 and the statutory 40 working day deadline for a decision is therefore 6 June 2018.

Counterfactual

39. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual), and generally adopts the pre-merger situation in the case of completed mergers as the counterfactual against which to assess the impact of the merger.[12]

40. 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 the pre-merger situation continuing

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[11] The CMA therefore considers that the share of supply test is met irrespective of whether the supply of pumps is considered separately to that of consumables (or if the supply of pumps and consumables is grouped together).
[12] 'Merger Assessment Guidelines', para 4.3.5

is not realistic, or there is a realistic prospect of a counterfactual that is more competitive than the pre-merger situation.[13]

41. In the present case, the Parties submitted that the correct counterfactual is one where absent the Merger, Animas would have exited the market. The CMA's assessment of this counterfactual is set out below.

Exiting firm counterfactual

42. The exiting firm counterfactual is most commonly considered when one of the firms is said to be failing financially. However, exit may also be for other reasons, for example because the selling firm's corporate strategy has changed.[14]

43. For the CMA to accept an exiting firm counterfactual, it would need to believe, based on compelling evidence, that the following cumulative conditions are met:[15]

(a) it was inevitable that Animas would have exited the market absent the Merger (through financial failure or otherwise) (limb 1);

(b) there was no substantially less anti-competitive purchaser for the Animas business or parts of the business (limb 2); and

(c) the Merger does not represent a substantially less competitive outcome compared with what would have happened to Animas' sales in the event of its exit (limb 3).

44. Where, based on the available evidence, the CMA cannot reach a sufficient level of confidence in relation to each of these conditions, it will adopt as the counterfactual the pre-merger conditions, provided that this is realistic.

Limb 1: Would Animas have inevitably exited absent the Merger?

45. J&J told the CMA that its decision to exit Animas followed a wider strategic review of its Diabetes Care business which took place towards the end of 2016, when the decision was taken to sell its Diabetes Care business, which comprised of three businesses, namely Animas, Calibra and LifeScan.

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[13] 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).

[14] 'Merger Assessment Guidelines', para 4.3.9

[15] 'Merger Assessment Guidelines', para 4.3.10

46. J&J told the CMA that Animas had not been 'financially viable', and that despite making substantial investments in the business, it had persistently generated losses since its acquisition by J&J in 2006.

47. J&J told the CMA that it undertook an extensive sale process for the Animas business, which lasted from December 2016 to July 2017, during which the possibility of winding down the Animas business was raised if no 'viable bidder' could be found by 31 May 2017.

48. On 31 May 2017, internal approval was sought from J&J's Executive Committee and Management Committee for the exit of the Animas business, highlighting that Animas continued to operate at a loss and had not generated a profit since it was acquired, with 'further significant investment' required to 'compete in the market'.

49. J&J told the CMA that J&J's Executive Committee finally took the decision, on 6 June 2017, to wind down the Animas business, and begin the process of identifying another pump manufacturer to whom it could transfer Animas patients to ensure their continuity of care.

50. For the CMA to accept that limb 1 has been satisfied, it would need (on the basis of compelling evidence) to believe that it was inevitable that the firm would exit the market (through financial failure or otherwise).[16]

51. J&J submitted that Animas was no longer financially viable. In the context of a firm exiting for reasons of financial failure, the CMA will consider whether the firm is unable to meet its financial obligations in the near future, and whether it is unable to restructure itself successfully. If it is not satisfied that these conditions are met, the CMA will consider whether exit was inevitable for other reasons, such as because the firm had taken a strategic decision to exit.

52. Animas' global revenues increased significantly under J&J's ownership, from $[✂] in 2006 to $[✂] in 2017. Animas failed, however, to generate profits at an operating level over this period, with cumulative operating losses of around [✂]. Pro forma balance sheets for Animas on a stand-alone basis, prepared by J&J for the purpose of the sale process, showed that in [✂].

53. The available evidence indicates that J&J had engaged in concerted efforts to improve Animas' financial performance. In particular, J&J told the CMA that since acquiring Animas for around $[✂] in 2006, it had invested a further £[✂] into Animas' R&D and $[✂] in capital expenditure from 2006 to 2016. However, J&J also told the CMA that, notwithstanding this level of investment,

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[16] 'Merger Assessment Guidelines', para 4.3.10

it had been too late in bring new products to the market, and had placed the 'wrong bets' on certain technologies. This position was supported by Animas' internal documents (including a management presentation to prospective purchasers), which acknowledged it was behind other suppliers in pump development.

54. Notwithstanding the operating losses that Animas had historically generated under J&J's ownership, the CMA notes that some of the available evidence indicates some scope for improvement in Animas' future financial performance (albeit that such improvement would likely require J&J to be willing to make further investment in the Animas business). For example:

(a) J&J's more recent restructuring of the Animas business, [✂], was implemented by the first quarter of 2017, and appeared to be yielding positive results. [✂].

(b) Animas was in the process of developing new products, including [✂], albeit this would have required further investment by J&J into its development.

(c) The Animas management presentation given to prospective purchasers during the sale process identified potential upsides in relation to Animas' future revenues and gross margins, as well as efficiency improvements.

55. The CMA notes, in addition, that Animas had in the past received financial support from its ultimate parent and would be in a position to do so in future. The CMA therefore does not believe that Animas' exit due to financial failure alone was inevitable.

56. The CMA therefore considered, taking into account the financial position of Animas, whether the business would have ultimately exited for strategic reasons.

57. J&J told the CMA that it independently decided to exit the insulin pump market, and that it only discussed the potential transfer of the Target Assets with Medtronic, having exhausted its options for the sale of Animas with several potential purchasers.

58. Based on the available evidence, the CMA considers that J&J's decision to exit from the Animas business was part of a wider strategic decision taken by J&J to ultimately exit its Diabetes Care business (of which Animas was a part). In particular:

(a) Having taken the decision to sell its Diabetes Care business, J&J pursued an extensive sale process for that business, which ultimately resulted in J&J's exit from all three businesses, including Animas.

(b) The formal decision to wind down the business was taken before J&J had approached Medtronic, and entered into discussions which ultimately resulted in the Merger. J&J's internal documents confirm that the formal approval by J&J's Executive Committee to wind down the Animas business was taken before Medtronic had been approached. J&J's contact schedule showed that Medtronic was first contacted on 9 August 2017 in relation to the Merger,[17] after J&J's Executive Committee had finally granted formal approval to wind down the Animas business. The CMA therefore believes that J&J's decision to exit was not taken in contemplation of a deal with Medtronic.[18]

59. On this basis, the CMA concludes that limb 1 of the exiting firm counterfactual has been met, and that Animas would have ceased operating and exited the market (subject to the CMA's consideration of limb 2 below).[19]

Limb 2: Would there have been a substantially less anti-competitive purchaser than Medtronic for Animas or parts of the Animas business

60. J&J told the CMA that Animas was marketed extensively throughout the first half of 2017. J&J told the CMA that after it had exhausted its options for the sale of Animas as a going concern, it initiated discussions with Medtronic in August 2017 in relation to the potential fulfilment of Animas' existing warranty obligations to its customers (in light of J&J's decision to wind down the Animas business). J&J told the CMA that the success of these discussions with J&J meant that there was no need to consider other potential counterparties for such a transaction.

61. J&J told the CMA that in order to take on Animas' patients in the UK, a suitable counterparty would need to be perceived by all stakeholders (eg NHS Trusts and patients) as a reliable replacement for Animas. J&J submitted that this meant, in practice, that the universe of potential counterparties was limited to suppliers that:

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[17] J&J's response to RFI 3 (29 March 2018), Appendix A, 'Overview of purchaser contact'

[18] 'Merger Assessment Guidelines', para 4.3.9

[19] That being the case, given J&J/Animas' ongoing obligations to users of its Animas pumps, CMA considers that J&J's exit from the Animas business would have been gradual, and that J&J would have continued to operate the Animas business only to the extent necessary to serve its exiting pump users through to the end of their pumps' warranty periods.

(a) have a presence in the diabetes care/insulin delivery business, in particular in the manufacture and supply of insulin pumps, which were CE mark approved (a regulatory requirement for supplying insulin pumps within the European Union);

(b) have pre-existing UK infrastructure to enable the transfer of customer service and warranty support, as well as have sufficient sales and training personnel to support NHS Trusts and patients transitioning over time; and

(c) have a proven track record of good patient service, in order to provide comfort to NHS Trusts and patients that quality customer care would continue as normal.

62. J&J told the CMA that it approached Medtronic based on its geographical remit, innovation and technology, ability to scale-up to meet demand in a quick and efficient manner and proven (global) track record in diabetes care.

63. For the CMA to conclude that limb 2 has been satisfied, it would need (on the basis of compelling evidence) to be confident that there was no substantially less anti-competitive purchaser for the firm or its assets.[20]

64. When considering the prospects for an alternative purchaser for the firm or its assets, the CMA will look at available evidence supporting any claims that the merger under consideration was the only possible merger (ie that there was genuinely only one possible purchaser for the firm or its assets).[21]

65. In the particular circumstances of this case, the CMA has considered both: whether there was an alternative purchaser for Animas as a going concern; and whether there was an alternative purchaser for the Target Assets.

66. As concerns the sale of Animas as a going concern, the CMA notes that between December 2016 and July 2017, J&J appointed Goldman Sachs to assist in its sale process to sell Animas on this basis. During this sales process, 11 strategic parties were approached, including healthcare companies already active in the diabetes care market, as well as pharmaceutical companies active in the manufacture of insulin. A further 32 inbound calls came from financial buyers following J&J's announcement on 24 January 2017 that it was reviewing its strategic options for its Diabetes Care business (including Animas).

67. J&J told the CMA that only [✂]

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[20] 'Merger Assessment Guidelines', para 4.3.10
[21] 'Merger Assessment Guidelines', para 4.3.17

(a) [✂]

(b) [✂]

(c) [✂]

68. [✂]

69. [✂]

70. The CMA reviewed J&J's internal documents regarding the sales process. The CMA found that these supported J&J's submissions that the process undertaken by J&J and its advisers for the sale of Animas as a going concern was extensive, and involved their engagement with each interested prospective purchaser over the course of a relatively long period. The evidence received by the CMA from [✂], was also consistent with J&J's submissions, that no viable purchaser had ultimately emerged from the process.

71. Based on the available evidence, the CMA considers that the process for the proposed sale of Animas as a going concern was extensive. The CMA also recognises the challenges faced by J&J in finding a purchaser for Animas on a going concern basis (given, in particular, its financial performance over time).

72. The CMA therefore concluded that there was no realistic alternative purchaser for Animas on a going concern basis.

73. As concerns the sale of the Target Assets, the available evidence indicates that Medtronic was the only prospective purchaser which J&J contacted regarding the sale of the Target Assets.

74. J&J told the CMA that given that its discussions with Medtronic were successful, it was not necessary to approach other purchasers. However, in the course of the CMA's investigation, certain insulin pump suppliers, currently active in the UK, confirmed that they would have been interested in the Target Assets had they been approached at that time. The CMA notes that certain of these suppliers are existing UK suppliers of insulin pumps, and therefore had the potential to satisfy J&J's purchaser criteria (as set out in paragraph 61). The available evidence does not enable the CMA to conclude that these suppliers would not have been realistic alternative purchasers that would have had a realistic prospect of successfully pursuing a bid.

75. The CMA is therefore unable to conclude, to the required legal standard, that there was no alternative, substantially less anti-competitive purchaser for the Target Assets. On this basis, limb 2 is not satisfied.

76. Given that the CMA has concluded that limb 2 is not satisfied, it is not necessary for the CMA to consider further whether limb 3 is satisfied.

Conclusion on the appropriate counterfactual

77. For the reasons set out above, the CMA does not believe that the conditions of the exiting firm counterfactual are satisfied in this case.

78. The CMA's guidance indicates that it will consider the effect of the merger compared with the most competitive counterfactual, providing always that it considers that situation to be a realistic prospect.[22]

79. In this case, the CMA does not believe that the pre-Merger conditions of competition are a realistic counterfactual because it considers, on the basis of compelling evidence, that Animas would have inevitably exited the market absent the Merger.

80. As explained above, the CMA considers that it is realistic that the Target Assets could have been transferred to an alternative counterparty that operated its own insulin pump business and had an existing presence in the UK. In addition, as described below (paragraphs 89 to 91), there are certain differences between tethered and untethered pumps, which suggest that a supplier of untethered pumps would not have been able to service (and potentially benefit from) the Target Assets in the same way as a supplier of tethered pumps. The CMA therefore considers that a realistic purchaser of the Target Assets, for the purposes of counterfactual assessment, would have needed to be an existing supplier of tethered insulin pumps.

81. On this basis, the CMA considers that the counterfactual, against which to analyse the competitive effects of the Merger, is one in which another existing supplier of tethered insulin pumps in the UK acquired the Target Assets.

Frame of reference

82. 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

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[22] *Merger Assessment Guidelines*, paragraph 4.3.5

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.[23]

83. As noted in its assessment of jurisdiction (paragraphs 24 to 37 above), the CMA believes the Merger may enable Medtronic to carry on the business previously supported by these assets. In the competitive assessment (paragraph 96 onward below), the CMA assesses what effect such a transfer of patients may have on competition for the supply of insulin pumps. In this section, the CMA therefore considers the appropriate frame of reference for the supply of insulin pumps.

84. The CMA has not considered the supply of consumables separately from the supply of insulin pumps. Consumables are aftermarket products which are manufactured for a specific supplier's pump and are not generally compatible with any other supplier's pump. The Parties confirmed that they do not manufacture consumables that are compatible with each other's pumps. There is therefore no competitive interaction between the Parties, separate from the supply of their insulin pumps, in relation to the supply of consumables.

Product scope

Segmentation between insulin pumps and other insulin delivery devices

85. The Parties submitted that insulin pumps compete with insulin pens (the most common method of insulin delivery). The Parties also, however, provided share of supply data on what they indicated was a plausible sub-segment within insulin delivery devices, comprising only insulin pumps.

86. The appropriate frame of reference for insulin pumps has not previously been considered by the CMA. The product market for insulin pumps was considered by the European Commission (the **Commission**) in *Sanofi/ Google/ DMI JV*.[24] While the Commission did not conclude on product market definition, it noted that insulin pumps were likely to comprise a product market separate to other delivery systems because insulin pumps (which can only administer fast-acting insulins) could not be used to administer the same types of insulin as other delivery systems.

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[23] *Merger Assessment Guidelines*, paragraph 5.2.2.
[24] *M.7813 Sanofi/ Google/ DMI JV*

87. The CMA's investigation found that, from a demand-side perspective, insulin pumps can be distinguished from insulin pens on several grounds, in particular:

(a) Insulin pumps are more sophisticated devices than insulin pens, and require a greater level of knowledge and training by patients prior to use;

(b) Insulin pumps are more precise than insulin pens, since they can rely on constant monitoring of glucose levels, and are better suited to more sensitive patients;

(c) Insulin pumps may be better suited than insulin pens for certain patient groups, such as children. In response to the CMA's market investigation, some NHS Trusts indicated that doctors tend to recommend insulin pumps for paediatric patients. This is consistent with guidance from the National Institute for Health and Care Excellence (**NICE**), which recommends insulin pump therapy for children under 12 (provided that multiple daily injections are considered impractical or inappropriate); and

(d) Insulin pumps are more expensive to purchase than insulin pens.

88. On the basis of the evidence described above, the CMA believes that insulin pumps should be considered in a separate frame of reference to insulin pens. However, it was not necessary for the CMA to reach a conclusion on the appropriate product frame of reference since, as set out below, no competition concerns arise on any plausible basis.

Segmentation between tethered and untethered (patch) insulin pumps

89. The CMA has considered a further segmentation by type of insulin pump, differentiating between tethered and untethered pumps.

90. The Parties did not make any submissions on such a segmentation. The evidence gathered during the CMA's market investigation indicated, however, that such a segmentation may be appropriate to reflect certain demand- and supply-side differences between the two types of pump. In particular:

(a) Two competitors noted that patients will have a preference for one type of pump or the other, and that it is difficult to switch patients from using a tethered pump to a untethered pump; and

(b) Certain NHS trusts tender by type of insulin pump, with separate lots for tethered and untethered pumps in their frameworks.

91. On this basis, the CMA notes that it may be appropriate to limit the frame of reference to tethered pumps only, being the narrowest plausible frame of

reference in which the Parties overlap. However, it has not been necessary for the CMA to reach a conclusion on this because, as set out below, no competition concerns arise even within this narrower frame of reference.

Geographic scope

92. The Parties submitted that Medtronic and Animas both supply insulin pumps to NHS Trusts and Health Boards throughout the UK.

93. The CMA notes that the Parties provide important aspects of service, such as technical support through telephone helplines, on a national basis. The relevant legislation and regulatory frameworks that govern the supply and use of insulin pumps are either national or EEA-wide in scope. Meanwhile, the CMA received no evidence that insulin pumps suppliers face any barriers to entry or expansion between different parts of the UK.

94. Accordingly, the CMA believes the appropriate frame of reference for insulin pumps to be at least UK-wide.

Conclusion on frame of reference

95. For the reasons set out above, the CMA has considered the impact of the Merger on the supply of tethered insulin pumps in the UK. However, it has left open the precise scope of the product frame of reference, since, as set out below, no competition concerns arise on the narrowest plausible frame of reference.

Competitive assessment

Horizontal unilateral effects

96. 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.[25] 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 supply of tethered insulin pumps in the UK.

97. As described above, the CMA has found that J&J had taken the strategic decision to exit from the supply of insulin pumps, and that the effect of the

[25] *Merger Assessment Guidelines*, from paragraph 5.4.1.

transfer of the Target Assets under the Merger may be to allow Medtronic to carry on the business previously supported by these assets. It has also found that the appropriate counterfactual against which to assess the Merger is one in which another existing supplier of tethered insulin pumps in the UK acquired the Target Assets.

98. The CMA has therefore assessed whether the acquisition of Animas' patients by Medtronic, rather than by another existing UK market participant, has any material effect on competition.

Insulin pump procurement

99. As healthcare provision in the UK is primarily government-funded, the principal customer of the Parties' insulin pumps is the NHS, which procures insulin pumps on behalf of patients.

100. The CMA's investigation found that there is some variation in the procurement practices of NHS trusts in relation to insulin pumps. The CMA's investigation identified two broad approaches to procurement (with variants or combinations of the two approaches sometimes used by different NHS trusts):

(a) First, a 'procurement-led approach', under which the NHS trust invites insulin suppliers to bid, in a single-bid, first-price auction, to be the Most Economically Advantageous Tender (**MEAT**). Based on criteria set out in the tender documents, a winning supplier is selected onto the framework. The NHS trust will then prioritise purchases to that supplier, although other suppliers may also be appointed to the framework and receive purchases (but will generally rank lower); and

(b) Second, a 'patient-led' approach', under which the patient is the key decision-maker in relation to the pump, which the NHS will procure on the patient's behalf. The patient is presented with a range of pump options, from a range of suppliers, and will choose (in conjunction with his or her medical advisor) the pump that he or she prefers, which the NHS trust will then procure. Under this approach, prices do not determine a supplier's ranking, and suppliers win the right to be considered by patients by meeting relatively simple requirements regarding quality and service.

101. The CMA has analysed the competitive effect of the Merger separately for each of these approaches.

Procurement-led approach

102. Under the procurement-led approach, competition between suppliers takes place at the tender stage, when different suppliers compete to be the winning bidder on the framework.

103. The available evidence indicates that the Merger will not bring about any material change in competitive dynamics, in particular because the number of bidders, and the competitive strength of each bidder (in terms of their ability to compete within future framework contracts), will remain the same post-Merger.

104. First, as the available evidence indicates (as described above) that Animas would have exited the market in any event, and that the only plausible alternative purchaser for the Target Assets would have been an existing UK market player, the Merger does not bring about any change in the number of bidders for future NHS tenders.

105. Second, the Merger will not bring about any change in the competitive strength of the suppliers bidding for those tenders. There is no evidence to suggest that the acquisition of additional patients in the UK would materially affect the bidding strength of either Medtronic or its rivals. The Target Assets do not comprise any physical assets or intellectual property and therefore the Merger will not alter the quality of Medtronic's existing products. Moreover, all UK market participants are active on a global basis, with most major costs (eg R&D spend, manufacturing assets etc.) being on a supra-national, if not global, basis. Any increased revenues that could arise from the transfer of Animas' UK installed patient base (or some proportion of it) are likely to be minimal within the context of a supplier's global cost base (and would therefore not bring about any material improvement in that supplier's cost-effectiveness). Moreover, costs that are incurred in the UK, such as the delivery costs of the consumables and the cost of patient support provided in person or via the telephone, do not exhibit significant economies of scale, such that an increase in the UK installed base would again not bring about any material improvement in that supplier's cost-effectiveness on a UK-wide basis.

106. Some NHS customers raised concerns that Medtronic may not be able to meet increased demand post-Merger. The CMA notes, however, that there is no evidence to suggest that the Merger would limit the ability of NHS customers to switch to alternative suppliers if dissatisfied with Medtronic's ability to supply them. Similarly, while a number of NHS customers raised concern regarding the loss of a supplier as a result of Animas' exit, this is not (for the reasons described in paragraphs 103 to 105 above) a result of the

Merger, as the available evidence indicates that Animas would have exited the market irrespective of the Merger.

Patient-led approach

107. Under the patient-led approach, competition between suppliers takes place at the point of the patient choosing their preferred pump. As the decision is patient-driven, price is unlikely to be a driver of choice (as the patient is not the paying customer), with factors such as product and service quality being more influential in patient decision-making.

108. The available evidence indicates that the Merger will again not bring about any material change in competitive dynamics, in particular because the number of bidders and the competitive strength of each bidder (in terms of their ability to compete within future framework contracts) is unchanged, including in relation to the quality of the products and services that suppliers offer.

109. In addition to the factors described in paragraphs 104 to 105 above, the CMA notes that Medtronic and other UK market participants develop their products on a global scale, for sale across the world. The CMA therefore believes that the quality of the pump product is unlikely to be affected by the allocation of patients in the UK market.

110. Moreover, while some aspects of a supplier's service offering are set nationally or locally – such as call centres to provide helpline services to UK patients and nurses working across a number of trusts to provide on-site medical support – there is no evidence to suggest that an increase in the number of UK patients would give the ability or incentive to substantially worsen these services. In any case, the CMA's investigation found that NHS trusts variously specify certain minimum quality standards that suppliers must meet in order to serve patients (eg in relation to providing 24/7 helpline services by appropriately qualified staff, comprehensive emergency repair/replacement services and patient training), which would limit the ability to deteriorate service quality in this way. In any event, the CMA notes that on-site support services, such as those provided by Medtronic nursing staff, are likely to act as an important tool for reducing patient churn. As any deterioration of this service would be detrimental to a pump supplier's ability to retain its patient base, the CMA considers that a supplier is unlikely to have the incentive to pursue such a strategy.

Other competitive constraints

111. On the basis of the evidence set out above, the CMA believes that the Merger will not result in any material change to competitive dynamics in relation to the supply of tethered insulin pumps in the UK (whether under a 'procurement-led approach,' a 'patient-led approach,' or variations or combinations of the two).

112. The CMA also notes that the available evidence indicates that new and recent entry by insulin pump manufacturers may exert an additional competitive constraint on Medtronic going forward.

113. In particular, Ypsomed (which has until recently acted as a distributor for Insulet (untethered) insulin pumps, entered the UK market with its own tethered insulin pump product in April 2017.

114. The CMA also notes that several suppliers of untethered pumps have recently entered the UK market (albeit that, for the reasons explained in paragraphs 89 to 91 above, untethered insulin pump suppliers are likely to be a more remote competitive constraint on tethered insulin pump suppliers). Some NHS customers who responded to the CMA's market investigation noted that purchases from these suppliers are currently limited. The CMA notes that a number of these suppliers have only very recently entered the UK market [✂].[26]

115. Finally, a number of NHS customers also noted that they were investigating supply from a number of insulin pump suppliers who were not currently active in Europe, but would be considered as viable suppliers as soon as their products were available in the UK.

Conclusion on horizontal unilateral effects

116. On the basis of the evidence set out above, the CMA believes that the Merger will not result in any material change in competitive dynamics in relation to the supply of tethered insulin pumps in the UK. 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 the supply of tethered insulin pumps in the UK.

Barriers to entry and expansion

117. 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

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[26] [✂]

assessing whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[27]

118. 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

119. 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.

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

Colin Raftery
Director, Mergers
Competition and Markets Authority
30 May 2018

[27] *Merger Assessment Guidelines*, from paragraph 5.8.1.