UK COVID-19 INQUIRY

WITNESS STATEMENT OF PAUL WEBSTER

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Statement No.: 1
Exhibits:
PBW1-INQ000347819
PBW 2-INQ000347820
PBW 3-INQ000347821

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MODULE 3 UK COVID-19 INQUIRY

WITNESS STATEMENT OF PAUL WEBSTER

I, **PAUL BARNABY WEBSTER**, will say as follows:

1 My role in assisting the Inquiry on behalf of Supply Chain Coordination Limited

1.1 I am the Executive Director of Governance, Assurance and Legal as well as the Company Secretary of Supply Chain Coordination Limited ("SCCL").

1.2 I am part of the team responsible for the management of SCCL and ensuring that SCCL is managed appropriately, being wholly funded by public money. I also perform the role of SCCL's in house counsel.

1.3 I have been directly employed by SCCL since October 2022. Before this date I was seconded to SCCL from the Government Commercial Office starting from the incorporation of SCCL in July 2017. Before SCCL's incorporation, I was part of the Department of Health and Social Care ("DHSC") team which set up the new operating model for the management of the NHS's purchasing and logistics function as far as it applied to medical devices and clinical consumables (as part of which SCCL was incorporated.)

1.4 I have been asked to provide this statement, on behalf of SCCL, to assist Module 3 of the Inquiry to consider the impact of the Covid-19 pandemic on healthcare systems in England, Wales, Scotland and Northern Ireland, particularly focussing on the period 1 March 2020 to 28 June 2022.

1.5 The information provided below is either information that is directly within my knowledge or, where that is not the case, I have consulted with colleagues in the preparation of this statement and therefore the information is corporate knowledge.

2 Role, Functions, Accountability, Statutory Powers, Legal Status and Responsibilities of Supply Chain Coordination Ltd across the four nations of the UK

2.1 SCCL (a company limited by shares) was created on 25 July 2017 by DHSC.

2.2 It was initially wholly owned by the Secretary of State who provided direction to the company through an appointed director on the SCCL Board. It was subsequently transferred to the ownership of NHS England/Improvement on 1 October 2021. It remains a separate organisation from NHS England.

2.3 The Future Operating Model ("FOM") for NHS Procurement was implemented in June 2017. The aim of the FOM was to move the majority of non-pharmaceutical procurement to one centralised body namely SCCL.

2.4 SCCL began operating in April 2018. It took full responsibility for the operation of the NHS Supply Chain from April 2019.

2.5 Historically, the NHS Supply Chain provided clinical consumables and non-pharmaceutical products only to NHS Trusts. Those Trusts were Acute, Mental Health, Community and Ambulance Trusts in England. The NHS Supply Chain does not normally supply GPs, community care organisations, care homes, social care nor dentists. This continued to be the case once SCCL began operation in April 2019.

2.6 The NHS Supply Chain was set up to manage the supply of these products in England only. From time to time, we have broadly done the same work, supplying the same products with and for the devolved health systems but that would constitute a very small percentage of our "business as usual" activity.

3 Role and Functions of SCCL in responding to the Covid-19 Pandemic

3.1 SCCL is purely a transacting body rather than a decision-making body. Its contracting and finance functions were used to facilitate solutions during the pandemic, for example facilitating payment for PPE. However, at all times SCCL acted on the express instructions of Central Government (including the Cabinet Office), DHSC, NHS E/I, PHE and the Army. SCCL had clear delegated authority from DHSC in relation to

any aspects of the pandemic response in which we were involved which were outside the scope of our business as usual activities, for example, contracts for additional storage.

3.2 SCCL had no role in determining the response for a pandemic such as:

3.2.1 What type of pandemic should be prepared for (e.g. influenza or a previously unknown cause);

3.2.2 What planning assumptions should be prepared for;

3.2.3 What products and in what quantities were required to meet those planning assumptions;

3.2.4 How the pandemic response would be delivered.

3.3 While SCCL was responsible for the management of NHS Supply Chain from April 2019 it contracted out both procurement and distribution to contractors, who in turn contracted with suppliers. Procurement was organised into a number of 'Towers'.

3.4 Demand for almost all non-pharmaceutical items due to Covid-19 was completely unprecedented. As a result, NHS Supply Chain struggled to meet its 'business as usual' commitments as well as, in particular, trying to keep up with the increased demand for PPE. Accordingly, an entirely separate PPE supply chain, involving procurement via the Cabinet Office, was set up with separate logistics provided by Clipper and the Army.

3.5 SCCL were also involved with the management of two stockpiles: the EU Exit Stockpile; and the Pandemic Influenza Preparedness Programme ("PIPP") Stockpile. As set out above, SCCL made no decisions as to planning assumptions or the nature or quantity of products required. Its management involvement in respect of these stockpiles was as follows:

3.5.1 The EU Exit stockpile held approximately 6 weeks' worth of all relevant products. SCCL were directed by DHSC that the stockpile should be used as part of the Covid-19 response. Please see paragraph 7 below for more information.

3.5.2 The PIPP stockpile was owned and managed by what was then Public Health England (PHE) on behalf of DHSC. PHE then contracted with SCCL

to manage the stockpile and SCCL subcontracted the storage and distribution roles to Movianto, a private contractor. SCCL therefore provided PHE with advice on logistics and supply chain management for the PIPP stockpile. Please see paragraph 8 below for more information.

3.6 During the pandemic SCCL were also involved in the establishment and equipping of the new "Nightingale Hospitals". A dedicated ICU supply chain was therefore set up. Please see paragraph 11 below for more information.

3.7 The last national pandemic test (Operation Cygnet) took place in 2016 (prior to the incorporation of SCCL) and therefore SCCL was not involved in national testing of pandemic response.

4 Government Departments, Agencies, Public Bodies, NHS Organisations and Advisory Groups with whom SCCL co-operated/worked closely in response to the Covid-19 pandemic

4.1 SCCL were part of a large response team which was made up of many national organisations. We primarily took our instructions from DHSC and NHSE. Others were also part of the response team, such as the Cabinet Office and the Health and Safety Executive ("HSE"). We had some limited communication with the Foreign and Commonwealth Office ("FCO") in relation to products being purchased from, for example, China. In addition, we would have had limited contact with the National Institute for Health and Care Excellence ("NICE"), Medicines and Healthcare Products Regulatory Agency ("MHRA") and the Office for Product Safety and Standards ("OPSS"). No separate co-operation agreements were put in place.

4.2 Aside from this there was the normal course of business interactions with Trusts which is set out in more detail in paragraph 5 below.

4.3 The role of SCCL during the pandemic was twofold:

4.3.1 Administering and managing stockpiles: in respect of which we took instructions from PHE; and

4.3.2 Purchasing and distributing medical products and consumables. In respect of PPE purchase and distribution this was at the direction of the Cabinet Office, DHSC and NHSE response teams and it was distributed via Clipper. For non-PPE items we purchased and distributed items in accordance with

the requirements of individual Trusts placing orders and in line with our business as usual procedures.

4.4 Throughout the crisis we acted on the express instructions primarily of:

4.4.1 DHSC: for example, see the Secretary of State's letter dated 1 April 2020 to receive instruction to purchase and to disapply normal expectations on PPE standards Exhibit PBW1 (INQ000347819).

4.4.2 PHE: Re Stockpiles

4.4.3 NHSE/I: Instructions around demand management and 6pm allocation meetings

4.4.4 The Army: who stepped in to provide logistics support and facilitate solutions which culminated in a separate PPE Supply Chain by 27 March 2020 managed by Clipper Logistics (now GXO).

4.5 From about February 2020 regular daily calls were instigated at 8.30am every morning between stakeholders at SCCL, PHE, DHSC and NHSE/I. The initial reason for these calls was as a result of an increased demand for certain products, linked to concerns about what was happening in other parts of the world (principally the Far East). At 8.30am all stakeholders would plan what needed to be actioned for the rest of the day in order to co-ordinate responses.

4.6 Update calls also took place at 10.00am, 2.00pm and 6.00pm.

4.7 The 6pm call (the daily demand management process / situation report with Clipper) covered what stock of PPE products and associated consumables existed where, where the demand was and how PPE might be targeted to particular locations. That enabled decisions to be made on inventory and requirements, creating a "pick list" for Clipper.

4.8 On 1 April 2020 the Cabinet Office took responsibility for purchasing decisions on PPE, setting up a PPE procurement cell (in conjunction with a dedicated supply chain for PPE). The cell made use of SCCL's established frameworks for medical products and several people, involved in purchasing PPE products from the Category Towers were seconded into that cell. However, the cell was managed by a combination of the Cabinet Office, NHS England and DHSC so SCCL's role in it was limited.

5 Communication with NHS Trusts to establish the supply of medical devices or equipment they required

5.1 SCCL was set up to service approximately 240 NHS Trusts and Foundation Trusts (in multiple locations and with multiple delivery points at those locations) in respect of a catalogue of business as usual products, via bulk deliveries. However, even under the FOM, it was never anticipated that SCCL would be the sole supplier to all Trusts and for all products. A number of Trusts had, and continue to have, their own procurement teams who source products directly from suppliers. This was the case prior to the start of the pandemic and continues to be the case even now.

5.2 Of those Trusts which did use SCCL not all customers buy the same amount. Some buy almost nothing and obtain deliveries from elsewhere. Some buy almost everything via SCCL and we are constantly discussing their requirements with them to some level or other. Those discussions increased as concern about Covid-19 grew.

5.3 From mid-February 2020 SCCL started to experience Trusts significantly increasing their orders. This was for all product lines, not just PPE. This was comparable to what was happening in supermarkets, as effectively Trusts were starting to stockpile too. It is important to understand that this stockpiling was not just for PPE and healthcare products but for many different items, and the demand included non-essential lines such as a 780% increase in demand for Penguin biscuits as an example. SCCL was also receiving orders from Trusts which had never ordered items or particular lines of items through it before.

5.4 A standard logistics response to a big increase in demand is to contact customers and seek to understand why they are ordering quantities greater than normal and with their agreement cancel down orders to a lower level. Typically, in order to protect stock levels SCCL would implement some demand control/rationing if possible. This would be similar to supermarkets limiting customers to the number of (for example) toilet rolls which they could purchase which was witnessed early on in the pandemic. This type of product rationing was an SCCL decision but is a standard methodology for dealing with a surge in demand and was supported by DHSC.

5.5 The level of demand for PPE and other healthcare products reached unprecedented levels by March 2020. On 18 March 2020 we were instructed by DHSC to ship as much as possible and this effectively lifted our 'rationing' on PPE by trying to control demand. This was SCCL's decision but based on the instructions it received from

DHSC. As a result, Trusts placed large "surge" orders considerably out of line, in most cases, with actual need. Demand reached record limits across PPE items. Demand for non-PPE also continued at peak levels. The peak daily demand reached 220,000 different individual product items (or SKUs "Stock Keeping Units"). By comparison, the demand figures for the same date in March 2021, 2022 and 2023 were 122,199, 144,532 and 126,224 SKUs respectively.

5.6 As set out above, demand from all customers increased, including from those who had not traditionally bought through us. What those other procurement teams were starting to find was that traditional lines of supply were closed down or exhausted so they all began to turn to SCCL. The behaviours exhibited by Trusts were a constant challenge. As an example, if we said a product was subject to demand management then Trusts would try to get around any restrictions imposed by (for example) ordering from multiple different requisition points within the same Trust. This happened irrespective of a resilience plan and the behaviours exhibited were analogous to the activity of the general public, namely stockpiling.

5.7 A major difficulty with the system as it was set up was that, while SCCL had an idea of what was being ordered by Trusts, it had no way of tracking what the individual Trusts actually already had as there was no centralised information on inventory. As such, it was quite likely that a Trust could be ordering more of a particular product while it already had significant existing stocks while another Trust might be legitimately ordering because it had run out. There was no way of tracking individual stock-holdings once the order had been delivered.

5.8 Accordingly, we did not have any way of tracking what Trusts ordering from us already had, in order to prioritise one Trust over another or one product over another. Our lorries have finite capacity and can only make a certain number of deliveries per day. Therefore it was recognised that a demand led system would not work. As such, around May / June 2020 Palentir were commissioned by DHSC/NHSE to develop a dashboard to attempt to gather the information to show what inventory was where and what the actual need was.

5.9 It is not possible to identify a particular Trust where there were particular problems with supply. They all had similar problems in that they changed their order pattern and looked to us to meet that when all other avenues that they may have previously bought through were constrained and everyone had supply issues.

5.10 On 1 May 2020 a letter was sent to all Trusts from DHSC (signed by Jonathan Marron and Emily Lawson of NHS England) directing that procurement of PPE should take place on a national basis and not by individual NHS organisations competing with one another for the same supplies.

5.11 The absence of a centralised inventory management system clearly gave rise to serious issues during the pandemic. SCCL is taking steps to address this in conjunction with NHS England and to instigate an inventory management system in more NHS Trusts but the extent of funding available for this is limited at the moment so progress is relatively slow. At the moment, only a relatively small number of NHS Trusts have an inventory management system. We would recommend that all Trusts have an inventory management system but we acknowledge that it comes at a cost.

6 Overview of healthcare products sourced, delivered and supplied prior to the Covid-19 Pandemic

6.1 In 2018 (May and July), NHS Supply Chain implemented the new FOM with 11 Category Towers Service Providers (CTSPs).

6.2 All products that NHS Supply Chain buys for customers are part of a specific category of products and categories were then allocated to one of eleven Category Towers of which six covered medical products, two dealt with capital products and three non-medical products. Each CTSP was responsible for developing and implementing a specific strategy for each of its relevant category of products.

6.3 There are two other elements to the Category Tower model dealing with logistics (warehouses and delivery) and IT.

6.4 The eleven CTSP contracts were established across seven separate service providers. Some providers have responsibility for more than one Tower.

6.5 The diagram at Exhibit PBW2 (INQ000347820) shows the high- level construct of the CTSPs and who the Service Providers were.

6.6 Each CTSP contract ran for an initial period of 3 years with two 1 year extension options.

6.7 The primary aim of the FOM was to:

6.7.1 deliver a cumulative £2.4bn of savings to the NHS; and

6.7.2 increase market share through the model to above 80%.

6.8 Prior to the pandemic, there was no specific category of PPE due to the relatively small amounts of products required each year. Items of what would now be categorised as PPE were procured mainly by Tower 2 but also by Tower 3 (hand hygiene) and Tower 11 (polymer – aprons, body bags, clinical waste bags).

6.9 As part of a programme of continuous improvement and lessons learned we have recently consolidated medical, clinical and consumables into a single category and brought the procurement in-house

7 SCCL's involvement with the management of the EU Exit Stockpile

7.1 In 2019, at the request and upon the instruction of the DHSC, SCCL procured a defined list of products and quantities that were to be used in the event of disruption following a no-deal exit from the EU. SCCL was the purchasing entity but had no role in deciding what or how much went into the stockpile. SCCL was responsible for cycling the products through, which means putting them into the main system and purchasing replacement stock.

7.2 The stockpile was put in place to address concerns about the implications of a "no-deal" exit from the EU and was co-ordinated by the DHSC and consisted principally of products that had to come into the country via the EU. Products that came from outside the EU were considered less vulnerable to the effect of a no-deal. The intention was to hold approximately six weeks' worth of stock of all the relevant products. The majority of the stockpile was situated outside of the core NHS Supply Chain network in one of two sites in the North-West.

7.3 Following the election in November 2019, SCCL were instructed to decommission the stockpile and all of the infrastructure that went with this was also removed. This included the National Supply Disruption Response team which was set up to co-ordinate the response and advise on priorities in the event of shortages. SCCL were also instructed to cycle the stock through its business as usual operation rather than ordering further products from the relevant suppliers. SCCL did not provide any advice on the logistics or management of the stockpile or how it should be decommissioned other than as set out below.

7.4 Things began to change not only when the impact of Covid-19 began to be understood but also because there had started to be a change in thinking about EU Exit planning in view of the hard stop on the transition period.

7.5 A review had just been initiated into what would be needed ready for January 2021 when Covid-19 hit. At that point, there was a clear direction from senior officials within DHSC that the stockpiles should be used as part of the Covid-19 response. There was a very clear direction about that in relation both to the EU Exit stockpile and the PIPP stockpile. Again, SCCL did not provide advice on the logistics or management of the stockpile as part of the Covid-19 response other than set out above.

8 SCCL's involvement with the Pandemic Influenza Preparedness Programme Stockpile

Intended Use

8.1 The objective of the PIPP stockpile was to ensure that the nation had a deployable depth of stock which could deal with the demands of a flu pandemic.

8.2 It was brought in following the 2009 swine flu outbreak to support the supply chain in the event of disruption and to cover the first waves of supply to the NHS.

8.3 The stockpile required a significant pallet hold (54,000) with some stock retained for long periods of time in storage. However, the procurement of the contract was based on the modelling for a flu pandemic which requires a particular sequence of products: first of all it requires a pharmaceutical response, the availability of anti-virals, and then supply chain support to hospitals of consumables, including PPE. This was an established model but not one that matched the needs of a Covid-19 outbreak.

Who decided what the stockpile should be used for?

8.4 The stockpile was established as part of a joint project between the DHSC and Public Health England (PHE). The NHS Business Services Authority (NHSBSA) was used as the vehicle for procurement of the products and the set up and management of the logistics arrangements. The strategy: which products were required and in what quantities, what locations the products were to be delivered to in what quantities, lead time and frequencies etc, was determined by the DHSC/PHE.

Who owned and managed the stockpile?

8.5 Originally the stockpile had been controlled and managed by DHL, as part of a supply chain contract put in place by the DHSC in 2006 and which was managed on its behalf by NHS Business Services Authority ("NHSBSA").

8.6 DHL were replaced by Movianto following an open procurement process in 2018. The new contract differed from the contract that had existed with DHL with an updated specification based on storage and distribution and with no procurement element as procurement was carried out via SCCL's business as usual arrangements. Responsibility for the management of the contract transferred from NHSBSA to SCCL when SCCL took over responsibility for NHS Supply Chain (as set out in paragraph 2 above).

8.7 Movianto operated from two sites, with two pharmaceutical grade warehouses in Bedford where the anti-virals could be stored and from where they could be pushed out to the South East of England, as the most likely place for serious numbers to be in a flu outbreak. The consumables are located at Haydock and would be used to backfill the supply chain sites around the country as needed.

8.8 The plan for a flu pandemic involves providing pharmacies with anti-virals. Hospitalisation from flu was considered less of an issue but there was an expectation of an increased demand for consumables including PPE. Under the flu pandemic modelling PPE would have been purchased and distributed through the normal supply chain with the stockpile being used to backfill that supply chain based on demand.

8.9 However, this modelling was not appropriate for the Covid-19 response. There was no requirement for anti-virals and the volumes of PPE required were significantly greater than those modelled for a flu pandemic.

8.10 An SCCL team managed the contract with Movianto to ensure they are performing to the contract. The SCCL Finance team hold the financial records and stock information for all the products.

8.11 The procurement of the pharmaceutical products follows a similar process. Whilst somewhere in the region of 60 to 70% of the stockpile is made up of consumables, the pharmaceutical products account for the majority of the financial value. PHE were responsible for the pharmaceutical procurement and it followed exactly the same forward planning process.

Size of the stockpile

8.12 I attach at Exhibit PBW3 (INQ000347821) a product list showing which products SCCL intend to stock rotate through NHS Supply Chain BAU going forward.

8.13 The list of products was created as a result of modelling used to inform the PIPP in 2009/2010 and owned by the DHSC. The product requirements were based on anticipated increases in use of these PPE and medical consumable products during the realistic worst- case scenario over a 26 week influenza pandemic. Subsequent changes to the product type or target volumes were made on the recommendation of the New and Emerging Respiratory Virus Threat Advisory Group which is an expert committee of DHSC (NERVTAG) and the Clinical Countermeasures Board (chaired by PHE/UKHSA). Most products were at target volume pre Covid-19. The only exception was gowns which had only been approved for procurement by NERVTAG in November 2019 and in respect of which SCCL was in the process of undertaking market analysis. Paper towels were not being replenished as they were not used widely during Covid-19 or Bird Flu. Due to the reduction in other hospital activity and visitors BAU supplies were able to support Covid demand.

8.14 **Changes to the Product List**: Some of the volumes of products changed influenced by the threat of Avian Flu and the availability of product from the PPE Cell stock - most notably gloves. The list of products remained largely unchanged, although it should be noted DHSC set up a Strategic Reserve of essential equipment that can be used to equip Nightingale type facilities in the event of another public health emergency. SCCL understood stocks of 1,000-3,000 items that would support each bed space were held, including beds, ventilators, pumps etc., Separately DHSC commissioned the UK Countermeasures Review which reported in October 2022 and they were evaluating this to decide what new products may be included and what adjustments to target volumes may be required.

8.15 During Covid-19 the DHSC took responsibility for PPE utilising products as part of their responsibility for the PIPP stockpile while UKHSA retained responsibility for the medical consumable products on the stockpile list as these largely supported vaccine administration and pharmaceutical treatment of patients.

8.16 **Shelf Life**: Most products have a 60 month shelf-life from the point of manufacture. Following discussion with the relevant manufacturers, some products (mainly FFP3 respirators) had their shelf-life extended for up to 10 years after 6 month accelerated

aging. Shelf life would only be extended after rigorous and approved testing usually undertaken by the original manufacturer. It involved sending off batch samples that are then 'accelerated aged' by aging them in a type of kiln for 156 days. The item will then be re-tested (either by the manufacturer or an independent tester) to validate its suitability for on-going use and performance. When product is in the stockpile and deemed appropriate for shelf life extension then this would be considered at 42 months. This would give time to prepare and send the samples for testing, having it aged tested and independently evaluated with the aim to complete this before the original expiration date. PHE in consultation with the manufacturer and the logistics provider would make that decision. Shelf life extensions had been carried out routinely since 2013/2014.

8.17 Once re-evaluated and approved the logistics provider (SCCL at the time of the pandemic) would re-label the product. Often a new label will be placed over the old label with a new expiry date. This is done to avoid damaging the product as might happen were the original label to be torn off and replaced. In any case, the labels actually come from the manufacturer of the products who, by doing so, are endorsing the new expiry date.

8.18 Before the start of the pandemic, the only product that had been stock rotated through NHS Supply Chain BAU activities was examination gloves. Stock rotation means shifting the stock from the stockpile and into the SCCL business as usual supply chain as it begins to approach its expiry date. This is to ensure that the product can be used within its shelf life rather than sit in the stockpile unused possibly well beyond its expiry date after which it can no longer be used. This stock rotation will usually take place in the last 15 months of the product's 36 or 60 month shelf life. This meant that DHSC only had to fund the purchase for PIPP once with replenishment funded through the sale of stock as it was cycled from the stockpile to business as usual. It also avoided the cost of waste, disposal and handling costs. Any high volume business as usual product, such as gloves, might be considered for stock rotation.

8.19 In addition to stock rotation there were some product exchanges and product swap outs. Product exchanges occurred where there had been, for example, production problems (aprons) or a change in specification (clinical waste containers). In those circumstances, PHE would agree to supply PIPP stockpile products into BAU which would then be replaced with the disruption had ceased.

8.20 Product swap out means that when a product goes out to tender bidders are offered the opportunity to include a 'swap out'. If a 'swap out' bid is accepted then this is set out in the contract. For example, a supplier may bid 45p for a cannula with a 60 month shelf life or 54p for a canula with a 'swap out' effectively offering a 90 months shelf life. Under this arrangement, the canula would be collected by the supplier after 30 months and replenished with new cannulas with a further 60 month shelf life. Effectively giving a 90 month shelf life within the stock pile. The original stock would then be sold by the supplier to their own customers. For DHSC a swap out represents effectively a longer shelf life within the stockpile and a significant saving over the whole life of the contract and for a supplier it enables them to maintain, or increase, market share.

8.21 Product Cycling: here I describe the process as it existed at the start of the pandemic. By the nature of the stockpile there were items in it that were there for some time but which also could not all be cycled into the normal supply chain as they got close to expiry because the normal demand did not match the amount of product retained. All of the information on incoming products was recorded and retained, including expiry dates where applicable. Movianto's responsibility was to capture the data, maintain its integrity and provide it in a report. That report was reviewed monthly by an SCCL team. The purpose of the review was to give a forward view of the inventory, look at expiry dates and, as necessary, arrange for re-testing of the product or the procurement of new product with the older product either being cycled into the normal supply chain or disposed of. The review focused on a procurement cycle of about 12 months. There were two broad categories of product movement: cycling product as part of the normal procurement cycle as described above or looking ahead and anticipating a degree of supply chain disruption and therefore asking UKHSA for permission to take inventory from the stockpile and then back fill and replenish that stock. In both cases, SCCL was concerned with value for money and has to prepare a business case which then goes to UKHSA to be signed off.

8.22 SCCL do not authorise any of the procurement decisions, it is required simply to present the business case to UKHSA and it is UKHSA's responsibility to authorise all decisions whether to go ahead or not. SCCL feed all procurement decisions from UKHSA to the CTSPs to instigate. A similar arrangement applies to any new items added to the stockpile. It is the responsibility of UKHSA to translate any government instruction into a procurement direction that can be implemented by SCCL. For example, when NERVTAG made a recommendation towards the end of 2019 for aprons to be added to the stockpile, it was PHE's responsibility to take a decision on

whether or not to comply with that recommendation. In many cases, SCCL would not be aware of the recommendation, but on receipt of an instruction would look at how the products could be procured, the likely timing and value for money and then wait for authorisation from PHE to proceed.

8.23 **Product Testing**: See sub-paragraph 8.16 above.

Advice that SCCL provided on logistics / management of stockpile

8.24 Any movement of product back into the normal supply chain would happen on the instruction of UKHSA following preparation by SCCL of a business case to obtain the necessary authorisation.

9 Safety, Quality and Efficacy

9.1 We have been asked to comment on any issues about which SCCL became aware relating to the standards of safety, quality and efficacy of any types of medical devices or equipment during the relevant period, as far as they are relevant to Module 3, and any action taken by SCCL in response to such issues.

9.2 It is our view that any issues which arose in relation to medical devices or equipment arose due to problems with availability and not problems of safety of the products themselves. As demand grew exponentially for all items of PPE there was limited world-wide product which countries around the world were trying to buy. The issue of safety arose in relation to ensuring sufficient items were available for the NHS to operate and that products which were being ordered met or matched applicable safety standards.

9.3 Our Clinical and Product Assurance team ("CaPA") ensured that products procured were fit for purpose and safe as well as meeting user needs and the then applicable standard. For medical devices (used for patients) this is regulated by MHRA and for PPE (used to protect healthcare professionals) this is overseen by HSE. Where a product is CE marked then it meets the regulatory requirements for its indicated use. Our Category Towers referred any queries as to whether regulatory requirements were met to the CaPA team so that they could refer them to the regulator. Decisions about standards or derogation from them would come from the regulators or PHE / DHSC and not SCCL. Up to 1 April 2020 the CaPA team rejected anything without a CE mark.

9.4 We were aware that numerous issues were arising on different items of PPE regarding equivalence of standards and how this should be dealt with. We worked with an assurance team from the MoD to develop essential specifications and a series of process maps consolidated into a "Playbook" which made clear what the standards were and what the process was for a claim of equivalence so the regulator could confirm. In tandem with that the web portal for suppliers became more sophisticated to ensure better questions were asked early on about what was being offered and how it had been certified and assured. This dramatically reduced the number of "fake" offers and counterfeit goods.

9.5 CaPA were concerned at the number of goods being sourced by Trusts which appeared not to have gone through any regulatory control.

9.6 On 1 April 2020 the Secretary of State for Health and Social Care wrote to SCCL's Chief Executive Officer with instructions which included the following:

9.6.1 To protect UK patient safety and ensure that essential equipment, including PPE, was rapidly available the approach would involve the disapplication of full third-party assessment of PPE manufactured during the pandemic or a derogation from the MHRA (where the PPE is a medical device).

9.6.2 As this would lead to purchasing directions from Cabinet Office to SCCL being made on this basis, SCCL was authorised to disapply normal expectations on PPE standards and to act on the basis of directions from the Cabinet Office.

9.6.3 This letter also acted as authorisation to disapply normal expectations on wider regulatory standards, should this be required, for other essential equipment where this had been agreed by DHSC with other Government Departments.

9.7 We understand that at one point in May 2020 there were 58 million items in quarantine pending quality assurance.

9.8 We are aware that products of varying standards which were bought are now being disposed of because they are not of the requisite quality.

10 SCCL's involvement in the sourcing and supply of medical devices/equipment connected to the Covid-19 pandemic

10.1 A range of products that became known collectively as PPE were the main requirements during the pandemic. These were:

10.1.1 Aprons

10.1.2 Body Bags

10.1.3 Cleaning Equipment

10.1.4 Clinical Waste Bags

10.1.5 Clinical Waste Containers

10.1.6 Eye Protection

10.1.7 Face Masks IIR

10.1.8 Respirators

10.1.9 Fit Test kits

10.1.10 General Purpose Detergent

10.1.11 Gloves

10.1.12 Gowns

10.1.13 Hand Hygiene

10.1.14 Pulse Oximetry

10.1.15 Swabs

10.1.16 Laundry Bags

10.1.17 Theatre Caps

10.1.18 Over shoes

10.1.19 Chlorine Tablets

10.1.20 Specialized Hoods and Suits

10.1.21 Shrouds

10.2 SCCL also sourced and supplied:

10.2.1 Oximeters

10.2.2 Breathing equipment and apparatus

10.2.3 Devices for invasive respiratory support (e.g. mechanical ventilators for intubated patients)

10.2.4 Non-invasive respiratory support (including high flow nasal oxygen and continuous positive airway pressure (CPAP) devices)

10.3 By contrast and in response to the specific request from the Module 3 team, very few orders for renal equipment were placed through SCCL.

10.4 Products and quantities held within the PIPP stockpile did not meet all of the Covid-19 pandemic requirements. Therefore, there was a requirement to procure all types of PPE during the pandemic period.

10.5 SCCL also had to maintain its business as usual procurement, albeit with reduced demand given the change in the nature of the services being provided by its NHS customers.

11 Trusts, ICUs and Nightingale Hospitals

11.1 In response to Covid-19, the DHSC decided to establish a stockpile of products used in the delivery of ICU care.

11.2 The initial planning for the number of ICU beds needed was 35,000 based on modelling from Deloitte, with the input of physicians. Equipping an ICU bed requires all the consumables that go with the bed. The original plan called for 921 products which equates to about 18,500 pallets. Subsequently, SCCL were advised that there would be 2,900 products equating to about 80,000 pallets.

11.3 A dedicated ICU supply chain was set up with DHL on 27 March 2020 and was operational by 30 March 2020. This shipping channel was operated out of a fulfilment centre at Skelmersdale in respect of which DHL were managed by SCCL. The purpose of the separate channel was to deal with surge demand for the Nightingale hospitals without impacting the BAU supply chain.

11.4 In the event, the Nightingale Hospital at London ExCel took very few patients and was stood down. Some other regional centres were opened but were never used. However, the supply chain provision had been made including the acquisition of consumables (which had to be stored) and the development of contractual arrangements with third parties (which no longer matched what was required).

11.5 The DHSC is better placed to provide details of the rationale behind the selection of products and what SCCL were instructed to procure.

12 Numbers of Contracts for medical devices or equipment connected to Covid -19 that SCCL processed

12.1 SCCL manage more than 7.7 million orders per year across 129,420 order points and 16,705 locations. SCCL delivers over 35 million lines of picked goods to the NHS annually, and our systems consolidate orders from over 930 suppliers. NHS Trusts purchase more than 60% of non - drug products that they use through the NHS Supply Chain – from baked beans to MRI scanners.

12.2 The principal method of purchasing by the NHS Supply Chain is through framework agreements. The framework agreements are usually in place for a period of four years (typically for an initial two years with an option to extend for a further two). There is a constant cycle of tenders. A total of 138 Frameworks are currently in place:

- Transactional product categories
    - 88 frameworks
    - 1814 suppliers
    - Current £2.28 bn spend per annum;

- Direct Product and service categories (where SCCL procures the framework but Trusts contract direct with the supplier)
    - 30 frameworks
    - 788 suppliers
    - Current £1.12 bn spend per annum; and

- 20 frameworks are currently under procurement

12.3 In total 2602 suppliers in total are currently involved. SCCL has a constant cycle of procurements of frameworks.

12.4 It is therefore difficult to provide an answer to the question about the number of contracts.

13 Supply Chain Issues Impacting on Safety or Security of medical devices or equipment

13.1 See points raised at question 9 above.

14 Involvement of SCCL in Changes made to Sourcing of Medical Devices or Equipment

14.1 See answer to question 9 above.

14.2 In addition, the purchase of PPE was moved to a dedicated PPE procurement cell outside of SCCL and managed by the Cabinet Office on 1 April 2020. As previously explained at paragraph 4.8 from that point purchasing direction came from the PPE Cell team in respect of essential equipment, including PPE, manufactured at pace by new and existing providers. This included PPE classified in UK regulations as a medical device as well as PPE classified under PPE regulations owned by BEIS.

14.3 The PPE cell bought in two ways, either through:

14.3.1 Existing SCCL procured frameworks

14.3.2 Direct awards put in place under Emergency Regulations by DHSC with new suppliers.

14.4 A dedicated supply chain for ICUs specifically for the new Nightingale Hospitals was also set up by SCCL with DHL.

14.5 SCCL continued to buy everything other than PPE required by NHS Trust customers reflecting their changing work patterns. For example, demand for procedure packs namely pre-packed surgical procedure kits containing a specified number and type of particular items such as drapes and instruments "*fell off a cliff*" (a figure of speech and

not a direct quotation) because routine surgical procedures were no longer taking place and these packs were therefore not required.

15 Potential Recommendations in the Event of a Future Pandemic

15.1 At various points both during the pandemic and in its aftermath, we have considered the extent to which we might work differently in the future, whether to prepare for a future pandemic or to respond were a pandemic to occur. That has involved considering both internal changes (i.e. those that lead to changes in our working practices) and external changes (those that reflect more systemic changes). In the early part of 2022, we carried out the most recent review.

15.2 Of particular relevance to Module 3 is the fact that SCCL recognise the importance of having a better understanding of what stock / products are held at what location, both as part of business as usual but more importantly when responding to any spikes in demand. We are currently implementing on a pilot basis an inventory management solution into individual Trusts to ensure a more unified system enabling the wider system to have the data in order to understand what stock Trusts hold. We think this is one of the most important takeaways.

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 .....

PAUL WEBSTER

Dated 07 December 2023 | 2:28:54 PM GMT December 2023