Witness Name: Mary Patricia Ryan
Statement No.: M5/Penlon/01
Exhibits: Annex A, 25 Exhibits
Dated: 3rd December 2024

UK COVID-19 INQUIRY

WITNESS STATEMENT OF MARY PATRICIA RYAN, PENLON LIMITED

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1. On behalf of Penlon Limited, I, Mary Patricia Ryan, Director of Innovation, Technology and Regulatory Affairs at Penlon Limited, make this statement in response to the request in a letter dated 27 June 2024 from the UK COVID-19 Public Inquiry ("the Inquiry") under Rule 9 of the Inquiry Rules 2006 (SI 2006/1838), requiring me to provide the Inquiry with a witness statement in respect of specified matters relating to Module 5 Reference: M5/Penlon/01. At the end of this witness statement are a list of exhibits 'Annex A' which are referenced throughout the statement.

2. I serve as the Director of Innovation, Technology, and Regulatory Affairs at Penlon Limited, and act as the Management Representative and Person Responsible for Regulatory Compliance (PRRC). I am providing this witness statement on behalf of Penlon Limited, given my direct involvement from the inception of the Ventilator Challenge project to provide ventilators at the start of, and during, the COVID-19 Pandemic. This included initial communications with the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the Rapid Manufacturing Ventilator Specification (RMVS) and my ongoing oversight of the development of the ESO2 Emergency Ventilator through all phases of the project.

3. As the Person Responsible for Regulatory Compliance (PRRC), I ensured that Penlon, as the legal manufacturer of the ESO2 Emergency Ventilator, complied with all relevant laws and regulations governing its operations. My responsibilities included drafting and managing much of the technical documentation to ensure safety and regulatory compliance, maintaining technical and clinical evidence, and overseeing post-market surveillance. Additionally, I monitored the safety and performance of ventilators in the market and ensured that robust processes and independent assessments were in place for each device prior to its final release, ensuring full conformance with our Quality Management System (QMS).

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4. I have been a key member of the Leadership Team at Penlon since January 2013, serving as the Management Representative, overseeing Quality Assurance, Regulatory Affairs, Development, and external Clinical teams. I hold a BSc (Hons) in Quality Management from Heriot-Watt University (1995) and an HND in Business Management, French, and Commerce (1992). With 30 years of industry experience, spanning engineering, consultancy, and senior management roles, I have developed deep expertise in medical device development and certification.

5. From 2007 to 2011, I held senior roles with a UK Notified Body, before returning to industry in 2012. My experience includes significant involvement in new product development, ensuring adherence to patient-centric clinical and safety requirements, as well as navigating global regulations for medical devices. I have also collaborated with various international Ministries of Health, facilitating the implementation of regulatory due diligence processes for medical devices entering their markets.

6. In my Leadership capacity at Penlon, during the Ventilator Challenge, my responsibilities encompassed a wide spectrum of duties, such as the approval of Consortium sister sites, the review and authorisation of all design modifications and temporary process changes, the preparation and compilation of the technical file dossier, and ensuring the safety and regulatory compliance before the final release of all ESO2 medical devices to the market.

7. The COVID-19 pandemic had a profound impact on the lives of millions globally. The uncertainty surrounding the novel disease, coupled with the challenges of managing it medically and the rising casualty reports, led to widespread instability across families, communities, workplaces, and the healthcare sector. This unprecedented situation placed immense pressure on medical systems, requiring rapid adaptation and innovative solutions to address the evolving crisis. As a result, there was an unprecedented demand for appropriate medical equipment to address the critical healthcare challenges posed by the pandemic.

8. The crisis brought unprecedented challenges for both the UK Government, the medical profession, individuals and society, but at Penlon, a small-to-medium anaesthesia medical device manufacturer based in Abingdon, Oxfordshire, we stood firm in our belief that we could contribute a solution to support the NHS. In response to UK Prime Minister Boris Johnson's call for assistance, and deeply moved by the courageous efforts of frontline medical staff witnessed on television and social media, senior Penlon personnel proactively contacted the UK Regulatory Authority, the MHRA, to request the specifications for intensive care ventilators, which were in critical shortage.

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9. Our New Product Development and Regulatory Teams united to develop an emergency ventilator to address the urgent needs of the NHS. This single innovation, designed to be a vital tool in saving the lives of our families, friends, and communities, fuelled our determination to take our place on the front line. Driven by our skills, expertise, professional collaboration, and sense of purpose, we committed to providing a solution at a time when a specific emergency ventilator specification was needed to meet the expected number of devices to service the medical demands arising out of COVID-19 was not available.

Call to Arms – March 2020

10. I have written this statement to the best of my recollection of events as they unfolded. On March 15, 2020, just a week before the national COVID-19 lockdown was announced, Prime Minister Boris Johnson issued an urgent appeal to UK industries. As the virus rapidly spread, the demand for ventilators to treat critically ill patients surged, prompting the government to call on manufacturers to help address the critical shortage and to support the NHS in the fight against COVID-19.

11. In these initial days, and in advance of the 'call to arms', Penlon's Product Manager and Development Manager attended a BAREMA Association meeting which flagged to the attending audience that Penlon and other respiratory anaesthesia companies could possibly bring a solution to the NHS.

12. In direct response to this urgent need, I, as Penlon's Director of Innovation, Technology, and Regulatory Affairs, contacted the Head of the UK Medicines and Healthcare products Regulatory Agency (MHRA), to propose that Penlon Limited, a well-established manufacturer of anaesthesia and ventilator medical devices, could provide a viable solution for ventilator production. I also requested the Rapid Manufacturing Ventilator Specification (RMVS) for the emergency ventilators. Simultaneously Penlon's Development Manager, reached out to the Clinical Director for Medical Devices, with a similar request for the RMVS.

13. In parallel, and in agreement with Penlon's CEO, Penlon's Product Manager contacted the Cabinet Office to make a formal application to the 'call to arms' on behalf of Penlon.

14. The MHRA (Medicines and Healthcare products Regulatory Agency) had responded swiftly to the urgent call for ventilators during the early stages of the COVID-19 pandemic. They collaborated with the UK Government and manufacturers to fast-track approvals for ventilator designs under the newly introduced Rapid Manufacturing Ventilator Specification (RMVS) See Exhibit MPR/01 [INQ000508406] The RMVS provided guidance on the minimum requirements

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for emergency ventilators, focusing on essential functionality and patient safety. This accelerated regulatory pathway allowed companies like Penlon to adapt and manufacture ventilators at speed, ensuring that the NHS could meet the rapidly increasing demand for life-saving equipment.

15. In the 5 days following Boris Johnson's announcement, I, and Penlon's development team started to devise a solution; a hybrid intensive care ventilator created out of 3 existing CE-Marked devices; a desktop anaesthesia machine, an anaesthesia ventilator and an absorber breathing circuit, qualified as meeting the RMVS by an independent Consultant Clinician, Dr Gabor Vereczkey. After days of testing and validation, the desk-top model achieved the MHRA's Rapid Manufacturing Ventilator Specification and was submitted to the Cabinet Office. Penlon's Development Manager and I were invited to present Penlon's ESO2 Emergency Ventilator to a select committee including the Cabinet Office, NHS, Department of Health and Social Care (DHSC) and MHRA via zoom on Friday 20th March 2020.

16. By the early morning of Saturday, 21st March 2020, just hours after the Zoom presentation, Penlon's CEO was informed that the ESO2 had been selected as the "clinician's choice" for the development of an emergency ventilator for the NHS. This decision endorsed Penlon's design, manufacturing capabilities, and compliance processes for the ESO2 Emergency Ventilator, confirming the company's expertise, competence, and regulatory knowledge necessary to meet the urgent demand for ventilators. A Consortium of representatives from British Industry arrived at Penlon on the same day, Saturday 21st March, to offer their services, facilities and resources to support a scale up for mass production of the emergency ventilator to meet the pandemic demands.

17. This Consortium was led by Dick Elsy of High Value Manufacturing Catapult (HVMC). The Consortium members pledged their support, without ego, to do whatever the Penlon Leadership Team deemed necessary to deliver the number of emergency ventilators required by the DHSC for the 4 UK nations. See Exhibit MPR/06 [INQ000508431] Consortium Agreement.

18. In the realisation that the upscaling activities could never be achieved without external help, Penlon's Leadership Team assessed the offers of support from the Consortium members based on the necessary skills, manpower, experience, expertise and capacity as well as their readiness to help.

19. In the following weeks, Penlon completed the development of the ESO2 Emergency ventilator, created the associated quality management procedures and work instructions and had it tested

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at the MHRA nominated laboratory in Birmingham 'MD-Tech' under the supervision of Professor Tom Clutton-Brock.

20. For my part, I also liaised directly with the MHRA and Southampton University Hospitals, to conduct an on-patient clinical trial. See Exhibit MPR/09 [INQ000508434] In response to the successful independent testing of the ESO2 Emergency Ventilator, Penlon were granted Exceptional Use Authorisation (EUA) from the MHRA to place the device on the UK Market. See Exhibit MPR/08 [INQ000283512]. Thereafter Penlon orchestrated and managed the outsourcing to Consortium partners for the manufacturing of critical assembly parts of the ESO2 Emergency Ventilator.

21. In this, Penlon trained and qualified each of the Consortium partners under the Penlon Quality Management System for the manufacturing of critical assembly parts of the ESO2 Emergency Ventilator. The qualification process and supplier approvals were sent to the MHRA and to the Certification Body and Notified Body and were subsequently approved by the MHRA and SGS. See Exhibit MPR/10 [INQ000508407]. Numerous offers of support for the project were received, prompting the assessment and approval of new suppliers in accordance with Penlon's Quality Management System to ensure compliance. The supplier approval process for the VCUK project was identical to that employed by Penlon during normal business.

22. The volume of individuals and companies offering assistance with the ventilator challenge was substantial and difficult to quantify. Whether through social media or direct emails to Penlon's Management Team, it proved challenging for our small and medium-sized enterprise (SME) to sift through or manage all these communications effectively. The physical supply chain management of components for the ESO2 Emergency Ventilator was overseen by McLaren, while all aspects of qualification and approvals were coordinated through Penlon's Sourcing team, in compliance with our Quality Management System.

Pre-Ramp up March 2020

23. In this initial stage of escalation, the Cabinet Office procured all of Penlon's existing stock of Anaesthesia products. All existing global orders for these products were cancelled (with some units requiring an update to UK specifications) and units were rapidly deployed to the Nightingale EXEL Centre and designated Nightingale hospitals. All sales of units and spare parts to Global (overseas) customers ceased in order to support UK NHS needs.

24. Our CEO, Head of Global Service, and I were engaged with the Cabinet Office to facilitate the purchase of all existing Penlon stock of Anaesthesia machines.

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25. At this point, elective surgery in the UK was paused and all Penlon's associated staff (Service Engineers, technical/applications trainers, sales managers) were redeployed to the Nightingale centres to support the equipment and train the clinical teams. These colleagues, under the management of our Head of Global Service, had to be kept separate from the factory at Penlon HQ as part of mitigating cross contamination measures. For the first 2 months, the Penlon Nightingale Teams were isolated at the Centre and away from colleagues and family. On a day-to-day basis, the Service Engineering team were working closely with the DHSC and the deployment of these devices together with the training and support for the Clinical Staff and Electrical and Biomedical Engineering (EBME) departments.

26. In conjunction with the MHRA, I prepared a public domain statement of the use of Penlon Anaesthesia devices for long-term ventilation. See Exhibit MPR/18 [INQ000508417].

Penlon and the Ventilator Challenge UK ("VCUK") Consortium

27. Penlon's primary contribution to the national effort was the resourcing, development, manufacturing, compliance testing and independent certification of the ESO2 Emergency Ventilator. As I say, the ESO2 device was adapted from 3 existing CE marked devices and scaled up for mass production to meet pandemic demands. Penlon collaborated with a consortium of leading British manufacturers, including, amongst others, the following companies; High Value Manufacturing Catapult, McLaren, Airbus, DHL, Siemens, GKN, STI and Ford, to ramp up production quickly.

28. It was Penlon's responsibility as the Design Authority of the ESO2 Emergency Ventilator to manage and oversee all outsourced and final release aspects of bringing this ventilator to serve the NHS.

29. I would describe the Ventilator Challenge as a superbly orchestrated, a 'Perfect Symphony', alluding to the visual of See Exhibit MPR/19 [INQ000508418] of an orchestral performance that draws upon its various elements, resulting in a harmonious and well executed outcome. The motivation, drive and talents of the various skilled volunteers worked together flawlessly in collaboration and unity to save lives. See Exhibit MPR/19 [INQ000508418].

30. In summary, whilst the UK Cabinet Office remained accountable for the decision of selecting Penlon as an onshore manufacturer, Penlon was a key member of the VCUK Consortium and had the responsibility of being a legal manufacturer to:

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a) Design and manufacture the emergency ventilator for the NHS

b) Complete all associated safety testing and technical documentation assessments for presentation to the various MHRA experts

c) Redesign the footprint of the Penlon manufacturing facility itself to accommodate new production lines and equipment

d) Source storage of existing devices whilst the manufacturing facility was being redesigned by Operations Management

e) Develop a health and safety, safe distance and enhanced hygiene program pertaining to the issued COVID-19 requirements for all personnel working on site

f) Engineer and release through quality management system (QMS) new work instructions for the assembly, test and inspection for the ESO2 Ventilator

g) Support the training of the resources of the consortium partners in the assembly and test of the ESO2 sub-assemblies

h) Provision of 24/7, full induction programs to all staff hired at the Penlon site including security access cards and training.

i) Approve the Consortium partners as critical suppliers

j) Govern all production, engineering, quality and regulatory processes across the consortium involved with the ESO2 Emergency Ventilator

k) Work with hospitals and clinical professionals in the preparation of all technical & clinical documentation to mitigate risks and assure safety of the ESO2 Ventilator

l) Facilitate external laboratory involvement to provide independent 3rd party assessment of the functionality and safety of the ESO2 Emergency Ventilator

m) Whilst the virus mutated and the disease progressed, Penlon would answer to any request from the MHRA and DHSC to modify the design of the ESO2 Ventilator and redevelop new breathing modes or technical capabilities when required, under the management of Penlon's quality management system.

n) Liaise (almost daily) with the MHRA and Notified Body (SGS) for the Exceptional Use Authorisation and thereafter CE marking and UKCA marking of the ESO2 device.

31. With an initial estimate of approximately 30,000 intensive care ventilators required for the NHS, Penlon faced the immediate challenge of scaling its supply chain to handle nearly 40 times its normal annual purchasing volume in less than four months. According to Penlon's Sourcing Manager, producing 30,000 ESO2 Emergency Ventilators necessitated procuring 11.4 million individual parts from 88 different suppliers across 10 countries.

32. Penlon's existing Supply Chain and Purchasing teams were unprepared for the rapid pace and high volumes needed to meet this demand. Additionally, with many components typically sourced internationally and a sharp decline in air freight alongside global travel restrictions,

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each part and supplier required a carefully considered approach. Under McLaren's leadership, project managers from McLaren, Ford, Airbus, Quick Release, and Penlon coordinated with approved suppliers, providing daily updates during the production shortage meetings. Every supplier was integrated into the team and assigned a dedicated project manager to ensure that there was progress with their respective components.

33. To meet the goal of delivering sufficient ventilators to the NHS, it was essential to foster a "one team" ethic with a shared objective. When significant challenges arose, the procurement team relied on the expertise of the "best athlete" in each commodity area. Where Consortium members' influence or purchasing power could be leveraged, such solutions were implemented to resolve issues.

34. There was no acceptance of the status quo; there was always a commitment to resolving problems and to 'stop at nothing' until a solution was found.

35. Throughout the Ventilator Challenge, Penlon's CEO and our HR Director, alongside the Consortium Heads, were invited to join the Cabinet Office Teams meetings to provide updates of the project and the challenges we were facing. All challenges were discussed, going through available options to help us achieve our goal. At all times, the Cabinet Office representatives were on hand to discuss and/or support solutions. From a project perspective, and particularly during the height of the Ventilator Challenge, the support from the UK Government, the DHSC and the NHS was exceptional. As part of the VCUK Consortium, Penlon maintained regular contact with the UK Government, primarily through PA Consulting. There were also numerous video messages and communications of encouragement from Ministers and other senior officials throughout the project. All teams worked tirelessly to ensure the NHS was provided with the necessary number of ventilators.

36. The Ventilator Challenge encountered considerable difficulties in recruiting skilled labour. Throughout the process, there was no bias associated with any aspect of the project; everyone was hired based on their merit, motivation, and ability to fill specific skill gaps.

37. Penlon entered into two distinct contractual obligations. The first contract, established just prior to the development of the ESO2 emergency ventilator, involved the purchase of Penlon's on-site anaesthesia devices to equip the Nightingale hospitals. The second contract was for the supply of up to 15,000 ventilators (reduced from the initial estimation – refer to point 31), including their accessories, upgrades, commissioning, and servicing. Within the specified timeframe, Penlon successfully delivered 11,683 ventilators. See Exhibit MPR/03 [INQ000508428] and Exhibit MPR/04 [INQ000508429].

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38. The UK Government took steps to mitigate and assume liability for risks faced by Penlon as a key participant in the Ventilator Challenge. Given the collaboration of multiple parties in the critical development of the invasive emergency ventilator project, it was essential that all participants were assured of the terms governing their involvement. Penlon, therefore, requested that the UK Government provide indemnity against various liabilities, including intellectual property infringement, product liability, professional liability, and other related risks. The indemnity agreement is referenced in 'Deed of Indemnity' document. See Exhibit MPR/07 [INQ000508432].

In response to the Cabinet Office's approach during the Ventilator Challenge, Penlon had no concerns regarding excessive liability arising from the proposed commercial arrangements. The Penlon Executive Management Team prioritised supporting the national effort, leveraging its expertise and resources to supply the NHS with critical invasive ventilators.

While Penlon typically operates with commercial margins around 40%, the Cabinet Office imposed a 15% margin cap for this initiative. Penlon accepted these terms in recognition that the primary objective was saving lives rather than commercial profit.

During the Ventilator Challenge, Penlon partnered with several organisations with whom it had no prior relationships. This posed no concerns, as all collaborating companies voluntarily offered their support, setting aside competitive considerations to contribute to the production of compliant, safe medical devices for the NHS.

All new partners were subject to thorough evaluation and approval under Penlon's ISO 13485-certified Quality Management System. This included auditing their facilities, infrastructure, communication systems, and personnel resources. Formal contractual obligations were only entered into after approval of the Consortium partner manufacturing facilities by both the Medicines and Healthcare products Regulatory Agency (MHRA) and SGS Certification Body.

Penlon ensured that all partners agreed to comply with, and remain subject to, ongoing assessment under Penlon's robust Quality Management System procedures.

Upon reviewing the initial draft agreement, Penlon sought the advice of independent legal counsel to ensure the terms were fair and reflective of standard business practices. It was the first cross-industry consortium of its kind, so there were standard obligations to suit all consortium partners. Following this review, Penlon was satisfied that the terms were reasonable within the scope of the contract.

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However, it is important to note that the nature of the contract was unprecedented, with no prior framework or established expectations. The agreement primarily outlined that each contractual partner would be remunerated as directed by the Cabinet Office, while Penlon would assume responsibility for the design, manufacturing, and certification of the emergency ventilators.

Penlon's commitment to the Ventilator Challenge extended beyond commercial considerations. In principle, Penlon would have willingly provided its services based solely on a letter of commitment from the Cabinet Office, given the urgency of the situation. This reflects Penlon's fundamental ethos as a medical device manufacturer: to prioritise safety and save lives through the provision of reliable medical equipment.

To the best of my knowledge, the only advance pre-payment requests submitted to the Cabinet Office during the Ventilator Challenge were specifically intended to secure the procurement of materials necessary to meet the substantial demand for ventilators required by the NHS.

From a cost transparency perspective, all invoices and payments were subject to real-time auditing by management consultants and financial auditors appointed by the Cabinet Office, specifically Deloitte. This ensured full transparency and accountability throughout the process.

Penlon had no concerns regarding surplus inventory during the Ventilator Challenge. Together with McLaren, who led the procurement activities, Penlon ensured the purchase of sufficient equipment to fulfil the NHS order.

Penlon had no concerns or disputes regarding the Cabinet Office's directives on expected delivery timelines. Moreover, Penlon found no basis to substantiate or engage with external media narratives suggesting delays in the manufacturing of high-risk, complex invasive emergency ventilators.

Drawing on its extensive expertise in the design and manufacture of emergency ventilators, Penlon, with the support of its Consortium Partners, successfully scaled up production at an accelerated pace to meet the Government's then targets. This effort was further enhanced by the close collaboration of the Medicines and Healthcare products Regulatory Agency (MHRA), Penlon's Certification Body, and accredited specialist laboratories, ensuring that compliance and safety dossiers for the finished devices were completed with meticulous attention to detail.

Penlon maintained a high level of transparency and accountability by providing daily and weekly forecasts in alignment with the Cabinet Office's purchase orders. The project was

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executed with urgency, adhering to a managed, compliant, and safe process to meet the NHS's critical needs efficiently and effectively.

The Ventilator Challenge contract was relatively straightforward, with the only notable exception being the inclusion of a unique indemnity clause necessitated by the urgency created by the pandemic. No contractual terms between Penlon and its suppliers and/or the Government resulted in any disputes. While the financial constraint of a 15% margin cap presented a challenge to Penlon, the company's primary focus remained on addressing the critical shortage of invasive ventilators in the UK and fulfilling the urgent needs of the NHS to support patients and communities.

Penlon's Core Team

39. Document See Exhibit MPR/20 [INQ000508420] details the individuals at Penlon who were involved in the preparatory efforts and the decision-making process for the Ventilator Challenge, along with their specific roles, responsibilities and chain of command within the project of developing the ESO2 Emergency Ventilator as part of the Ventilator Challenge UK.

The Goal, The Pace, The Timeline

40. During the early phase of the outbreak: in March 2020, the Cabinet Office required invasive ventilators for COVID-19 primarily due to the severe respiratory complications caused by the virus in critical cases. COVID-19 was understood to lead to acute respiratory distress syndrome (ARDS), a condition where the lungs are unable to provide sufficient oxygen to the blood. In severe cases, non-invasive forms of ventilation like continuous positive airway pressure (CPAP) devices were found to be not enough to support patients. Invasive ventilators would take over the work of breathing when a patient's lungs were failing. These ventilators deliver oxygen directly into the lungs via a tube inserted into the windpipe (intubation). During the peak of the pandemic, the demand for invasive ventilators surged as hospitals needed to ensure they could provide life-saving treatment to patients suffering from severe COVID-19 symptoms. The Cabinet Office, working alongside the NHS, the MHRA and other health departments, sought to scale up the supply of these type of ventilators to manage the overwhelming number of critical cases. In addition, as COVID-19 treatment protocols evolved, it became clear that invasive ventilators were a crucial part of managing the most severe cases, prompting government initiatives to increase their availability across healthcare systems.

41. In close coordination and agreement with the MHRA, and in response to the urgent demand at the Nightingale hospitals, I drafted a formal statement on the 'off-label use' of Penlon's anaesthesia machines. This was intended to support clinicians in using these machines as an

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emergency solution for invasive ventilation, specifically for patients suffering from severe cases of COVID-19. The statement was crucial in ensuring that clinicians had the necessary guidance if using the anaesthesia machines in emergency circumstances, for ventilating the most critically ill patients. See Exhibit MPR/18 [INQ000508417].

42. The Cabinet Office subsequently issued a number of purchase orders to Penlon culminating in a requirement for 15,000 ventilators. See Exhibit MPR/03 [INQ000508428] and Exhibit MPR/04 [INQ000508429].

43. The timeline for delivering approximately 15,000 ventilators was exceptionally demanding with no established processes or precedents to follow. This initiative was unprecedented, presenting unique challenges without any prior experience to draw upon.

44. Penlon's ESO2 Ventilator Challenge was divided into 3 distinct project stages:-
Stage 1: Design, development, manufacturing, outsourcing and final release of ESO2 Emergency Ventilators together with VCUK Consortium sites, achieving 11,683 devices to the NHS. This fulfilled the requirement for the NHS as the pandemic evolved and fewer ventilators were required from the original estimation of 30,000. VCUK Stage 1 was from 20th March 2020 – 5th July 2020. With the scrutiny of both the MHRA and the independent Notified Body 'SGS Belgium', Penlon achieved the accredited safety CE Mark for the ESO2 Emergency Ventilator on 25th June 2020. See Exhibit MPR/12 [INQ000508409] for initial certificate with minor error and re-issued as Certificate Exhibit MPR/13 [INQ000508410]. The infographic Exhibit MPR/21 [INQ000508421] describes the timeline from the initial 'call to arms' from Prime Minister Boris Johnson in mid-March 2020, to delivering 11,683 ventilators by early July 2020.

45. *Stage 2*: The ESO2 Emergency Ventilator Upgrade Project. In response to data gathered by the MHRA regarding the evolving impact of the SARS-CoV-2 virus, the DHSC and NHS clinical teams requested Penlon to develop a new breathing mode tailored to support the most vulnerable patients requiring invasive ventilation. This led to the decision to recover and upgrade the 11,683 ESO2 units that had already been manufactured, prior to their redeployment. For logistical and safety reasons, the project was based at the NHS warehouse, CEVA Logistics in Lutterworth, an emergency distribution facility managed by the DHSC. See Exhibit MPR/14 [INQ000508411] & Exhibit MPR/14a [INQ000508412] for ESO2 PEEP Modification and ESO2 PEEP Project Status Report.

46. The project, overseen and funded by the Cabinet Office, operated under the expectation that all 11,683 devices would be upgraded within an aggressive three-month timeframe. Penlon

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staff, who had previously been isolated at the Nightingale hospitals, were redeployed to the CEVA Logistics warehouse, where they remained isolated from colleagues and family.

47. Given the scale of the project, Penlon was supported by PA Consulting and Quick Release to construct a temporary factory within the CEVA Logistics facility. This included setting up infrastructure for gases, electricity, heating, break areas, and temporary toilets. Additionally, 120 contract staff were hired to work around the clock in shifts to expedite the upgrades. Daily Teams meetings were held with Penlon teams and the Cabinet Office to provide progress updates and ensure the project stayed on track. VCUK Stage 2 was fully implemented from October 2020 – December 2020.

48. I subsequently made an application to the European Notified Body SGS Belgium to confirm a significant change to the ESO2 Emergency Ventilator and accredited CE Mark certification was updated. Exhibit MPR/15 [INQ000508413].

49. *Stage 3*: The DHSC approached me with a request to modify the clinical use of the ESO2 Emergency Ventilator. Originally intended for COVID-19 patients, the aim was to expand its use as a generic ventilator that could be used in an Intensive Care Unit (ICU). This adaptation would provide the NHS with greater flexibility in deploying the ESO2 device for patients requiring invasive ventilation in conjunction with other medical procedures, helping to address the backlog of operations that had been cancelled or postponed during the pandemic. See Exhibit MPR/16 [INQ000508414] & Exhibit MPR/16a [INQ000508415] for the DHSC communications in relation to the change of clinical use and the associated strategy between Dr Tom Clutton-Brock, MD-Tec and Myself.

50. To achieve this, I collaborated with several clinicians to update the clinical research and evaluation dossier for the ESO2. We then presented the revised dossier to Penlon's Approved Body, SGS. As a result, Penlon was awarded the UKCA mark for the ESO2 Ventilator, enabling its broader application within intensive care settings. See Exhibit MPR/17 [INQ000508416]. VCUK Stage 3 spanned from December 2020 until UKCA certification for the ESO2 Ventilator was granted on 16th June 2021.

51. Penlon produced a total of 11,683 ventilators from the initial concept in mid-March 2020 until July 5, 2020, coinciding with the 72nd anniversary of the NHS. See Exhibit MPR/25 [INQ000508425] for a visual of the Ventilator Challenge Team shipping the last truck of ESO2 Emergency Ventilators to the NHS Warehouse from Penlon.

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Ventilator Challenge: Penlon's Planning Assumptions

52. There were many planning assumptions that were relevant to Penlon's role in the Ventilator Challenge. The key items are described as follows.

53. Resource Shadowing: During Penlon's initial meeting with the Consortium, it became immediately evident that the scale of operations and the volume of ventilators required within the tight timeframe set by the Cabinet Office would necessitate additional leadership support. In response, the Consortium deployed top experts across various domains to provide Penlon with critical assistance and support in key areas, ensuring the successful execution of the project.

54. Facilities: In order to comply with government COVID-19 guidelines, Penlon's HR Director and Head of Operations, managed the comprehensive redesign of the Penlon HQ manufacturing facility to incorporate a one-way system, ensuring that employees could not come into direct, face-to-face contact. Access control measures were implemented, with different groups assigned specific entrance and exit routes at designated times. Shift patterns were organised around detailed workstation cleaning schedules, and each shift was assigned dedicated cleaning staff to further mitigate the risk of cross-contamination between shifts. These measures were crucial in maintaining a safe working environment while minimising disruption to production.

55. Hygiene: With support from Consortium members, Siemens Healthineers and Quick Release Management Consultancy, full risk assessments were undertaken, including use of cleaning products, frequency of cleaning all touch points, break out areas with plus 2 metre distancing in place at all times.

56. Supply Chain: The existing Penlon Supply Chain and Penlon Purchasing Team was not prepared for the speed & volumes required; to achieve the ramp up required, each part and supplier needed a considered approach. Each supplier was treated as part of the team & given a dedicated contact (project manager) to gain traction on their components. It was crucially important to be 'one team' with a common goal. Where required, strong existing business relationships and consortium influence was used. Where volumes did not reach requirements, all possible solutions were explored, often with multiple avenues followed concurrently.

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57. Purchasing: The Consortium management assigned McLaren to lead the purchasing element of the VCUK. McLaren management led a team of project managers from McLaren, Ford, Airbus, Quick Release and Penlon who liaised with approved suppliers and reported daily to the production shortage meeting.

58. Information Technology (IT) Infrastructure: While much of our core IT infrastructure was already robust, the VCUK project highlighted areas that needed urgent enhancement. One significant challenge was supporting our employees who were suddenly working from home on a much larger scale than ever before. The shift to remote work required reliable and secure access to our systems, effective communication channels, and uninterrupted connectivity.

59. Additional IT equipment: Whilst Consortium sister-sites were trained and competence increased every day, just like with all manufacturing facilities, there were day to day technical queries. One solution that supported the project greatly was the use of the Microsoft HoloLens that was supplied during the project on loan from Ford. This technology enabled Penlon's technical engineering and production staff to debug issues real-time from remote locations to other subcontractor sites.

60. Electronic Device History Records (eDHR): In parallel, on-site operations faced increasing pressure from the need to meet shorter deadlines. As the pace of production ramped up, it became clear that manual processes were causing bottlenecks. Our traditional method of using paper-based device history records was slowing down the flow of information and creating delays through a relatively high percentage of document errors or omissions in testing and approval, causing significant documentation rework. To streamline operations and eliminate these bottlenecks, a new electronic Device History Record (eDHR) system was engineered in partnership with Veeva Systems. This digital application replaced the manual paperwork, connecting all the sites involved in the VCUK into one unified platform. The Veeva Vault eDHR system allowed real-time tracking, streamlined testing, and enhanced visibility throughout the production process, significantly reducing delays and improving overall efficiency.

61. Implementing Veeva Vault eDHR solution involved training and equipping our testers with iPads, enabling them to input data directly into the system. Given the urgency of the project, it was crucial that the devices were immediately operational, even in areas with limited Wi-Fi coverage. To address this, the solution leveraged mobile cellular networks, ensuring that testing and data capture could continue uninterrupted across all locations.

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62. Secondary Site for Final Release Authorisation: As production intensified, we needed to establish another site close to Penlon to support operations. This secondary location at GKN, Abingdon which was situated across from Penlon in the same business park, required full communications and connectivity to Penlon's existing infrastructure, essentially becoming a duplicate site with mirrored services. Penlon and GKN staff worked side-by-side in the final test, inspection and release of the ESO2 Emergency Ventilator. Establishing this connection involved replicating key IT systems, extending secure network access, and ensuring that both sites were seamlessly integrated. The swift deployment of communications and connectivity solutions was essential to keeping production aligned across both locations.

Regulatory Approvals

63. As Director of Innovation Technology and Regulatory Affairs, I was Penlon's Management Representative and Person Responsible for Regulatory Compliance who requested the MHRA to issue the RMVS 'Rapid Manufactured Ventilator Specification'. On successful appointment of the ESO2 solution, I progressed with the completion of the design with the New Product Development Team and creation of the associated technical documentation and regulatory evidence in compliance with the EU Medical Device Regulation 93/42/EC to achieve Exceptional Use Authorisation.

64. In parallel, I worked closely with the MHRA Vigilance Team to devise a separate aspect of the 'MHRA Yellow Card System' to allow for any complaints relating to the ESO2. This information was included within the information provided with the ESO2 Ventilator.

65. The development and certification of the ESO2 Emergency Ventilator was overseen by the MHRA until Penlon received the internationally recognised EU CE Mark from Notified Body, SGS. During this interim period, the ESO2 was operating under Exceptional Use Authorisation (EUA), granted on the condition that Penlon maintained regular communication with the Notified Body and that the ESO2 technical file was undergoing independent assessment by SGS until full accredited certification was secured.

66. Technical File Assessment and Certification: The EUA for the ESO2 was contingent on SGS's independent review of the technical file. Continuous dialogue was maintained between Penlon and SGS to ensure timely updates and adherence to the regulatory requirements. This process ensured that the ESO2 development complied with safety and functionality standards until the formal CE certification was issued.

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67. Adaptations to COVID-19 Specifications: In the months following the receipt of the first RMVS, the MHRA introduced technical changes to the ESO2 specifications as the understanding of the COVID-19 virus evolved. See Exhibit MPR/05 [INQ000503474] which is the updated RMVS v 4. Penlon's engineering team incorporated these changes into the product development process to ensure ongoing compliance with updated standards and to enhance the ventilator's performance in response to the pandemic's emerging needs.

68. Independent Evaluation and Testing: To formally demonstrate compliance with the updated specifications and ensure the ESO2's efficacy, safety, and functionality, Penlon's Development Manager collaborated with MD-Tec, an independent MHRA-appointed laboratory in Birmingham. The ESO2 was subjected to a series of rigorous evaluations at MD-Tec to confirm that all engineering changes had been successfully implemented and met the required standards.

69. Collaboration between Penlon and the Regulators: The collaboration and transparency of communications between Penlon, the MHRA, and SGS, along with the continuous technical assessments at MD-Tec and independent hospitals and clinicians, ensured that the ESO2 Emergency Ventilator met all regulatory and safety requirements. This process culminated in the successful certification and market approval of the device, supporting the UK's response to the COVID-19 pandemic. At all times the MHRA and SGS remained fully impartial whilst assessing the ESO2 Emergency Ventilator as a safe option for our NHS patients. The collaborative effort came through the ability to prioritise communications with dedicated teams across Penlon, MHRA and SGS.

70. In summary, we did not encounter any concerns regarding the quality, safety, appropriateness, or effectiveness of the ventilators we designed and manufactured, all of which adhered strictly to medical device regulatory and quality management standards.

71. As the individual responsible for ensuring the ESO2 met MHRA specifications, as well as overseeing its safety and compliance, I was also tasked with post-market surveillance once the device was released. During this time, I received no reports indicating that the device failed to meet either the required specifications or the needs of patients. In fact, an on-patient clinical assessment conducted within the first month of production confirmed that the devices were not only safe and effective but also intuitive for clinical use.

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VCUK Consortium Collaboration

72. Penlon maintained close and frequent collaboration with all sister sites within the ESO2 VCUK Consortium, engaging in multiple daily consultations. These meetings covered a wide range of critical topics, including strategy, device cost, challenges, resource allocation, facilities, component sourcing, supplier management, training, engineering updates, and the status of the EU MDD technical file. Performance indicators were regularly assessed across all sites, with trend data analysed to monitor progress. Logistics discussions included tracking the number of sub-assemblies completed at each site daily and the number of devices released to the NHS warehouse.

73. In addition to operational details, the meetings were infused with motivational support, featuring messages of encouragement from celebrities, UK Government officials and clinical professionals, recognising and positively lifting the efforts of the teams involved. Notably, these sessions were characterised by a unified focus, with all participants working towards the shared goal, free from ego or individual agendas, fostering an environment of collaboration and collective achievement.

74. Ford were identified as the 'Project Management Lead' for the morning Consortium Executive and Operations Meetings. McLaren would lead the daily meetings for sourcing of components. Penlon would lead the daily quality and compliance meetings.

75. Due to the rapid pace at which the Consortium operated, formal minutes were not generated for every meeting. Instead, progress was often tracked using spreadsheets for reference, or team members would present their data directly to their counterparts at other sites to compare statistics, accomplishments, and challenges.

Meeting the Standards Required

76. To ensure that Penlon's ESO2 Emergency Ventilator would meet the relevant regulatory standards, I presented to the Cabinet Office, MHRA, DHSC, NHS and other stakeholders, Penlon's solution of the Emergency Ventilator as well as a history of the existing accolades that Penlon had achieved in its lifetime, e.g. 4 times winner of the Queens Award for Innovation and Export, certification to the latest medical device quality management systems ISO 13485:2016, EU Medical Device Directive 93/42/EC, independently audited against US FDA 21 CFR part 820 and cleared to place our devices on regulated markets across the globe.

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77. In mid-March 2020, the MHRA released the Rapid Manufacturing Ventilator Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak. This guidance set out the minimally acceptable clinical requirements and was based on the opinion and consensus of the anaesthesia and intensive care medicine professionals and medical device regulators. Penlon's New Product Development and Regulatory Teams, which I managed at the time, used the Rapid Manufacturing Ventilator Specification as a checklist against the development of the ESO2 Emergency Ventilator.

78. The MHRA identified MD-TEC Laboratory in Birmingham, headed up by Professor Tom Clutton-Brock, as the independent test laboratory to verify the various device submissions against the specification.

79. I requested the assistance of Dr Gabor Vereczkey, Consultant Anaesthetist at Shepton Mallet hospital to perform an independent functional and clinical safety evaluation of the ESO2 prototype against the MHRA RMVS at the Penlon site. See Exhibit MPR/11 [INQ000508408]. The outcome being that the desk-top prototype achieved all minimum specifications outlined by the MHRA.

80. On 20th March, I emailed the draft ESO2 emergency ventilator solution directly to a wide selection of VCUK stakeholders, that is, members of the Cabinet Office e.g. Gareth Rhys Williams, Dan Webster and John Lang and their Management Consultant company PA Consulting; members of the MHRA e.g. Duncan McPherson, Emma Rookes and Ben Satchell; members of the DHSC e.g. as Chris Stirling and Helen Lawrence, members of the NHS Snr Team e.g. Professor Ramani Moonesinghe (Professor of Perioperative Medicine at University College London (UCL) and a Consultant in Anaesthetics and Critical Care Medicine at UCL Hospitals) and Professor Mike Grocott (Professor of Anaesthesia & Critical Care) and others in preparation of the zoom interview with the select panel. See Exhibit MPR/02 [INQ000508419] and Exhibit MPR/02a [INQ000508426] & Exhibit MPR/02b [INQ000508427].

81. Ongoing throughout the VCUK project, Penlon's Development Manager would travel to MD-TEC to present the Penlon ESO2 prototype and each change thereafter, to evidence that the device met all safety, functional and clinical specifications.

82. Producing sufficiently scrutinised technical and clinical documentation over the first few weeks of the VCUK project to the MHRA, and in conclusion of a successful on-patient clinical assessment, Penlon were granted Exceptional Use Authorisation to place the ESO2 Emergency Ventilator on the UK market. See Exhibit MPR/08 [INQ000283512].

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Working with the NHS

83. Penlon worked in tandem with the NHS during the early days of supplying the Nightingale Hospitals with anaesthesia workstations and after the ESO2 Emergency Ventilator was brought to market, throughout the three stages of the ventilator challenge I have described above.

84. I worked directly with several independent clinical advisors to ensure that the design and usefulness of the ESO2 device would, and could, be used as intended.

85. Our Service team worked with various hospitals Electrical and Biomedical Engineering teams (EBME's) and the DHSC regarding the deployment, movement, decontamination, commissioning, training and support of all Penlon devices.

Procurement of Components

86. Penlon's procurement of components, as part of the bill of materials for each device, adhered strictly to the procedures outlined in Penlon's Quality Management System (QMS) and traceability requirements, in accordance with our ISO 13485:2016 certification. This ensured comprehensive compliance, rigorous quality control, and effective supplier management throughout the VCUK project, as it does during standard operations.

87. Given the significant production scale-up from between 500-700 ventilators per year pre-COVID to approximately 400 ventilators per day during the initial phases of the pandemic, McLaren assumed responsibility for the procurement of components as stipulated within the Consortium agreement. Their sourcing teams, well-versed in operating within environments requiring stringent traceability and supplier approvals, effectively worked within the framework of Penlon's QMS under the guidance of Penlon's Sourcing Manager.

NHS Working with Penlon's Devices

88. In the initial weeks of supplying NHS Nightingale Hospitals with Penlon Anaesthesia machines, each device was delivered with its corresponding user manual and commissioned by our Service Engineers, who also provided on-site training as needed.

89. Since the ESO2 Emergency Ventilator integrated the AV-S anaesthesia ventilator as one of its sub-components, it was clinically anticipated that professional clinicians experienced in anaesthesia and critical care would have a strong familiarity with the device's operation. This

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assumption proved correct. Each unit was supplied with a comprehensive User Manual and a simplified 'Quick Start Guide.' Additionally, in collaboration with the NHS, an instructional video was made available online for prospective users.

Expertise

90. The expertise in designing and manufacturing the ESO2 Emergency Ventilator originated from Penlon. The ability to scale production to meet the Cabinet Office's targets was made possible by the consortium's effective collaboration, functioning as an extended and unified team.

91. At every level, this remarkable partnership saw teams of people sacrificing personal time to support one another in pursuit of a singular objective: producing as many emergency ventilators as possible for the NHS to save lives. The collaboration with Regulators and the NHS was pivotal in defining the precise requirements for mechanical invasive ventilation. Meanwhile, the Cabinet Office played a key role by providing vital support to the ESO2 project, helping to overcome logistical challenges and facilitating the bulk procurement of components.

Auditing and Managing Cost

92. To ensure financial transparency in the procurement of ESO2 ventilators during the pandemic, all purchase orders for the Consortium were processed through Penlon, with goods and services recorded in Penlon's ERP Sage system, serving as a single source of truth. To support Penlon, Deloitte provided senior finance personnel on-site, who led a multidisciplinary team that focused on financial management, assurance, tax, supply chain, and governance.

93. An accurate baseline program budget was developed and agreed upon within days, resulting in minimal revisions throughout the project. The team diligently tracked and controlled costs, providing regular updates to both the Consortium senior management and the Cabinet Office regarding items such as bill of materials costs and cash flow.

94. When Penlon's established supply chain was unable to meet the increased demand, alternative suppliers were identified. Penlon was responsible for reviewing all new suppliers to ensure they met the company's quality requirements, and all new suppliers were approved to provide products for use by Penlon in accordance with its Quality Management System (QMS) requirements.

95. To ensure real-time auditing of the VCUK program's financials, Deloitte was appointed to collaborate with Penlon and the Consortium, overseeing the project's financial management.

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Deloitte assigned a member of their staff to work on-site at Penlon alongside Penlon's Head of Finance. Together, they managed the financial processes.

96. All funds from the Government, including costs for services provided by Consortium members, were channelled through Penlon. Deloitte's role was to ensure proper management of this process, maintain audit trails, and ensure accurate bookkeeping. Deloitte's fees were included in the service costs incurred by the UK Government, separate from the product costs. Penlon maintained full transparency regarding manufacturing expenses, and Deloitte's oversight ensured that all costs were accurately tracked and accounted for.

97. Part of the daily executive meetings focused on managing device costs and leveraging the Consortium's collective buying power to minimise the cost of the bill of materials and associated services. In alignment with the agreement with the UK Government, Penlon's profit margin was capped at 15%, with all financial due diligence and monitoring independently conducted by Deloitte.

98. Following the establishment of the Consortium, Penlon did not make any independent spending decisions. All major financial decisions were made collectively by the Consortium, in consultation with PA Consulting, who served as the primary liaison with Cabinet Office Ministers.

99. Penlon were not responsible for the associated costs of transporting the ventilators to the NHS central distribution hub. Sourcing for key partnerships in componentry and services was the responsibility of McLaren.

Miscellaneous Matters

100. I have been asked to comment on the Guardian newspaper article published on 4th May 2020, titled "The inside story of the UK's NHS coronavirus ventilator challenge". I stand behind my belief that this does not accurately reflect the contributions of Penlon and its Consortium partners in the design, development and upscale of the ESO2 Emergency Ventilator. In my view, the article focuses primarily on the attempted innovations by various non-medical industry leaders, highlighting their struggles to meet the stringent clinical and regulatory requirements for ICU ventilators. It neglects to acknowledge the successful efforts made to address the urgent shortage of ventilators that the UK Government, DHSC, and NHS deemed critical for patient care. The article also misidentifies the Penlon ESO2 Emergency Ventilator, referring to it as the "Penlon Prima EOS2," which is incorrect.

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101. Throughout the 18-month Ventilator Challenge, Penlon received minimal media coverage, apart from a brief soundbite from our Product Manager on local news, while the majority of public relations were handled by Consortium partner HVMC. Moreover, the third phase of the ESO2 ventilator's clinical update, which allowed its use for non-COVID patients requiring invasive ventilation, was completely overlooked by both social and mainstream media. Penlon as a legal and responsible medical device manufacturer is a well-established organisation with decades of experience in designing safe, regulated life-saving respiratory equipment. Despite this, the public spotlight never focused on the Penlon team, the innovators, regulatory specialists, operations or clinical staff, who worked 18–20-hour days during this campaign. There was no pursuit of financial gain, as Penlon agreed to a capped margin of only 15%, and in fact, the company experienced a direct loss by redirecting existing equipment meant for global customers to NHS Nightingale Hospitals to support our community.

102. While the UK Government set ambitious targets for the procurement of Ventilators that could be used in an Intensive Care environment, Penlon and the Consortium members rose to the challenge, fulfilling its mission to save lives. With the support of a small consortium of cross-industry partners, Penlon successfully delivered 11,683 CE certified ventilators to the UK NHS.

103. I have been asked to comment on whether the UK's decision not to join an EU procurement scheme for ventilators in the early stages of the pandemic had any impact on Penlon's role within the Ventilator Challenge UK Consortium or on the Ventilator Challenge itself. Personally, I do not have sufficient insight into the UK Government's policies or decision-making processes regarding such matters. My focus has always been on addressing patient needs, rather than speculate without a deeper understanding of the UK Government's decision-making process, or the underlying factors involved.

Lessons Learnt for the Future

104. There were many examples of good practice and lessons learnt from Penlon's point of view as part of the Ventilator Challenge that might be used to inform the response to any potential further pandemic. See Exhibit MPR/22 [INQ000508422] which is a top-level output produced as part of a slide deck on the valuable lessons learnt on the completion of the Penlon VCUK Consortium's work in producing the necessary number of emergency ventilators.

105. From my perspective, additional lessons for the future include:

- That the UK invests in onshore design and manufacturing for devices required for a future pandemic and that these devices are maintained as a minimum as part of the national reserve to serve the 4 nations and other geographies where needed. This

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is because of the UK's reliance on imported goods, especially from China (equipment, parts, raw materials) is far too great and poses a real risk.

- There was an initial target set of sub £10k per emergency ventilator which was achieved by onshoring the manufacturing and development and upscale of the ESO2 Emergency Ventilator Production, a more commercially viable solution to purchasing equivalent CE marked devices from overseas.
- There was unparalleled access to high-ranking members of the UK Government who would work dynamically with Industry, removing roadblocks as the project progressed, even as far as to authorise the passage of individuals going about their business to support the Ventilator Challenge during lock-down.
- The removing of 'Ego and bureaucracy' amongst the VCUK members, there were boundaries established as to who were the decision makers at Penlon and that the Consortium efforts were there to support and enable the Penlon ESO2 solution to be upscaled.
- The value of innovation, speed and collaboration across industries to serve a common goal.
- No-one was industry centric, only with a single goal to save lives, the focus was serving our communities and hospitals.
- Highly effective collaboration between some of the best resources that Britain can offer; cross industry expertise leading to fast data-driven decisions across complex problems, coupled with decades of proven experience and regulatory boundaries.
- The generosity across supply chain. Across the board, our partners, both long-term collaborators and new allies, recognised the urgency of the situation. Many stepped up with offers of services and equipment, often provided free of charge and without any expectation of repayment, a spirit of shared responsibility.
- In essence, I believe that The Cabinet Office may have saved time, money and effort if they had been better attuned to the regulatory requirements that relate to medical products, by this I mean that several projects were launched and funded that had no chance of being used on patients within a useful timescale.
- Ultimately the lack of an Industrial Policy to support the next pandemic by several generations of UK Governments was visible. There are very few, if any, UK manufactured ICU ventilators, PPE and many other essential items. The UK was therefore put in a vulnerable place and had to rely on the policies of the Governments in the other countries where these medically essential products are made. Furthermore, the NHS purchase policies make no effort to purchase UK manufactured products where they are available, even when such equipment is less expensive. If these mistakes are not being addressed, it may once again become apparent when the next pandemic occurs – 'Build Coalition, not Concern'.

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Given the urgent nature of the perceived need for invasive ventilators, I believe that the time constraints did not allow for the Ventilator Challenge to be conducted as a competitive dialogue, an innovation partnership, or a procurement process for research and development services. In my opinion, the Prime Minister's call to arms was a direct and urgent appeal to the nation to mobilise resources and deliver the critical equipment needed to save lives, as the available supply was insufficient to meet the country's needs. This urgency was driven by the clinical expertise of the NHS, the Department of Health and the MHRA Competent Authority, which identified an immediate and pressing demand for ventilators.

106. It is not my place to comment on the internal politics or challenges faced by the UK Government during the procurement of ventilators. However, as part of the Ventilator Challenge Consortium, Penlon encountered several project challenges, which are detailed in Exhibit MPR/23 [INQ000508423] (Initial Project Challenges) and Exhibit MPR/24 [INQ000508424] (Engineering Challenges).
I have also provided additional commentary below:

- Given the UK's limited manufacturing capacity for anaesthesia and invasive ventilation equipment, outsourcing production to non-medical manufacturers and partners required continuous consultation with individuals possessing specialised knowledge. As someone involved in the design of the ESO2 Emergency Ventilator, I was primarily responsible for managing teams, liaising with clinical experts, overseeing the outsourcing and approval of Consortium sister sites, ensuring documentation accuracy, and maintaining compliance and safety for every device manufactured. This role demanded extensive working hours, with my first meeting typically starting at 6:30 am and my day often ending around 1:00 am, after reviewing and tabulating manufacturing data and production faults for the next morning's meetings. Working around the clock for months was both humbling and rewarding, but also extremely exhausting.
- I also recall our HR Director, working split shifts to ensure she was available across all production shift patterns within a 24-hour period, only taking brief rests before returning on-site for handovers.
- The scale-up from approximately 100 to 500 personnel on-site, while adhering to COVID-19 workplace guidelines, presented a significant challenge. Project management support was enlisted to assist the Head of Operations and the HR Director in reorganising the factory layout, managing access permits, providing adequate restroom and dining facilities, and organising shift patterns to accommodate the increased workforce. Full induction programs were provided to all

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staff; site maps, COVID questionnaire, H & S induction, secured access cards and training. All levels of competence were assessed through skills and experience which was prescribed through the Penlon QMS.

- Part shortages were an ongoing issue; however, with the Consortium's considerable buying power and McLaren's leadership, no challenge proved too difficult to overcome.
- Differences in documentation practices between industries also caused early project delays. While some industries relied on electronic documentation formats, Penlon initially used physical paper records. This issue was addressed by transitioning to an electronic device history record (eDHR) Veeva Vault system, which helped streamline operations and prevent further delays.

Conclusion

107. As we await the findings of the COVID-19 Inquiry and the assessments of others regarding the decisions made about the critical care ventilator appeal and the necessity of procuring sufficient medical devices, I believe that the contributions of Penlon and the broader consortium deserve recognition. These organisations stepped forward selflessly, demonstrating unwavering commitment to protecting the most vulnerable in society. For the first time since World War II, industries from all sectors united to serve the four nations, ensuring the provision of emergency ventilators to our NHS and supporting our communities throughout the pandemic.

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.

PD

Mary Patricia Ryan

Director of Innovation, Technology and Regulatory Affairs

Penlon Limited

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Annex A: Exhibits Schedule for the Witness Statement of Mary Patricia Ryan

Exhibit Ref	Date	Document Information	Statement Paragraph Ref
MPR/01	16th March 2020	MHRA Ventilator Specification RMVS V1	14
MPR/02 MPR/02a MPR/02b	20th March 2020	Penlon ESO2 Device Submissions to Cabinet Office, DHSC, NHS and MHRA	80
MPR/03	26th March 2020	Cabinet Office Confirmation of Order 5,000 devices.	37,42
MPR/04	29th March 2020	Cabinet Office Confirmation of Order 10,000 devices.	37,42
MPR/05	10th April 2020	MHRA Ventilator Specification RMVS V4	67
MPR/06	12th April 2020	Consortium Agreement	17
MPR/07	12th April 2020	Deed of Indemnity	38
MPR/08	15th April 2020	ESO2 Exceptional Use Approval - Penlon Site, by MHRA	20,82
MPR/09	15th April 2020	Clinical Ventilator Assessment - Patient Trial, Southampton Hospital.	20
MPR/10	30th April 2020	MHRA Exceptional Use Authorisation of Penlon ESO2 and additional consortium manufacturing facilities.	21
MPR/11	27th May 2020	ESO2 Independent Clinical Evaluation Summary	79
MPR/12	24th June 2020	ESO2 CE Certificate - Incorrect	44
MPR/13	25th June 2020	ESO2 CE Certificate - revised certificate wording	44
MPR/14 MPR/14a	14th Sept 2020 18th Oct 2020	Request & Status for Clinical Scope Modification of ESO2 to include 'PEEP' function - DHSC & CO PEEP Status Report _ M Ryan & PA Consulting	45
MPR/15	1st Dec 2020	CE Certificate for ESO2 for 'PEEP' Modification	48
MPR/16 MPR/16a	10th Dec 2020 6th Dec 2020	Request for Clinical Change of Use Scope Modification from DHSC and MHRA (non-COVID-19 patients) Combined strategy for Clinical Change of Use Scope, MD-Tech & Mary Ryan	49
MPR/17	16th June 2021	UK MDR UKCA Certificate ESO2 (removing specifics for COVID-19 patients)	50
MPR/18	30th March 2020	Anaesthesia Devices Off Label Use Statement MHRA Approved	26, 41
MPR/19	2024	"Perfect Symphony"	29
MPR/20	2024	COVID19 Inquiry Penlon & Consortium Key Individuals	39
MPR/21	2024	Stage 1_The Goal, The Pace	44
MPR/22	2024	VCUK Key Learnings	104
MPR/23	2024	VCUK Initial Project Challenges	106
MPR/24	2024	ESO2_Engineering Challenges	106
MPR/25	2024	Happy Birthday NHS	51

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