Witness Name: Julian Fagge
Statement No: 1
Exhibits: SMI/01 – SMI/64
Dated: 8 November 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF JULIAN FAGGE ON BEHALF OF SMITHS GROUP PLC

I, Julian Fagge, will say as follows: -

Introduction and Clarification

1. The UK Covid-19 Inquiry (the "**Inquiry**") sent a letter dated 27 June 2024 to both: (i) Smiths Medical International Limited ("**Smiths Medical**"); and (ii) Smiths Group plc ("**Smiths**"); with a Request for Evidence pursuant to Rule 9 of the Inquiry Rules 2006 (the "**Request**"). The Inquiry sought information and documents relevant to the Request for the date range 1 January 2020 to 28 June 2022 (the "**Relevant Period**").

2. A response letter was sent dated 9 July 2024, confirming that Smiths sold Smiths Medical as part of a wider divestment to ICU Medical, Inc ("**ICU**") in January 2022. Smiths Medical was the primary legal entity through which Smiths contracted with the UK Government and consortium partners during the Relevant Period. Although, as this statement will address, Smiths' (and Smiths Medical's) involvement with all matters relating to the UK Ventilator Challenge ("**UKVC**") ceased in November 2020.

3. In the interests of assisting the Inquiry, given Smiths' corporate knowledge and involvement (at a group level) with the UKVC during the Relevant Period (including as a consequence of Smiths Medical being a wholly owned subsidiary of Smiths at that time), this statement has been prepared and addresses (insofar as it is able to) the matters set out in the Request. However, from a procedural perspective, it should be noted that this statement is not provided on behalf of Smiths Medical (which is a distinct legal entity for the purposes of contractual obligations and performance) and, if the

Inquiry were to require such a statement, enquiries should be made directly to (or via) ICU.

4. This statement is set out in three main sections as summarised below:

   a. **Section A: Executive summary and chronological overview of key documentation** – an executive summary and chronological overview of the documents that Smiths still has access to (in the context of the Smiths Medical business having been sold) and which have been considered relevant to the Request. Following the sale of Smiths Medical, Smiths no longer has access to: (i) all relevant documentation; or (ii) input from relevant Smiths Medical individuals. The chronological summary has therefore necessarily been prepared predominantly on the basis and content of the key documents which Smiths has reasonably been able to locate for the purposes of this exercise.

   b. **Section B: Inquiry's specific questions** – section addressing the Inquiry's specific questions, as set out at Annex A of the Request, to the extent that they have not been answered as part of **Section A**, or through the accompanying exhibits; and

   c. **Section C: Closing remarks** – closing remarks on behalf of Smiths.

5. The statement is accompanied by a bundle of exhibits, referred to throughout the statement with the prefix "**SMI/x**".

SECTION A: EXECUTIVE SUMMARY AND CHRONOLOGICAL OVERVIEW OF KEY DOCUMENTATION

Executive Summary

6. Smiths' involvement in the UKVC was, and remains, a source of great pride. It would have been a uniquely challenging project to undertake in any circumstances, but even more so in the context of global pandemic and national crisis. In real terms, the position that Smiths and its consortium partners achieved in a number of weeks would, ordinarily, have taken years. The success of the project was dependent upon an extraordinary level of collaboration, innovation and effort on the part of everyone involved.

7. Whilst there were inevitably challenges associated with the project, which this statement will address, these should be seen in the context of what was being attempted. The project required the creation of new supply lines (sourcing, procurement and logistics) for components against a backdrop of a global scarcity, the creation of new manufacturing lines at consortium partner sites who had no prior experience of producing medical devices, the creation of systems to rapidly train a significant number of people working on those manufacturing lines, and ensuring throughout that all relevant and necessary testing and quality assurance standards were met to ensure the safety of patients on whom ventilators were to be used.

8. Whilst this statement will address various disputes which arose between the Smiths consortium and the Cabinet Office, I acknowledge that they were operating within an extremely pressurized set of circumstances. I recognise that trying to balance the objective of rapidly seeking solutions to respond to the pandemic, whilst remaining accountable for the responsible use of public funds, is a perfectly legitimate and difficult task. I hope that the various learning points which I set out towards the end of this statement will be of assistance to the Inquiry.

Smiths' Background

9. Smiths is headquartered in London and listed on the London Stock Exchange. It is a diversified engineering company currently organised into four divisions: John Crane, Smiths Detection, Smiths Interconnect and Flex-Tek. At the time of the UKVC in 2020 it had a fifth division, Smiths Medical, which was sold to ICU, a US Corporation, in January 2022. It was Smiths Medical's paraPAC plus 300 pneumatic ventilator ("**paraPAC**") that was selected for the UKVC.

10. In 2020, Smiths had approximately 20,000 staff across its 5 divisions, in more than 50 countries. Approximately 5000 of those staff were employed directly by the Smiths Medical division.

11. Smiths supplies the following market sectors: General Industrial, Safety and Security, and Energy and Aerospace. In 2020, through Smiths Medical, it also supplied medical devices to the healthcare sector. Smiths Medical designs, manufactures and supplies infusion systems for delivering fluid and medication for pain management for acute and chronic diseases, vascular access products enabling the delivery of fluid and

medication, vital care products including devices to manage patients' airways (including the paraPAC) and systems to maintain body temperature during surgery.

12. The paraPAC had been on the market since 2010 and (both during the Relevant Period and currently) is used in the majority of ambulance fleets across the UK. The paraPAC was designed in the UK and has all necessary certifications, including CE marking and compliance with relevant standards (BS EN794-2 and ISO 10651-3). At the time of the UKVC, it was a well-established and approved medical device, capable of being used in both a hospital and ambulatory setting.

13. At the time that the UKVC was initiated, Smiths Medical had an existing manufacturing facility based in Luton ("**Smiths Medical Luton**") which produced the paraPAC units. By way of context, it is my recollection that production rates out of Smiths Medical Luton for the paraPAC, before the UKVC, were approximately 20 units per week. Smiths Medical had an existing contract to supply paraPACs to the NHS, via a distributor (Prometheus). Smiths no longer has access to the Prometheus distribution agreement nor the ordering history / patterns for Smiths Medical Luton.

14. It should be noted that Smiths Medical Luton was not formally part of the UKVC project. Smiths Medical's production lines and supply chains were kept separate from those of the consortium, to ensure that the UKVC did not disrupt Smiths Medical Luton's operation and the pre-existing contracts which were in place. It was recognised from the outset that, while Smiths Medical Luton could (and would) "ramp up" production, it would not be able to meet the anticipated increased demand; hence the need to establish the consortium. Whilst a significant amount of knowledge and experience was held within Smiths Medical Luton, which was used to inform the consortium project and particularly the manufacturing and testing processes, it was an entirely separate undertaking. Accordingly, the agreements reached between Smiths Medical and the Cabinet Office for the provision of paraPAC units were based upon production and delivery from new consortium lines.

Dramatis Personae

15. For reference throughout this statement (and the relevant exhibits), I have set out a brief overview of some key Smiths' individuals, to include their job title (during the Relevant Period).

16. I, Julian Fagge, was Smiths' Strategy and M&A Director. I led Smiths' response to the UKVC, which included interfacing with leadership teams at the Cabinet Office ("**CO**"), consortium partners, and senior stakeholders within Smiths and Smiths Medical.

17. James Mortensen was Smiths' Group Head of Mergers and Acquisitions. James reported to me and managed day-to-day matters relating to the UKVC (including cost-modelling), which included working closely with the CO and consortium partners. James Mortensen is no longer employed by Smiths.

18. James Down was Smiths' General Counsel (Corporate). He was the senior internal lawyer engaged on the UKVC project team, providing day-to-day legal advice and support, particularly around contracts and cost disputes. James reported to Smiths Group General Counsel.

19. Matt Clark was Smiths' Vice President, Technology and Product Development (Smiths Detection). Matt reported to me and was a senior project manager working on the UKVC. He worked closely with production teams and consortium partners to resolve the substantial number of issues that were being faced, in relation to supply, manufacture, and quality assurance / testing.

20. Andrew Reynolds Smith was Smiths' Chief Executive Officer and was involved in some key correspondence between Smiths and the CO, at a senior level. Andrew Reynolds Smith is no longer employed by Smiths.

21. Sir Kevin Tebbit was Smiths' Senior Vice President, Corporate Affairs. Sir Kevin also provided senior input into the UKVC project and liaison with the CO, given his previous roles within the UK Government. Sir Kevin is no longer employed by Smiths.

Commencement of Smiths' involvement in the UKVC

22. At the outset of the Covid-19 pandemic, it became known within Smiths that the UK Government had issued a "call to action" for industry to try to rapidly manufacture large numbers of ventilators within the UK. As set out above, Smiths Medical had a fully approved and trusted medical device (the paraPAC) which was already being manufactured in the UK, out of Smiths Medical Luton. It made sense to propose the paraPAC as a potential solution to the UK Government's initiative. I understand that

James Mortensen made initial enquiries via contacts on LinkedIn to offer the paraPAC for consideration as part of the UKVC.

23. On 19 March 2020, Helen Rogers of PA Consulting ("**PA**") sent an email to James Mortensen with a formal invitation to present the paraPAC for consideration as a viable contender in response to the UKVC by the CO, the NHS, clinicians and a technical review team. The email set out questions and topics that Smiths' presentation would be required to address. James Mortensen responded to that email on 20 March 2020. The email chain is exhibited as **SMI/01** [INQ000504070].

24. The presentation slides attached to that email are exhibited as **SMI/02** [INQ000504088]. The user manual for the paraPAC was also attached to that email and is exhibited as **SMI/03** [INQ000504098]. The presentation provided a brief overview of the paraPAC and its key characteristics. The presentation also confirmed that Smiths Medical was already taking steps to "ramp-up" production of the paraPAC at Smiths Medical Luton, even before its involvement in the official UKVC response had been confirmed.

25. At this initial stage, the extent of Smiths' proposed involvement was limited to offering the full use of the design rights for the paraPAC to the UK Government, for manufacture by its industry contacts, together with the "ramp-up" of production at Smiths Medical Luton (from the existing production rate of approximately 20 units per week). At this stage, there was no suggestion by the CO, nor an offer from Smiths, that Smiths Medical would lead a consortium to oversee the creation of an entirely new supply chain and manufacturing lines for the paraPAC.

26. On 23 March 2020, Gareth Rhys Williams (Government Chief Commercial Officer, CO) sent a letter of commitment to Smiths, which is exhibited as **SMI/04** [INQ000477913] The letter thanked Smiths for its excellent efforts in responding to the UKVC and the CO's intention to give Smiths and its supply chain the confidence to scale-up production. Specifically, the letter committed to:

    a. Purchase 5,000 units of the paraPAC, which met the issued Rapidly Manufacture Ventilation Supply ("**RMVS**") specification v2.1 and regulatory approval;
    b. Reserve a further 5,000 units (potential total of 10,000 units in total); and
    c. Support with the establishment of a supply chain and to provide a letter to manufacturers to prioritise components that can be used to produce ventilators.

27. The letter of commitment and figures being referred to by the CO was interpreted by Smiths and the wider consortium members to mean: (i) deliver 5,000 units; and (ii) put yourself in a position to deliver a further 5,000.

28. Smiths was invited to provide a commercial proposal in response to the CO's commitment, to include reciprocal commitments to prioritising volume for purchase by the UK Government, a commitment on volumes for the first 6 weeks and potential schedule of production, proposed pricing structure and the costs that would be incurred before knowing whether the product would be approved.

29. Notwithstanding the necessary establishment of a consortium, comprised of major UK manufacturing companies (without which the project would not have been possible), the scale of the challenge to hit the required targets in the letter of commitment was evident and acknowledged by all parties from the outset.

30. In a letter dated 24 March 2020, Nadhim Zahawi MP (Minister for Business and Industry) wrote to Dick Elsy CBE (CEO of the High Value Manufacturing Catapult) to provide reassurances in relation to the approach being taken by the UK Government and in the absence of any formal contract. The letter is exhibited as **SMI/05** [INQ000504124].

31. Mr Zahawi acknowledged the "*significant financial cost*" that was associated with the undertaking and that substantial financial commitments would be made by industry, outside of "*normal contractual arrangements*". Mr Zahawi confirmed the Government's intention to reimburse those costs, in recognition of the "*goodwill and shared sense of national purpose behind this work*".

32. Mr Zahawi's letter is a fair reflection of the basis upon which Smiths, and many other companies, felt assured that this was a collaborative project, at an unprecedented time, where "*normal*" contractual arrangements and commercial metrics would be considered secondary to the main objective that everyone was seeking to achieve: to rapidly produce ventilators and save lives.

Scale of the project

33. I refer to specific milestones and statistics later in this statement (see para 104) which demonstrate the scale and achievements of the Smiths consortium project but, for

context, provide the following high-level overview of the workstreams required for the CO's order to be fulfilled at all:

a. Millions of components needed to be sourced, purchased and shipped from suppliers across the world (in direct competition with other countries, facing similar challenges) within incredibly short timescales;
b. Testing equipment (which, until that point, was located entirely within Smiths Medical Luton, in commensurate numbers to the relatively low production rate of that facility) needed to be built and quality assured, to ensure the safety of the end product and retain its approved medical status;
c. Manufacturing space which had previously been utilised for non-medical industries (automotive and aeronautical engineering) needed to be converted to house the new manufacturing lines and meet necessary standards; and
d. Training needed to be devised and implemented, to ensure that the hundreds of individuals staffing those new manufacturing lines were competent to assemble the products to the necessary standards.

34. Beyond the logistical scale of the project, it was recognised that it would necessarily require an extraordinary level of collaboration between parties who had not previously worked together in the medical device field. As such, from the outset, there was a clear delineation of roles and responsibilities and daily meetings were arranged to ensure that: targets and progress was being monitored; issues and challenges could be discussed openly in order to identify solutions; and to keep track of the costs being incurred. Each of these meetings were attended by individuals from Smiths, Smiths Medical, members of the consortium and PA, who were managing the project on behalf of the CO. It was important for us to ensure that there was complete transparency on the project, both in terms of estimated delivery and cost, so that the CO could make effective decisions in the context of their handling of the pandemic.

Initial contractual negotiations and consortium formation

35. On 25 March 2020, James Down sent an email to the CO NR and NR Wells) to provide Smiths Medical's standard terms and conditions. The email is exhibited as **SMI/06** [INQ000504135] and the standard terms and conditions are exhibited as **SMI/07** [INQ000504142]. This was seen as a sensible starting point for contractual negotiations, in response to the CO's letter dated 23 March 2020, requesting a commercial proposal.

36. On 28 March 2020, NR responded with a proposed purchase agreement for the supply of ventilators by Smiths Medical. The proposed purchase agreement is exhibited as **SMI/08** [INQ000504143] together with a template order form at **SMI/09** [INQ000504144]. The proposed agreement was circulated internally within Smiths / Smiths Medical, for comment. The relevant email chain is exhibited as **SMI/10** [INQ000504073]. There was significant concern (within Smiths) regarding the terms of the proposed agreement and approach being taken by the CO, particularly with regards the terms relating to liability and indemnity. These were wholly contrary to the collaborative and pragmatic approach that Smiths had understood and expected the Government to take, in the context of the unprecedented importance and urgency of the UKVC project and given our knowledge of how strict, and often complex, regulations relating to UK medical devices were.

37. A brief overview of Smiths' concerns with the CO's initial approach are as follows:

    a. Whilst it was entirely accepted that the pandemic and UKVC constituted "extraordinary circumstances" and that Smiths was prepared to be flexible and enter into commercial arrangements on terms that it would not ordinarily contemplate, it was fundamentally unreasonable for those arrangements to expose Smiths Medical to excessive liability;
    b. The CO's proposal did not properly reflect the fact that Smiths Medical would not be the sole manufacturer, and that the nature of the consortium would require Smiths Medical to partner with a number of third parties with whom there was no pre-existing relationship, and where those third parties had no prior experience in the manufacture of ventilators or other medical devices or components;
    c. Significant goodwill and endeavours in the national interest had been demonstrated by Smiths, and its proposed consortium partners, to effectively (and quite rightly) operate on a "not-for-profit" basis. This was notwithstanding the considerable difficulties and associated costs being faced by all parties to enable them to operate above and beyond normal capacity. The Government's initial proposal did not properly recognise this fact; rather, the draft agreement reflected normal, "arms-length" contractual terms; and
    d. Smiths was worried that the approach would result in protracted commercial negotiations which would inevitably have a negative impact on the urgent production and delivery timescales.

38. At this stage, there had been ongoing discussions about which company should "lead" the consortium for the production of the paraPAC units, to fulfil the CO's letter of commitment dated 23 March 2020. It was initially believed that this role would be fulfilled by GKN Aerospace Services Limited ("**GKN**") because the majority of the project (particularly the new manufacturing lines) would be taken on by them.

39. It was clear that the CO wanted to deal with one party, as the leader and "spokesperson" for the consortium, both for the purposes of contracting and also taking responsibility for the overall project management. It should be noted that it had not been Smiths' intention or desire to lead the consortium, at the point at which the paraPAC had been offered to the CO. It was not an attractive prospect to effectively assume liability, as the "main" contractor, for parties which Smiths had no established relationship with and who had no prior experience in the medical device sector.

40. However, due to Smiths Medical's knowledge and understanding of the paraPAC device, including its component parts and the necessary testing and quality checks to meet medical standards, a pragmatic decision was taken whereby Smiths Medical would lead the consortium to produce the paraPAC units and be the main point of the contact with the CO, on behalf of the consortium. Smiths Medical formally assumed this role on 30 March 2020.

41. On 31 March 2020, Smiths had a further meeting with the CO and presented its proposed plans to work with consortium partners and "*planned production ramp up and risks*". The presentation deck used for that meeting is exhibited as **SMI/11** [INQ000504076].

42. The presentation (at page 3) provides a useful overview summary of the various roles and responsibilities attributed to Smiths Medical and its consortium partners, for consideration by the CO. Without reciting the entirety of the document, the following summary is provided for ease of reference and to demonstrate the scale of the operation:

    a. Smiths Medical was to be the main contracting entity with the UK Government, with responsibility for overall project management, with oversight on design, product requirements and the manufacturing process;
    b. GKN's role was "Scale Up Leader", with responsibility for the overall coordination of the industrial scale up of all partners and also the manufacture of selected components;

c. Rolls-Royce PLC's ("**RR**") role related to the supply chain and project management support, with responsibility for coordinating the supply chain and the associated processes. This was a huge undertaking given they were effectively standing up a completely new supply chain;
d. Siemens Healthcare's role was to provide quality assurance and support to Smiths Medical and consortium partners, by ensuring appropriate medical quality process controls;
e. Thales was responsible for developing training material and providing that training to consortium partners in respect of the new manufacturing and assembly processes which were being implemented; and
f. Formula 1 teams (McLaren, Williams, Renault, Toyota Racing) were responsible for enabling rapid developments of components that were hard to source, innovating design solutions where necessary, and producing test boxes to check / confirm unit performance to the relevant standards.

43. Mike Dobby of Deloitte LLP ("**Deloitte**") was also present at the meeting. Deloitte was engaged on the project by the consortium to oversee and audit the financial aspects and to ensure that there was a transparent approach to managing costs from the outset, for the benefit of all parties.

44. The presentation provided a status update, confirming the establishment of a new component supply chain, purchase orders raised for critical components totalling £1.5m, and the milestone of successfully building the first prototype paraPAC (out of Smiths Medical Luton) using the new component supply chain.

45. The planned production timescales and delivery forecast was set out at page 5 of the presentation. This envisaged a best-case scenario, subject to the "*Key risks to meeting this ramp*" set out on the same page, of producing 8,074 paraPAC units within 8 weeks (i.e. by week commencing 19 May 2020). This target was ambitious and had been based upon the letter of commitment received from the CO (see para 26) whereby the initial indication had been for a potential order of up to 10,000 paraPAC units.

46. The presentation (pages 6 & 7) also set out an update on supply chain issues, most notably in relation to a key component of the paraPAC, namely the demand valve. This was a customised "off-the-shelf" component which, until that point, had been entirely manufactured by a single source based in California. Smiths, in conjunction with its consortium partners, was in the process of exploring alternative options to re-engineer

and manufacture the demand valve in the UK, to allow sufficient numbers to be produced to meet the demand of the ramped-up production requirements. Ultimately, a re-engineered product was not needed as an adequate number of the existing demand valves could be secured.

47. Finally, the presentation (page 8) sets out the basis of a request for a pre-payment by the CO on account of costs being incurred by Smiths, GKN and RR, to facilitate the ordering of components according to the Bill of Materials ("**BoM**") and manufacturing costs. The presentation sets out the substantial investment which had already been made by RR and GKN to progress the project (which, for context, had been done entirely on the basis of the letter of commitment – i.e. without firm contractual arrangements in place).

Deed of Indemnity

48. On 1 April 2020, NR (CO) sent a further email with the CO's revised proposals on the indemnity issue (see paras 36 and 37). This resulted in further internal discussion within Smiths, with the full relevant email chain exhibited as **SMI/12** [INQ000504077]. It was Smiths' view, and one which it considered would be shared by the wider consortium, that the onerous indemnity being proposed by the CO had the potential to have a significant adverse impact on Smiths (and the consortium's) response to the UKVC. At best, it was going to cause delays and disrupt the ability for consortium partners to work quickly and collaboratively (due to the unacceptable level of risk and liability, which needed to be re-negotiated) and, at worst, it could entirely impact upon the willingness of some parties to be involved at all.

49. Smiths continued to work with its consortium partners to resolve the impasse which had been reached with the CO.

50. On 2 April 2020, further to the presentation and meeting with the CO on 31 March 2020, pre-payment invoices were submitted by Smiths Medical for processing by the CO. The relevant email chains are exhibited at **SMI/13** [INQ000504078] and **SMI/14** [INQ000504083] with the associated invoices at **SMI/15** [INQ000504084]. The total pre-payment figure was £23,497,976.

51. On 4 April 2020, Smiths and its consortium partners met with the CO to discuss, and hopefully resolve, the indemnity issue. We have not identified any minutes relating to this meeting.

52. Following further discussion and negotiation, the indemnity issue was finally resolved on 13 April 2020, whereby a deed of indemnity regarding the production of ventilators in a national emergency (the "**Deed**") was executed. The executed version of the Deed is exhibited as **SMI/16** [INQ000504085].

53. The context and rationale (from the perspective of Smiths and its consortium partners) for the Deed is neatly summarised at Recital E(ii) whereby the Government acknowledged "*The Consortium Members are not customarily engaged in such activities with respect to the Product* [the paraPAC] *and/or are making changes to their normal activities in an unusually accelerated manner in the course of a national emergency and/or are participating in the Consortium on commercial terms which generate no profit (or profit substantially lower than that arising from normal arms-length commercial activities)*". The resolution of the indemnity issue meant that the contractual arrangements could be finalised and ensured that the consortium could focus properly on production and delivery which, in Smiths' view, should always have been the primary concern (see para. 32).

CO's amended order & contract

54. On 17 April 2020, Smiths received a letter from Gareth Rhys Williams (CO) thanking us for the "*inspirational*" commitment Smiths had shown in responding to the UKVC and acknowledging the "*pace, collaboration and innovation*" which had been demonstrated by the consortium. The letter is exhibited at **SMI/17** [INQ000504086].

55. On 20 April 2020, Smiths received a further letter from Mr Williams (CO), exhibited at **SMI/18** [INQ000504087] The letter confirmed that the development of three production lines should be stopped and that the total order demand would be limited to 5,000 paraPAC units and therefore the CO would no longer require the "reserve" 5,000, as referred to in the letter of commitment dated 23 March 2020. The CO acknowledged that whilst the removal of three production lines would result in a substantial cost saving (c.£2m) it would also have an impact upon the delivery date for the remaining 5,000 units.

56. Despite only being circa. three weeks into the project, the CO's letter dated 20 April 2020 foreshadowed the issue of excess inventory (and associated cost wastage), which will be dealt with later in this statement. In line with the CO's letter of commitment dated 23 March 2020, components to allow for the production of c.8,000 paraPAC units had already been purchased by RR, at an approximate cost of £6.9m.

57. The decision to purchase 8,000 units' worth of components was taken by RR in good faith and was, in our view, entirely justified. When the letter of commitment was received from the CO, there was an understanding that up to 10,000 units could be ordered. The global market for components was incredibly competitive (requiring minimum order quantities) and exacerbated by the pandemic; RR took a real-time decision to purchase and secure the components (without the benefit of a contract being in place and therefore at their own risk and based upon the assurances of Mr Zahawi's letter) to ensure that, if needed, the upper-end of the CO's order could be met.

58. On 24 April 2020, Smiths' Investment Committee held a meeting to discuss and formally agree to enter into the supply agreement with the UK Government, and associated contracts with its consortium partners. The minutes of that meeting are exhibited at **SMI/19** [INQ000504068] together with an accompanying analysis note produced at that meeting by James Mortensen, exhibited at **SMI/20** [INQ000504069].

59. Together, these documents provide a comprehensive summary of the position which had been reached, the scale of the challenges that Smiths (and its consortium partners) were facing and had overcome, the costs which were estimated to be incurred, and the proposed contractual arrangements that would be entered into with each party.

60. Without seeking to recite the content of the exhibits in full, the Inquiry is respectfully directed to the following sections of **SMI/20** [INQ000504069] which are particularly helpful:

    a. The flow diagrams set out at Annex Two, which provide a useful overview of the proposed contractual arrangements (pages 10 -11);
    b. The summary of the indemnity, by virtue of the Deed, set out at Annex One (pages 8-9);
    c. The summary of the proposed supply agreement between the UK Government and Smiths Medical (pages 4-6);

d. The summary of various proposed agreements between Smiths Medical and its consortium partners (pages 6-7); and
e. A financial assessment (pages 2-3).

61. Smiths' Investment Committee resolved to approve the contract with the UK Government. The final contract was signed on 29 May 2020 (see para 90).

Consortium challenges

62. Later in this statement, in the context of disputes which arose between Smiths and the CO on the issue of perceived "delay", I address various challenges which were faced by the Smiths consortium in the initial weeks of the project (see para.102-104 and exhibit **SMI/42** [INQ000504113]). Those challenges were arising throughout this period and, through collaboration and significant effort on the part of the consortium, were overcome.

63. A high-level summary of the challenges which were faced during this time are as follows:

a. It was a fundamentally complex project, requiring the accelerated production of a high-precision, regulated medical device (with complex testing requirements appropriate for a medical device) being manufactured under Covid-19 lockdown restrictions (i.e. majority of project management work was conducted remotely and there were initial delays associated with operators returning from furlough);
b. Consortium members were acting outside of their usual course of business in a highly regulated and specialist field. This necessarily required an extensive training regime to be designed and implemented, to ensure that quality standards were being met;
c. Quality / functionality issues were encountered with a number of printed components;
d. An entirely new manufacturing footprint, capable of producing thousands of units were created, across three non-medical device locations; and
e. A significant number of technical issues and challenges were encountered in relation to test boxes, which are fundamental pieces of equipment needed to ensure the correct functionality and validation of the medical devices being produced. No blueprints existed for these multiple different pieces of equipment, which required them to be "reverse engineered" and the subsequent production of one complete set of test boxes per new manufacturing line.

64. In retrospect, the unforeseen challenges around the test boxes likely had the greatest impact upon the project, with regards to the estimated forecasts for production and delivery. The reverse engineering process took time and they were a critical aspect of the manufacturing process, from an end-user safety perspective. The consortium had successfully and quickly (through significant effort and collaboration) resolved all other supply and manufacturing challenges, to facilitate the production ramp. I expand upon this point further, later in this statement (see para. 135).

Ongoing correspondence with the CO

65. On 7 May 2020, Smiths received a letter from Gareth Rhys Williams (CO) dated 7 May 2020, which is exhibited at **SMI/21** [INQ000504089] The letter referred to the invoices which had been submitted to the CO (see para. 50) for advance pre-payments. The letter also referred to discussions in which it had become clear that the sum actually expended by Smiths (or the consortium) against those advance pre-payments was less and that the CO required repayment of the difference.

66. On 7 May 2020, I sent an email to **NR** of the CO to provide a financial update and full breakdown of the amounts which had been paid out by Smiths to consortium partners versus the advance pre-payments which had been received from the CO. The email, together with **NR** response on 8 May 2020 is exhibited at **SMI/22** [INQ000504090], where invoices were requested to support the spend to date.

67. The repayment of the balance was made by Smiths to the CO on 12 May 2020 (email chain exhibited at **SMI/23** [INQ000504091].

68. On 13 May 2020, I sent a letter to Gareth Rhys Williams, which is exhibited at **SMI/24** [INQ000504092]. This provides an update and summary of the scale of the undertaking and the extraordinary results that had been achieved by that date, resulting in the first paraPAC unit bring produced from a consortium line: "*It is an incredible achievement, and the product of a considerable amount of cross-industry hard work, ingenuity and collective spirit in overcoming numerous challenges to achieve, in 7 weeks, a goal that would ordinarily take 18 months. It is a major feat that all involved in the project should rightfully be very proud*".

69. In the letter, I provided an update in relation to the increased numbers of paraPAC units being delivered direct to the NHS from Smiths Medical Luton, together with the other

consortium lines which would soon be commencing production, to enable the target of 5000 units to be produced and delivered by the end of June 2020.

70. The letter went on to address a point of dispute which had arisen between Smiths (together with, and behalf of, its consortium partners) in relation to surplus components which had been ordered. This is the issue which I reference at para. 55. Components had originally been ordered to meet a figure of 8,000 units (in the context of a total potential order of 10,000, as per the CO's letter of commitment). The additional potential 5,000 units were now no longer required.

71. In terms of Smiths' position, I cannot really expand further upon the content of the letter itself, which stated: "*Since this project began, we have all been operating under the conditions of a national emergency. Decisions have been made quickly without following the protocols that would be typical for a project such as this. Consortium members have taken actions at risk and incurred upfront costs to establish and operate a manufacturing footprint and to build an entirely new supply chain against a backdrop of scarcity of supply. No decision has been motivated by anything other than the desire to help the country faced with a severe shortage of ventilators and to ultimately save lives, and all parties have acted in good faith on an undertaking that they will not suffer a loss and that costs would be reimbursed*". The sentiments expressed in this letter reflected, what I perceived to be, a departure by the CO from the assurances provided by Mr Zahawi at the outset [see para. 31].

72. The surplus inventory amounted to a liability of £2.8 million. The letter set out Smiths' proposal to resolve the surplus inventory issue. In short, the proposal was for Smiths Medical to purchase 1,000 paraPAC units from consortium lines to sell to third-party customers and for Smiths Medical (together with RR & GKN) to absorb the remaining components. This was on the basis that "*Smiths is best placed to sell ventilators and mitigate the liability*". The proposal required the CO to waive the fixed cost reimbursement right for the first 1,000 consortium produced units, as this was inflating the potential retail price beyond the capability of the market which had been identified (i.e. the "full" costs of the units produced through consortium lines, taking into account the investment to manufacture them, could not appropriately be passed on to third parties).

73. In making this proposal, Smiths' genuine intention was to resolve the issue on the best possible terms and to the satisfaction of all parties. The proposal also meant that Smiths

would be taking on the majority of risk from the surplus inventory issue, which was explained in the letter: "*This proposal is not without risk. As of today, we do not have the corresponding orders to support these additional units, the ventilators won't be available for shipment to prospective customers until early July (customer enquiries are consistently requesting ventilators to be available sooner than this), and future orders will not have the benefit of the UK Government indemnity*".

74. In a letter dated 14 May 2020, Gareth Rhys Williams responded to our letter and the proposal (exhibited at **SMI/25** [INQ000504093]). He acknowledged the efforts which had been made and had resulted in the first paraPAC unit from consortium lines. However, there were a number of issues which flowed from the remainder of this letter, which I address below.

75. He went on to confirm "*As you are aware the Cabinet Office has been working closely with clinicians and the NHS system to deliver ventilators to combat this crisis. At the same time, we are routinely reviewing the overall demand for ventilators in the NHS system and the impact this has on the UKVC Programme*".

76. It was apparent that the CO's position was changing in relation to the base need for ventilators (as first indicated by the CO's letter dated 20 April 2020 limiting the order [see para. 55] and in subsequent communications, including in this letter). It was my understanding at the time, in line with Mr Williams' comments above, that demand for ventilators had decreased as a consequence of the advice received from the NHS and the evolution of knowledge regarding Covid-19 treatment methods, which suggested that ventilators were not as effective as initially thought.

77. However, Mr Williams then sought to justify a substantial reduction in the CO's order by reference to alleged delay in the delivery schedule: "*Given the Smiths manufacturing schedule has slipped since we started, and the content of your most recent delivery plan (14th May 2020), we need to revise our volumes and delivery timeline with you. We will take delivery of all units Smiths are able to manufacture up to a maximum of 4,000 (this includes the units already supplied through Smiths Luton) by the 19th June 2020, subject to concluding an acceptable contract with Smiths…However, we will not require any further ventilator units beyond that volume or after that date.*"

78. It is important to note that at this point the contract with the CO had not yet been signed. The significant amount of work which had been undertaken by Smiths Medical and its consortium partners had effectively been completed in good faith and "at risk".

79. In my view, Mr Williams' characterisation and allegation of delay was a misrepresentation and lacked context: it did not properly account for, or recognise, the aspirational nature of the proposed delivery schedules, the complexity of the product being produced and the scale of the undertaking and the extraordinary outcomes which had been achieved by that date. I refer back to my quotation set out at para. 68.

80. I entirely recognise and appreciate the challenges that the CO were facing in their own right; in terms of the need to appropriately manage public finances, drive the project forward and ultimately deliver ventilators to the NHS. Throughout the project, the Smiths consortium had worked hard to ensure that there was full transparency on every aspect of the work being undertaken and that costs were constantly kept under review and minimised wherever appropriate.

81. I was disappointed that the CO chose to try to justify reducing its order for ventilators in this way, rather than acknowledging what I perceived to be the real reason – the external factors resulting in decreased demand – and engaging in pragmatic, collaborative discussions about options to reduce the order which fairly reflected the commitments made, and difficulties faced, by both parties. The decreased demand and delays to the delivery schedule were two distinct points which should not have been conflated and, in my view, showed a lack of recognition of the considerable efforts which had been made by Smiths and its consortium partners, on a non-commercial, humanitarian basis, up to that point, in particular the individual sacrifice and hours of work spent by consortium team members (most of whom were working all hours, seven days a week, during a very difficult period for many on a personal level) all of which were motivated by the desire to do the right thing and make a difference. The tone now being adopted by the CO was a drastic departure from the previous comments from Mr Rhys Williams (see para. 54) in which he described Smiths' commitment in responding to the UKVC as "*inspirational*" and acknowledged the "*pace, collaboration and innovation*" of those involved.

82. In response to Smiths' proposal to resolve the surplus inventory issue, the CO's position was equally disappointing. As set out previously, and made clear to the CO, those costs had been incurred by the consortium based upon the original figures estimated to be required by the UK Government and also on the understanding that we were operating

in a unique and fluid set of circumstances, beyond the normal parameters of a commercial endeavour (see para. 71).

83. The letter also sets out the CO's concerns with an apparent lack of cost transparency and sought clarification around a number of costs which had been submitted. The CO's observations ignore the mechanics in place to ensure cost transparency, including the roles of PA (who were advising the CO) and Deloitte (appointed as an independent intermediary), who were responsible for ensuring cost transparency. Indeed, PA and Deloitte joined the consortium's almost daily meetings (see para 34) where production issues and costs were discussed openly and understood by all those in attendance.

84. Andrew Reynolds Smith responded to the CO in a letter dated 19 May 2020, exhibited at **SMI/26** [INQ000504094]. That letter expressed the disappointment felt by Smiths and its consortium partners, the disparity between the CO's letter dated 14 May 2020 and discussions which had been taking place before. He requested an urgent meeting to discuss the issues which were forming.

85. The letter concisely summarised the position on several overarching points such that I do not feel the need to expand upon them further, but for ease of reference repeat them here:

    a. "*We and our Consortium colleagues responded to the call of the UKVC as a matter of altruism and in some instances on the direct and personal appeal by Cabinet Ministers. At all times, our actions have been driven by the objective of protecting the NHS and saving lives, and not by commercial advantage or profit motive for ourselves*";
    b. "*Your letter of 23 March requested 5,000 ventilators to a "potential total" of 10,000. In view of the exceptional circumstances that existed in late March we were prepared to act urgently, in advance of a contract being in place, to expend resources, incur costs and make massive efforts, based on the undertakings that were given to Consortium members at the time*";
    c. "*No time stipulation or delivery schedule was included in your letter or at any other time as everybody has understood that this is not a commercial programme and cannot be managed as such. However, we have fully understood the urgency and, as a result, have always worked at maximum pace at great personal cost to all involved including 7 days working, 18 hour days and no down days for week after week*";

d. "*While our aspirational volume delivery schedule has been pushed out, your office has always been kept fully briefed of the status of the project, the complexity and interdependencies of different workstreams and the risks of delay that we have all shared*";

e. "*Moreover, it is acknowledged by all involved that we have achieved in a matter of weeks what would normally take many months, despite the challenges of dislocated supply chains, transportation and labour as a result of the pandemic*";

f. "*As regards costs, from the very beginning the Consortium has had an "open book" approach to costs. Our team has regularly shared the cost model and been in almost daily dialogue with your office and PA Consulting to discuss each line of the model. It is well understood by them that the cost model contains estimates and these estimates have been revised regularly as we get greater visibility of the costs involved in the project*"; and

g. "*Furthermore, in line with guidance from your office and consistent with the assurances provided in the letter from Nadhim Zahawi on the 24th March 2020* [see paras. 30 and 31] *we have an agreed procedure for claiming, assuring and paying these costs using Deloitte as an independent intermediary. This method was agreed as a practical alternative to obtaining up-front approval for every cost item which would have slowed us down. The accusation of "egregious costs" and lack of transparency is without foundation*".

86. The letter goes on to address the issue of the surplus inventory and reiterates the basis upon which those components were originally sourced and purchased, with full visibility to, and in the knowledge of, the CO at the relevant time.

87. The letter also addressed the CO's change in tone (presumably linked to the reduced demand for ventilators as part of the medical response to Covid-19 – see para. 75) and that this was resulting in the project being "*treated as a normal commercial deal*" despite the context in which Smiths and its consortium partners had "*stepped forward in a national emergency*" and "*out of goodwill and a sense of social responsibility at a critical time for our country*". The request for an urgent meeting to seek a resolution was reiterated.

88. On 22 May 2020, we were informed that the CO was able to meet. In preparation for that meeting, a "key messages" document was prepared in collaboration by Smiths, RR and GKN. The document is exhibited at **SMI/27** [INQ000504095]. The document

provides clear summaries of the consortium position in relation to issues raised by the CO regarding:

a. **Cost transparency:** including the level of interaction (almost daily) with the CO and PA, ongoing revisions to estimates to match known figures, together with an explanation as to why the costs of the paraPAC units produced by the consortium were higher than those normally produced for the NHS out of Smiths Medical Luton, during non-Covid times;

b. **Delivery timelines:** including a high-level explanation of the complexities which had been encountered (particularly in relation to test boxes, quality issues associated with accelerated manufacture, and the importance of maintaining the paraPAC's associated CE marking and approved medical device status). It also sets out how, in light of those complexities, Smiths Medical Luton had been utilised to deliver paraPAC units to the CO in priority to Smiths Medical's other contractual commitments, to its detriment. The document articulates the key point, which only unfortunately needed to be made as a result of the approach and critical tone being adopted by the CO, that "*Were Smiths to have been motivated by commercial considerations of profit, we could have sold our production* [i.e. units from Smiths Medical Luton] *into the export market several times over, rather than proceeding, as we have to date, to prioritise HMG and the NHS*"; and

c. **The surplus inventory issue:** addressing the fact that the CO originally reserved up to 10,000 units and the response by the consortium to source scarce components, to meet that demand, together with the consortium's proposals to mitigate the impact.

Key contractual overview

89. Beyond the complications relating to supply and manufacturing, the contractual arrangements relating to the consortium project were equally complex and required a significant dedication of time to negotiate and resolve.

90. The documents governing the contract between Smiths Medical and the CO are exhibited at **SMI/28** [INQ000504096], and are comprised of:
    a. Ventilator Equipment Order Form dated 29 May 2020;

b. Covering email and letter dated 27 May 2020 from MHRA confirming authorisation to supply Rapidly Manufactured Ventilator Systems ("**RMVS**") for final use, together with the user manual for the paraPAC; and
c. Terms and conditions for the supply of ventilators in a national emergency, which contains an estimated cost model (together with detailed assumptions) at Annex 1.

91. Schedule 5 (Additional Terms) of the terms and conditions contains a useful, and contractually agreed, summary of the unprecedented nature of the pandemic and the supply agreement being entered into. It confirms:
    a. "*the circumstances created as a result of the Covid-19 pandemic are exceptional and fast-moving*"; and
    b. "*The Authority acknowledges that the members of the Consortium are not customarily engaged in activities of the nature set out in this Contract in respect of the Goods and/or are making changes to their normal activities in an unusually accelerated manner in the course of a national emergency and/or are performing their obligations in relation to the Goods on commercial terms which generate no profit (or substantially lower than that arising from normal arms-length commercial activities*" [emphasis added].

92. Schedule 6 (Pricing and payment rider) contains further relevant acknowledgments relating to the financial aspects of the agreement. Particularly that:
    a. The "*Estimated Cost Model*" was indicative only as at the date of the contract and may vary;
    b. Costs had been incurred by both Smiths Medical and the consortium members prior to the date of the contract and "*it is the Authority's intention that all such costs shall be reimbursed*"; and
    c. "*The final unit cost of each Unit delivered to the Authority under this Contract may, due to the exceptional circumstances in which the Goods have been supplied, vary from the unit cost of ventilator units supplied by the Supplier* [Smiths Medical] *through its existing manufacturing operations* [Smiths Medical Luton]".

93. Schedule 6 also sets out the position that was agreed in relation to a "Licence Fee", being "*the sum of* **I&S** *per Unit that has been completed and delivered to the Authority in accordance with the terms of this Contract*". The rationale for the Licence Fee was in recognition of the fact that, as a result of participating in the UKVC, there was a real risk that the commercial value of both the paraPAC unit and Smiths Medical Luton could be

severely diminished, due to ostensibly "flooding the market". In reality, whilst the Licence Fee did account for a level of revenue generation for Smiths Medical, this was almost entirely nullified by the level of cost absorption relating to the disputes which arose with the CO (see para. 115 onwards) and did not reflect the significant amount of time dedicated to the project by Smiths, at a central level.

94. The documents governing the sub-contract between Smiths Medical and RR are comprised of:
    a. Executed Order Form dated 29 May 2020 (**SMI/29**) [INQ000504097];
    b. Manufacture and Supply sub-contracting agreement dated 29 May 2020 (**SMI/30**) [INQ000504099];
    c. Agreement for the Supply of Components dated 29 May 2020 (**SMI/31**) [INQ000504100]; and
    d. Quality Agreement dated 21 May 2020 (**SMI/32**) [INQ000504101].

95. The documents governing the sub-contract between Smiths Medical and GKN are comprised of:
    a. Executed Order Form dated 29 May 2020 (**SMI/33**) [INQ000504102];
    b. Manufacture and Supply sub-contracting agreement dated 29 May 2020 (**SMI/34**) [INQ000504103]; and
    c. Quality Agreement dated 2 May 2020 (**SMI/35**) [INQ000504104].

96. A side-letter agreement in respect of excess inventory was entered into between Smiths Medical, GKN, the High Value Manufacturing Catapult Limited and RR, dated 29 May 2020 (**SMI/36**) [INQ000504105].

97. I also exhibit at **SMI/37** [INQ000504106] a copy of the engineering support agreement dated 17 April 2020, entered into by Smiths and PA, which sets out the level of support they provided to Smiths in the scale-up of paraPAC production within the consortium.

Post-contract correspondence

98. On 3 and 5 June 2020, the CO and Smiths exchanged further letters relating to the issue of "delay" (exhibited at **SMI/38** [INQ000504107] and **SMI/39** [INQ000504108] respectively). I do not consider it necessary to summarise the contents of these letters, given that they simply expand upon the topics which have already been covered in detail above. In short, the CO continued to allege delay and adopted a position of "normal"

contractual expectation and delivery, and Smiths continued to explain the full context in which the project was being undertaken, what was being achieved and the difficulties encountered by its consortium partners, who were doing everything within their power to "*ramp up production against a backdrop of their own challenging market and business conditions*".

99. The majority of the subsequent correspondence within this section of my statement expands upon the same themes. Save for where further commentary is required for necessary context, I have simply exhibited the relevant documents. Generally, the CO's criticism, evident in its correspondence throughout June 2020, of the work which had been undertaken was unnecessary, undeserved and unjustified. I can only assume it was either a result of a lack of real understanding of the logistical feat which was being achieved, or an overzealous and unhelpful attempt to hold the consortium "to account". I reiterate my understanding of the CO's need to responsibly manage the use of public funds, however the tone by the CO was, in my view, at best unhelpful and at worst unpleasant.

100. Smiths' letter of 5 June 2020 also clarified the discussions regarding "*overseas opportunities*", which had been raised by Mr Williams.

101. A further letter from the CO dated 9 June 2020 is exhibited at **SMI/40** [INQ000504110] which reiterated the same points in relation to perceived delay and cost.

102. To try and move matters forward, a conference call was scheduled to take place on 15 June 2020. Exhibited at **SMI/41** [INQ000504111] is the email appointment for the call, showing the attendees and circulating a presentation deck for use during the call. The call was attended by representatives of Smiths, the CO, PA, GKN, RR and others. The presentation deck is exhibited at **SMI/42** [INQ000504113].

103. The presentation made the following key points in relation to criticisms about delivery and cost:

    a. The Smiths consortium was on track to continue production ramp up in line with the committed plan;
    b. The estimated programme costs were down £5.2m from the pre-contracting estimate; and

c. A cost mitigation program was being pursued to off-set the excess stock being produced through consortium lines and on account of the surplus inventory issue.

104. In relation to perceived delay, there is a useful diagram at page 9 of the deck, which neatly sets out the scale of the project and the challenges which had been faced, and overcome, along the way through the tireless efforts of Smiths and its consortium partners who were all driven by a desire to make a difference at a time of national crisis. Some of the key successes which are worth noting are:

a. 3.56m parts were secured from 115 suppliers in 5 countries within 4 weeks. 2.5m of those parts were delivered within 2 weeks;
b. Toyota Racing Development re-engineered complex testing equipment to ramp up validation of a critical oxygen demand valve component from the supply chain;
c. Maintained the CE mark, to ensure the paraPAC had a life after Covid-19. All sites passed their audit by BSI and MHRA;
d. At GKN Luton, 475 sq/m of aerospace manufacturing space was converted to ventilator production. 145 man weeks (3 man years) of work completed in 3 weeks to establish the first ventilator production line;
e. At Smiths Medical Luton, the existing site was scaled up from producing 20 ventilators a week to 174 a week at its peak, equating to an 8.7 times increase in production output; and
f. McLaren, without drawings, reverse-engineered, designed, procured, built, tested and commissioned 144 test boxes to be used on the production lines for final testing to ensure the safety of the products. In April 2020 alone, the McLaren team worked over 12,000 hours – equivalent to more than 6.5 man years.

105. The remainder of the presentation deck provides an "Operations deep dive" of the scale and challenges encountered at each stage of this unprecedented project.

106. A further email exchange between Andrew Reynolds Smith and Gareth Rhys Williams on 15/16 June 2020, which dealt with this continuing theme, is exhibited at **SMI/43** [INQ000504114].

107. On 22 June 2020, a further meeting was held between the CO and the Smiths consortium, the presentation deck for which is exhibited at **SMI/44** [INQ000504115]. The deck dealt with the following:

a. An update on production output;
b. A financial update, confirming that estimated costs remained £5.1m down from the pre-contracting estimate;
c. A "high confidence" figure of delivery was provided to the CO based on the ramp up of production, equating to a target of 1,383 paraPAC units being delivered by 30 June 2020; and
d. Smiths was continuing to explore overseas demand for the extra units, in order to mitigate costs for all parties.

108. At pages 11-13 of the presentation deck, three different options were offered to the CO, which related to when production would cease and the impact that date would have upon units produced versus price per unit. In summary:

a. Option 1: Cease production on 30 June 2020, 1,383 units, c. I&S per unit;
b. Option 2: Cease production on 5 July 2020, 1,617 units, c. I&S per unit; and
c. Option 3: Cease production on 31 July 2020, 3,177 units, c. I&S per unit.

109. The additional point to be noted from these options is that, by this stage, the "ramp-up" had demonstrably been achieved. The number of units which were capable of being produced from consortium lines was growing exponentially, week upon week, which had been the entire goal of the project.

110. In a letter dated 24 June 2020 from Gareth Rhys Williams, the CO confirmed that they wished to proceed with Option 1 (**SMI/45**) [INQ000504116].

111. On 29 June 2020, an email update was sent to the CO (with a supporting presentation deck) which is exhibited at **SMI/46** [INQ000504117]. The headline points from the update were:

a. 430 units produced in the previous week, against a target of 330;
b. Remained on track to deliver at least 1,383 units by 30 June 2020;
c. Estimated program costs now c.£12m down from pre-contracting estimate; and
d. Mitigation efforts had further reduced program costs by c.£0.6m.

112. On 1 July 2020 (i.e. the day after ceasing production), a meeting was held between the CO and the Smiths consortium. The covering email and presentation documents for that meeting are exhibited at **SMI/47** [INQ000504118]. These set out the following key points:

a. The target of 1,383 paraPAC units had been exceeded by 187 ventilators;
b. "*There have been additional deliveries through Promeseus* [sic - i.e. from Smiths Medical Luton], *bringing total to 1,754 if they are included*"; and
c. Draft guidance for the shutdown of production lines was provided.

113. In a letter dated 10 July 2020, from Gareth Rhys Williams to Smiths Medical, a draft agreement was provided whereby Smiths Medical would purchase the surplus inventory of the project, from the CO, and attempt to resell it. The letter and draft agreement are exhibited at **SMI/48** [INQ000504122].

114. On 17 July 2020, Andrew Reynolds Smith received a letter from Rt. Hon. Michael Gove MP, formally acknowledging and thanking Smiths for its efforts in responding to the UKVC and to "*take stock of everything that has been achieved by the UKVC*". The letter is exhibited at **SMI/49** [INQ000504123]. It was a welcome letter which echoed the basis upon which Smiths sought to become involved in the UKVC, "*in the interests of the wider public good*".

Surplus Inventory Issue and final cost negotiation

115. Exhibited at **SMI/50** [INQ000504125] is a memorandum dated 21 July 2020 on behalf of Smiths and RR, to the CO, with considerations on the surplus inventory issue. Whilst this document is headed "*Draft and Subject to Change*" we have examined associated internal communications around this time and believe that this was the final version issued. The memorandum set out the full background to the UKVC, including the difficulties that the project initially faced in terms of the supply chain. It also contained an assessment of the final inventory position and the items which comprised it, together with an analysis of how the surplus could be utilised in order to return maximum value for money from the programme investment.

116. On 23 July 2020, a letter was received from the CO, providing their view on the "*key outstanding points*" from the project and disputing the costs attributable to various aspects, including the ERP system, the labour rate, the cost of delays, storage costs and VAT. The letter is exhibited at **SMI/51** [INQ000504126].

117. An internal Smiths' email chain is exhibited at **SMI/52** [INQ000504127], dated 23-24 July 2020, where the CO's letter of 23 July 2020 was discussed in more detail.

118. In a letter dated 29 July 2020, Gareth Rhys Williams provided a further draft agreement for the proposed sale of surplus inventory to Smiths Medical, which is exhibited at **SMI/53** [INQ000504128]. We have not been able to locate a signed copy of this draft agreement, however I exhibit at **SMI/54** [INQ000504129] a schedule of components which was provided to Deloitte to build into the cost model which matches the figures in the Annex to the CO's letter dated 29 July 2020. I therefore assume that agreement was reached on the basis of those components and associated costs.

119. Exhibited at **SMI/55** [INQ000504130] is an email chain ranging from 30 July – 5 August 2020, discussing and responding to the cost disputes set out in the CO's letter of 23 July 2020 (see para. 116). In terms of the Smiths consortium position, the chain confirms the following, "*the Consortium disagrees with your position in relation to Accenture costs, Labour and Overhead charges and Cost of delays – we strongly believe these are reasonably incurred costs in line with our contractual agreement, and we have already provided considerable support to demonstrate this through presentations, back-up materials or otherwise*". The chain provides a detailed analysis of each of the areas of dispute, together with input from GKN and RR.

120. There followed further exchanges which ultimately resulted in the cost dispute being resolved, which I refer to as follows:

    a. A letter dated 14 August 2020 (**SMI/56**) [INQ000504131] from the CO, providing a proposed settlement offer for the disputed costs, as scheduled in Annex A, together with a summary of the CO' position;
    b. A letter dated 20 August 2020 (**SMI/57**) [INQ000504132] to the CO, referring to a discussion which had taken place on 19 August 2020 whereby a revised settlement offer had been discussed;
    c. A letter dated 21 August 2020 (**SMI/58**) [INQ000504133] from the CO, providing an updated settlement offer, based upon the discussions at the meeting on 19 August 2020;
    d. A letter dated 25 August 2020 (**SMI/59)** [INQ000504134] to the CO, with a counter-proposal;
    e. A letter dated 1 September 2020 (**SMI/60**) [INQ000504137] from the CO, with a further revised settlement offer;
    f. A further letter dated 2 September 2020 (**SMI/61**) [INQ000504138] from the CO, replacing the letter dated 1 September 2020;

g. A letter dated 4 September 2020 (**SMI/62**) [INQ000504139] to the CO, with a further counter-proposal; and
h. An email dated 7 September 2020 (**SMI/63**) [INQ000504140] from the CO, confirming that the counter-proposal was accepted.

SECTION B – INQUIRY'S SPECIFIC QUESTIONS

121. The chronological summary of Smiths' involvement in the UKVC and the accompanying exhibits, as set out above, addresses most of the Inquiry's specific questions. Where I have identified issues not specifically addressed above (and upon which I am able to comment), I provide the additional comments below.

122. In terms of a full audit trail of programme financials, beyond what has been exhibited to this statement, Deloitte would be best placed to provide a full set of documentation.

123. In terms of the total cost of transporting ventilators produced by the Smiths consortium, the relevant distribution agreement was between DHL and RR. Exhibited at **SMI/64** [INQ000504141] are a series of cost statements (covering the period April – July 2020) from DHL to RR, submitted to Deloitte in August 2020.

124. Smiths did not work directly with the NHS, or any other relevant experts, during the Relevant Period and was not involved in any advice or discussions regarding the specific deployment, use or effectiveness of ventilators in response to Covid-19. This includes consideration of the equality and diversity of any end users, or the percentage of staff within the NHS or care sector who were female or from ethnic minorities or religious backgrounds.

125. In relation to the Guardian article dated 4 May 2020, and the extract referred to in the Inquiry's Request, I do not think that it was directed at the Smiths consortium project, nor does it fully characterise Smiths' experience of participating in the UKVC. The suggestion of "*early panic and confusion*" may be a fair assessment of the overall climate of the national crisis that Covid-19 caused; however, that did not extend to the manner in which the Smiths consortium operated. Smiths did consider itself to be a company "*with expertise*" and, importantly, a tried and tested medical device, such that the paraPAC ventilator was selected by the CO as a viable candidate. I cannot comment upon the other devices which may have been selected by the CO and the extent to which they had "*questionable designs*".

126. In terms of the final sentence describing the "*desperation of a government setting targets and then deciding it didn't need to meet them after all*". I have acknowledged that the Government was having to make difficult decisions in the midst of a dynamic and ever-changing crisis; suggesting that their necessary reactions to fast-moving circumstances was out of "*desperation*" seems unduly harsh. I have the same sympathy in relation to the criticism of the Government "*setting targets and then deciding it didn't need to meet them*", given the evolving environment they were operating in. From Smiths' perspective, I think that there was perhaps a degree of naivety in terms of what working with Government during a crisis would be like. It was not something that we had done before and, if we were to do it again, while we would continue to be motivated by the desire to do the right thing, I think we would likely be more circumspect and robust in requiring contractual agreements to be in place from the outset, rather than operating on the basis of good faith and trust.

127. The Smiths consortium was not impacted by the UK's decision not to join an EU procurement scheme for ventilators.

128. I am not aware of any issues with the quality, safety, appropriateness or effectiveness of any of the paraPAC units delivered to the CO during the UKVC.

129. I do not have any personal knowledge of circumstances where a patient who needed a ventilator was not able to get access to one.

130. In terms of examples of good practice, I have nothing but admiration and praise for the thousands of people throughout Smiths, Smiths Medical and our consortium partners who worked tirelessly, at great personal cost, during their participation in the UKVC. The speed at which key relationships were forged between companies, with tasks and responsibilities being allocated and project managed, was remarkable – particularly given that the majority of it was being done remotely. I think that Dick Esly CBE did an admirable job of pulling groups of people together that would not ordinarily have overlapped, to enable to consortium to get off the ground.

131. In terms of the challenges experienced during the UKVC and how these were overcome, these are set out in a great degree of detail in the exhibits to this statement. These exhibits also provide context of how these challenges were explained and justified to the CO at the relevant time. As for high-level comment, I think the challenges can best be

described as a predictable consequence of trying to rapidly manufacture an approved medical device in the context of a global pandemic. It was only possible with the help of extraordinarily talented companies such as RR, GKN, McLaren, Williams Racing, Toyota Racing, Thales and many, many others; all of which did not have any prior experience of manufacturing medical devices. There were inevitably issues associated with sourcing sufficient components, which were overcome. There were inevitably issues associated with ensuring that the devices were properly tested and certified, to ensure and maintain their approved status and safeguard against any potential quality issues during their use. The monumental human element of the UKVC should also not be overlooked, in terms of expectations to work around the clock to deliver a project which, in normal circumstances, would have taken years. Placing that effort within the context of working remotely, in an uncertain economic landscape for all involved, is a remarkable challenge to have overcome.

132. In terms of lessons learned, I have already referred to the manner in which Smiths entered into the UKVC and began working closely with Government during a national crisis, and how clearer contractual agreements and commitments should have been made at the outset. I think that the escalation in tone between Smiths and the CO, which is clear in the correspondence, is regrettable and could potentially have been managed in a more pragmatic and collaborative manner.

SECTION C: CLOSING REMARKS

133. The achievements of the Smiths consortium in response to the UKVC cannot be understated. To go from a position of initially seeking to offer the use of the design rights of a well-established ventilator product (paraPAC) to assist the Government's response to Covid-19, to leading a consortium consisting of British industry giants was a challenge that Smiths threw itself behind. I am proud of the work that both Smiths and its consortium partners did during those months, in seeking to do the "right thing" out of a sense of altruism and to rally together at a period of significant domestic (and global) uncertainty.

134. Whilst there were "delays" associated with the Smiths consortium aspect of the UKVC response, in terms of the numbers produced versus the ambitiously forecasted timescales, this needs to be properly and fully considered in the context of what was happening and what was trying to be achieved. Supply and manufacturing lines were created at a speed bordering on the impossible, with substantial cost and man-hours

being invested in the spirit of the national emergency, with the desire of achieving an almost unachievable goal.

135. The complexities around the test boxes were simply not anticipated at the outset of the project. The test boxes in situ at Smiths Medical Luton were old pieces of equipment, without drawings, and were comprised of some parts which could not be readily sourced. The work undertaken by McLaren to reverse engineer the test boxes was outstanding and ultimately ensured that the units produced from consortium lines retained their approved medical device status. This aspect of the project was the main barrier to the "ramp-up" being achieved any earlier but, in real terms, only delayed the project by a number of weeks.

136. The same points can be made in response to any insinuation that profit costs were a factor in Smiths' involvement in the UKVC. There was a real risk that participating in the UKVC, either by offering the design rights to the paraPAC as originally conceived, or by effectively "flooding the market" by scaling-up production in such an expedited manner, was going to significantly impact upon demand for the product and may have rendered both it, and Smiths Medical Luton, redundant for a number of years. Had profit costs been a factor for Smiths – as alluded to in correspondence with the CO - this could have been simply achieved by taking advantage of the global demand for ventilators, not by entering into a consortium to solely benefit the UK Government and at a "base-cost" price per unit. As above, the rationale for Smiths' involvement was entirely on the basis that it was, I believe, the correct and only response to the effective "call to action" in the national interest.

137. In terms of further learning points from this experience, I have no hesitancy in saying that should a similar situation present itself, that Smiths would offer the same level of assistance and investment of its resources, should they be needed. I fully appreciate that the UK Government was operating in unprecedented times and was attempting to do its best, both in terms of seeking solutions in a rapidly evolving environment and to retain control of costs, which are perfectly appropriate (albeit sometimes conflicting) aims.

138. I am not going to otherwise comment on the Government's preparedness for the Covid-19 pandemic or the other contracts which were awarded in response to it. I am immensely proud of Smiths', and its consortium partners', response which demonstrated the true power and spirit of British ambition, philanthropy, industry and engineering

innovation; I reiterate the sentiment expressed in my letter dated 13 May 2020 as referred to at para. 68.

139. It would be a shame if, in the event of another pandemic or other national crisis, there were any hesitancy from other companies to become involved in a similar challenge with the same intentions in mind.

140. I consider the Smiths consortium project to have been a triumph. Ultimately, it transpired that ventilators (despite the initial and genuine belief of their importance held in March 2020) were not the most effective form of treatment for those suffering from Covid-19. That development resulted in a dramatic scaling back of the project, within a few short weeks of its inception. Had ventilators remained the envisaged, critical treatment for saving lives during the pandemic, by the end of June and going forward, the manufacturing lines created under the Smiths consortium would have been capable of producing sufficient approved medical devices to service not only the UK but also, potentially, the world.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: Personal Data

Dated: 07 November 2024