Government Internal Audit Agency

Department for Health and Social Care

Analysis of PPE issue – Advisory Review

Consulting Engagement Report - Final

Date of issue: ~~12~~ 21 September~~August~~ 2020
Engagement reference: 20/21-DHSC-01

Contents

Executive summary

Background

The Department of Health and Social Care (DHSC) is the lead Government department for planning for a human influenza pandemic. Tiger Eye Protectors were part of the Pandemic Influenza Preparedness Programme (PIPP) Personal Protective Equipment (PPE) stockpile procured by the then Department of Health (DoH) in 2009. As part of the response to the COVID-19 pandemic, these eye protectors were issued by DHSC in large numbers to NHS Trusts, Local Resilience Forums (LRFs) and the Devolved Administrations.

Following a complaint raised in relation to this product, DHSC commissioned a review of the eye protectors for safety and quality. It was found that although the items are CE marked, there was no documentation of safety standards met or of tests conducted. The British Standards Institution (BSI) conducted tests on the items and found that the product failed to meet the specification for splash protection required in EN 166: 2001 and testing requirements documented in EN 168: 2001.

The products were subsequently recalled and the DHSC Permanent Secretary requested that GIAA review the adequacy of the controls which were in place in the end to end procurement, storage and distribution system to assure that the PPE products were fit for purpose and could be safely used in a clinical setting by healthcare professionals across the health and social care network.

Having initially focused on the issues relating to Tiger Eye Protectors (providing an 'interim findings report to DHSC management on 7 July 2020), we subsequently examined the policy decisions, procurement, storage, and quality testing for all items within the PPE stockpile (previously held).

A further 15 products were held in the PPE stockpile list (pre Covid 19). Some of the products consisted of two parts (e.g. a lens and frame); some products included more than one line (e.g. Respirators - valved and unvalved, or gloves in three different sizes); and for some lines the same product had been purchased from more than one supplier hence it was deemed as a separate product line.

This report records the findings in respect of the entirety of our review.

Overall, we conclude that quality assurance processes in respect of the purchase, receipt, storage and issue of Personal Protective Equipment held to form the Pandemic Influenza Preparedness Programme stockpile have been lacking. There is a risk that items may not be safe and effective for use by front line staff.

Key Findings / Conclusions – Tiger Eye Protectors

Available evidence suggests that the Tiger eyewear purchased as part of the 2009 swine flu stockpile, which was brought into use during the Covid19 pandemic, was never fit for purpose.

At the point of purchase, there was a lack of clarity regarding the necessary safety standards for the product and evidence indicates that checks on receipt of the goods lacked rigour.

Crucially, contracts with Tiger Medical care were terminated in 2011 because of concerns over their supply chain and the validity of CE safety certificates in respect of other products in their range. No linkage was made to items held in the pandemic influenza stockpile – meaning the opportunity to test items held was missed.

Governance arrangements over the stockpile are complex and accountability for monitoring and flagging the need to re-test items in the stockpile is unclear. The assurance framework is weak and the eyewear was not tested prior to release.

Overall, multiple procedural weaknesses or oversights over the period 2009 to date led to unfit eyewear being issued to the NHS in 2020.

Key Findings / Conclusions: Wider PPE stockpile

For the 15 lines audit tested from the stockpile list, in the majority of cases, there was no documentary evidence to demonstrate that the PPE line had been procured to a pre-defined expected standard and that the item met the required quality standard on an ongoing basis. In the absence of documentary evidence/assurance, product testing would be needed to confirm whether each line meets respective clinical quality standards (since the pandemic began, the only testing undertaken of PPE stockpile has been where PHE (pre-response or DHSC (during the response) has been seeking to extend original shelf-life of products/provide quality assurance), or in response to complaints about products.

Summary View

Reflecting on this issue, there are clear parallels between the operational environment in play during the 2009 H1N1 (Swine Flu) Pandemic, when Tiger Eye Protectors (and the wider stockpile) were initially purchased, and the current Covid-19 pandemic.

In both cases emergency procurement regulations were invoked to help the Department meet the projected increases in demand for PPE within the UK's health and social care system against a backdrop of global shortages, increased competition to secure supplies and new suppliers entering the market. Latterly, controls over the quality assurance of PPE entering the UK in response to COVID-19 have improved, however there remains a lack of transparency regarding decisions taken and accepted risk within the end to end procurement process.

Accountabilities for the end-to-end specification, procurement, storage and distribution of pandemic influenza supplies are complex and fragmented across a number of organisations (see Annex 2 for diagram) which means there is increased likelihood that key tasks might be missed. Within the "Health Family" this encompasses DHSC, Public Health England (PHE), Medicines and Healthcare products Regulatory Authority (MHRA), NHS Business Services Authority (BSA) and Supply Chain Coordination Limited (SCCL). Health and Safety Executive (HSE) also has a role in the process in terms of quality inspection of PPE items if/when requested. There are a number of contracts with third parties to actually supply the services; and underpinning this there is the global market for PPE.

A number of governance forums are in place in respect of the supplies and these should provide an appropriate structure for reporting quality assurance issues with the items in the PPE stockpile. There has however been:

- an ineffective assurance framework in place regarding PPE stockpile quality standards;

Commented [GT1]: This is not relevant to the PIPP stockpile but rather the procurements done by DHSC during the response. Is this really in scope of this review as it has no relationship to the PIPP stockpile.

Commented [AZ-G2R1]: In our opinion this aspect is important to set the overall risk context of the operating control environment under which PPE has or is being purchased

No amendment required

Commented [GT3]: Might be reasonable to call out HSE too.

Commented [AZ-G4R3]: In terms of governance and accountability, HSE is not part of the health family hence not mentioned here.

amendment has been made though

- a lack of a clear focus on quality elements relating to the stockpile amongst all stakeholders and within commercial arrangements and Service Level Agreements (SLAs) across the supply chain; and
- accountability for monitoring and flagging the need to re-test items in the stockpile is also unclear, with a range of stakeholders having an interest but no apparent focal point with overarching accountability. Nor has there been any relevant upwards reporting of such information into DHSC.

Interviews with key stakeholders have provided an inconsistent picture of how robust the checks in place to assess the quality standards of items upon receipt would have been in 2009. Periodic checks on existing stock are undertaken, but these primarily focus on volumetric counts and visual inspections to assess whether there is any physical damage. These regular checks do not incorporate an assessment of whether the products remain fit for use in the context of related (and ongoing) quality standards.

There is evidence that the Department had concerns about Tiger Medical and its suitability as a supplier at the time of the procurement. Tiger Medical was a new supplier (not a manufacturer) with an untested track record in supplying PPE products, and the overall financial resilience of the company (including whether it had sufficient working capital to fulfil the order) came under scrutiny in 2009. When the order was placed a number or conditions were set out including the need for the Department to have samples of the product and for appropriate quality certification to be in place. We have been unable to find any clear evidence that the right samples were received and appropriately tested, or that the quality certification was received (post-delivery). There does not appear to have been any follow up review undertaken to obtain the relevant quality certification.

There is some evidence from underpinning procurement documentation from 2009 that the Department set out the technical specification that the eyewear needed to comply with, however subsequent examination of samples (if they were ever received and tested properly) and checks upon receipt of goods were inadequate, and failed to correctly identify that the eyewear did not meet key EN standards for use. The items failed on two discrete elements of EN standards. Whilst the standard relating to resilience of the lenses to impact would have required testing in laboratory conditions, a visual examination by anyone with a working knowledge of the standards should have identified that the products would not meet EN 166: 2001 specification for splash protection because of obvious and fundamental design limitations.

In 2012, the MHRA conducted an investigation relating to counterfeit quality certification associated with procurement of items from Tiger Medical to supply the Choices for Health Programme. Whilst no legal action was taken at the time, the Department was aware of the issue and the question was raised whether any other products purchased from Tiger Medical should be tested to assess whether they were fit for purpose. There is no evidence that any further action was conducted, and this represents a missed opportunity to review and take appropriate action at an earlier stage with the Tiger Medical products which were held in the PIPP PPE stockpile.

In respect of the wider stockpile the importance of gaining appropriate independent assurance regarding the quality of the PPE products stands out, in particular as some items which had their use-by extended and were deployed have been subsequently withdrawn because of quality / degradation issues.

The above scenarios makes clear the importance of the Department not being wholly reliant on reports and certificates of conformity provided by suppliers or other third parties. This risk is exacerbated when extending the life of products, as it increases the likelihood of large scale

Commented [GT5]: From my perspective one of the key reasons we employ SCCL is to provide SME in this space. Anything reported would have been reported onwardly to CCMB and DHSC Policy are members of this governance forum. Remedial action would have been directed accordingly.

Commented [AZ-G6R5]: Noted, however, based on fieldwork this is our conclusion as there has been a lack of clear accountability/reporting. The SCCL contract does not cover this and nor have we seen this documented elsewhere

No amendment required

Commented [GT7]: But these are provided by independent parties to the manufacturer and as such are sources of independent assurance albeit at the procurement / receipt stage. Are we being asked to do it twice which is what this would effectively mean? The question will be (and the report might come into this) what approach should be taken as the stock ages.

Commented [AZ-G8R7]: The issue needs managing going forward as placing sole reliance on a third party (who often might not be a UK based organisation or CE may be fraudulent if from overseas) is a significant risk. Due to volume of expenditure incurred on PIPP PPE it may be prudent to seek additional validation to ensure satisfactory CE are held and products tested again to provide assurance.

No amendment required

product recalls being necessary when they have been deployed during a pandemic, and the Department having to go to market to source replacement PPE at a time when there is increased demand and other risks associated with the global supply chain for PPE.

We note that on at least one occasion advice was provided by an advisory Group (NERVTAG) that it would be good practice to conduct fit tests of equipment purchased at the procurement stage (rather than when deployed during a pandemic) to ensure that items are of an appropriate size and fit for end users. We found no evidence to demonstrate that the advice from NERVTAG had been acted upon and in our opinion, this was another missed opportunity for the stockpile products to be tested for quality post purchase.

NERVTAG also provide guidance regarding the circumstances where the use of PPE is appropriate which has implications on the optimal volume of items required in the stockpile, and there are indications that elements of the stockpile were below this threshold at times – we are aware that this is within the scope of the NAO review of PPE and so we have not investigated further at this time.

Commented [GT9]: Useful to understand this better as I don't think I'm sighted?

Commented [AZ-G10R9]: To discuss with Gareth

No amendment required

Commented [SG-G11R9]: This came out of some of the detailed info we got around the assurance regime.

Commented [GT12]: It is normal for stockpiles to not be at the target level as this would require many small scale procurements to align with shelf-life expiry. We only do large volume procurements and so stock levels flux either side of the target level.

Commented [AZ-G13R12]: Noted, GIAA not undertaken further testing on this aspect as not in scope, hence we have stated that we have not investigated further.

No amendment required

Commented [SG-G14R12]: This was not a case of volumes being slightly below acceptable levels – there were material differences in the volumes as the NERVTAG advice had fundamentally shifted and the overall levels remained well below for a sustained period

Detailed findings

Missed opportunities to identify and remedy quality issues with Tiger Products

In 2012, the Department was aware of issues with Tiger Medical products; however, it failed to take any action in terms of considering the impact on other products obtained via Tiger Medical. This was a key missed opportunity that could have identified the issues with the Tiger Eyewear which have subsequently emerged.

We have established that in 2012 an investigation into Tiger Medical was conducted but this did not extend to eyewear. Issues related to the quality of personal hygiene products which were distributed to the NHS as part of the Choices for Health Programme. Serious weaknesses in the quality assurance processes within the supply chain and potentially counterfeit CE certificates were identified which resulted in a number of items being recalled. This led to litigation action between the Department and NHS Supply Chain (delivered at the time by DHL) who had allowed the products to be released into the NHS. A subsequent MHRA investigation was also undertaken regarding this serious incident.

Correspondence between the Department's commercial directorate and NHS BSA, and with NHS SC at the time indicate mutual concerns that other items procured from Tiger Medical may not be fit for purpose and could fail vital safety tests. The Department apparently did not act on this opportunity to review any Tiger products which may have prevented this incident occurring. After 2012, the Department no longer had a commercial relationship with Tiger Medical.

We consider that this situation may have been avoided if there were clearer / potentially streamlined governance arrangements for circumstances where there is multi team and multi organisation involvement in addressing a risk. Representation at governance forums needs to be appropriate and clarity is needed regarding roles and responsibilities as well as intelligence sharing protocols. See Recommendation 1.

Monitoring of the legislation, regulations or standards over the acceptable protective equipment for use in pandemics, and where applicable, the rechecking of products in storage where the applicable quality standards are amended, to ensure that the products stockpiled remain safe and fit for purpose.

Accountabilities for the PIPP stockpile are complex and fragmented across a range of organisations. There are a number of governance forums in place, which have appropriate, cross-cutting expert membership, and escalation processes, however, there has been a lack of focus on obtaining assurance on the quality of items held within the PIPP PPE stockpile. See Recommendation 1 & 2.

A range of bodies are involved in setting standards for PPE equipment, although the EN standards that the Tiger Medical eyewear have failed have been unchanged and in place since the original procurement in 2009.

New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advise the Department on the type of PPE to procure to mitigate the impact of influenza pandemics, and PHE also has their own medical and scientific advisors. The PIPP Board is chaired by DHSC and is the senior stakeholder forum with a wide ranging focus where pandemic influenza planning is discussed.

The Clinical Countermeasures Board (CCMB) is where PPE is primarily discussed and can escalate to the PIPP Board if necessary. CCMB is chaired by PHE (with representatives from DHSC, other Arms' Length Bodies (ALBs), Devolved Administrations (DA's) and medical / scientific advisors). CCMB receives regular reports on the PIPP stockpile, however these are primarily focused on volumes, procurement pipelines and the stock audits. There is an absence of routine reporting in place to provide assurance over the ongoing quality of the products in the stockpile.

We consider that processes and practices should be introduced so that regular assurance can be gained on the quality of items held within the PIPP PPE stockpile. See Recommendation 2.

The procurement processes that were in place at the time that the Department procured the items held in the PIPP stockpile.

There is evidence that there were concerns/doubts about the supplier "Tiger Medical" and there is no clarity whether risks regarding potential product quality were considered at the time of purchase.

Tiger Eyewear procurement was undertaken during the Swine Flu pandemic in 2009 using emergency procurement processes under Section 32 of the Public Procurement Regulations. Whilst key procurement controls may not have been fully relaxed, such provisions ease the requirement to conduct open tender competitions where there is a recognised national emergency, and in this instance there was an overriding requirement to ensure stocks of PPE were available to meet projected need (although the pandemic was not as severe as expected and these items were never actually used). The Department ordered c30m items of eyewear to bring the stockpile up to required levels of 34m units.

There is evidence that there were concerns about Tiger Medical specifically as a supplier, for example:

- The Department had never used Tiger Medical before. Tiger Medical do not manufacture as they act as an intermediary supplier;
- Tiger Medical were a relatively atypical supplier for the provision of PPE. The Department has tended to use larger organisations, for example Bunzl, 3M, Kimberly Clark (who are all blue-chip nationally recognised names), and even smaller suppliers have tended to be more established names in the market for example British Polythene Ltd, who have been trading since 1939;
- Issues around Tiger Medical's financial resilience – questions had been raised (as evidenced in emails) about whether they had sufficient working capital to fulfil the order as there had been requests for partial pre-payment from Tiger Medical and suggestions that the Department could transfer funds into an Escrow account to provide some sort of financial surety. Credit reference checks were apparently undertaken, and the exercise proceeded;
- The price per unit being charged for the eyewear was higher than the normal unit cost and the Department were concerned about whether the procurement provided a value for money solution.

We have already advised on the strength of the due diligence process as operated under Covid19 (per separate note shared with the DHSC finance team) and have revisited in light of this review – see our separate report 'Risk and control deep dives - Covid19 impacted areas'.

Commented [GT15]: But PHE would expect stock issues to be reported by exception by SCCL into this governance. Anything raised what have then created visibility for the stakeholders and agreed actions on resolution.

Commented [AZ-G16R15]: The issue noted here is not about stock volume issues but about quality of products on an ongoing basis. In the absence of control to ensure such, nothing is reported to stakeholders. We have not seen any evidence to state that SCCL will test ongoing quality and report such.

No amendment required

Compliance with procurement processes, including the creation of the tender specifications and quality standards set out for the protective equipment to be procured

There is evidence to suggest that the Department produced technical specification for the eyewear to be procured against, but that subsequent examination of samples and checks upon receipt of goods were inadequate and failed to identify that the eyewear did not meet key EN standards for use. At the point of purchase, there was a lack of clarity regarding the necessary safety standards for the product.

We have not reviewed detailed procurement documentation (because this does not need to be retained for more than 6 years after the purchase), but there is some evidence within the Departments archives to indicate that technical specifications -to support the procurement exercise were determined by the policy team. Protective eyewear has a number of related EN standards, which in the context of use in a medical setting relate to general fit and construction materials (EN166), ocular quality of the lenses (EN167) and the level of protection provided by the item (EN168).

There was a lack of clarity regarding the precise standards that needed to be met at the point of the procurement (internal correspondence between the PIPP Team and relevant Commercial Directorate states that the requirement was for splash resistance but incorrectly states that there is no standard for this - EN166 has tests for splash resistance for both goggles and for visors). Recent testing has indicated that the items have failed on both splash protection because the glasses do no provide adequate area of facial coverage, and that the lenses are not robust enough to protect the user from debris and carry a risk of shattering. These tests indicate that the items were never fit for purpose and we can deduce through this that appropriate quality testing was not conducted upon receipt of the items in the UK.

What we have discovered from contemporaneous records relating to the procurement process is the following:

- The Department's representatives had visited some of the manufacturing plants used by Tiger Medical in China;
- Samples of the eyewear were requested, and emails suggest that they were received and examined prior to the confirmation of the order (it is not known how or by whom they were tested). We currently have no supporting evidence of the extent that they were tested against conformity with specified standards;
- The order was contingent on receipt of CE certificates of conformity that the product met the required specification. There is no evidence that these were received or that the Department followed this up with Tiger Medical;
- Tiger Medical needed to assume product liability and have appropriate insurance in place. However, we have been unable to find any additional evidence that this was in place.

Clear understanding of safety standards is essential here. We have made a recommendation focused on needing clarity of understanding regarding current product specification at procurement stage, to mitigate the risk of substandard items being purchased and accepted into the PPE stockpile (testing and quality assurance processes feature elsewhere as recommendations). See Recommendation 3.

Goods receipting processes at the time of the procurement, and any quality or safety checks that were carried out on the goods received.

In terms of the extent of goods receipting checks undertaken at the time, interviews with key stakeholders has provided an inconsistent picture of how robust the checks in place upon receipt would have been. Audit trails of documents also yield no evidence to demonstrate if quality checks were undertaken post-delivery.

Anecdotally, there is a view from (PHE) that DHL who held the contract for procuring the items at the time, were very risk averse and would have not accepted the goods into storage without appropriate CE certificates. PHE has also stated that they would have expected DHL to have checked that the product received, matched what had been procured, however, the Tiger eyewear has never met the required specification and a visual examination by someone with knowledge of the standards should have been sufficient to identify this fact. We have as yet been unable to source copies of the CE certification from the Department or any of its ALBs who were involved in this process. The procurement exercise took place in 2009, and there has been numerous machinery of government changes since then in terms of organisational responsibilities.

Advice from National Archives relating to retention of purchasing and contract documentation is primarily driven by the Limitation Act 1980 and the Prescription and Limitation (Scotland) Act 1973. These acts state that any proceedings to recover money must be instituted within 6 years of the money becoming due. If proceedings are not instituted within the relevant period, the claim is statute barred. A direct effect of this is that most purchasing and contract documentation needs only be retained for a period of six years after the end of the contract, although National Archives advise that Departments undertake a risk assessment of the destruction of contractual records to ensure that action taken is commensurate with accountabilities. Whilst the procurement exercise was concluded some time ago and is a point in time purchase, the shelf-life of these products is often significant, and the stockpile by design results in them being stored for extended periods before being distributed at times of emergency.

Good practice would be to retain documentation relating to the procurement of PIPP PPE stockpile until the products have expired or have been used. See Recommendation 5.

Active refresh of the stockpile by placing items nearing the end of the shelf line into use within the NHS would also mitigate risks associated with degradation (as is more recent practice). See Recommendation 45.

Commented [GT17]: Whilst I understand the principle to cycle there are some barriers to this. For example the volume of stock to cycle can be far too large compared to BAU usage such as to make it impractical. Distortion of the market is also a risk.

Commented [AZ-G18R17]: Noted. Have split the para to make it clear.

Standards in place for the appropriate storage of the product e.g. temperature, length of time in storage, expiry dates of the items and periodic checks in place to ensure the products were being stored appropriately and were free from damage or degradation.

None of the stakeholders interviewed expressed a view that storage conditions could have impaired the item's performance in recent quality tests. Periodic checks on existing stock are undertaken, but do not incorporate assessment of quality or whether the products remain fit for use.

All PPE items should have specified storage conditions associated with them. Anecdotally (we will be checking the records for each line specifically) these are for ambient temperature conditions rather than chilled. The items are made from materials that do not readily degrade, which gives them a long shelf-life (although sterile items can only be marked so for 5 years from production). The use by date of non-sterile items such as glasses, waste bags etc. can be extended using accelerated age testing, this is referred to as "re-lifing" the products.

The storage and logistics contracts have requirements for regular assurance that storage conditions were as specified in the contract.

Regular stock audits are also conducted, but these tend to focus on volume and more visual checks that items have not been damaged or degraded through infestation etc. rather than the technical testing required to assess conformance with CE standards ***(see our earlier observations on this and also the section below regarding 'Maintenance of products held in the stockpile').***

Parallels between the procurement environment in 2009 and the present day (Covid 19 operating environment)

There are clear parallels between the circumstances in place during the procurement of Tiger Medical eyewear in 2009 and the current Covid-19 pandemic.

Discussions with key stakeholders involved in the current procurement process have reflected on ongoing risks and issues with incoming products.

There are heightened risks that the supply chain could be targeted by those seeking to exploit the current crisis. The Army has stated that supporting documentation for incoming goods at the Clipper Logistics hub is highly variable in terms of its completeness and reliability. There is a dedicated and embedded Quality Assurance team working on the assurance of products with representatives from Health and Safety Executive (HSE), MHRA and Office for Product Safety and Standards (OPSS). This team examines quality certificates and has a working knowledge of the applicable quality standards, so provide a control over unfit products entering the NHS supply chain.

Whilst there is an imperative to release items for use by frontline health and social care professionals, safety is a primary concern and stakeholders strongly felt that appropriate checks are in place to assure new stocks entering the supply chain. Some parts of the NHS may have purchased their own PPE and there are potential gaps in the assurances available for these direct purchases.

We are aware that DHSC has recently commenced a lessons learned exercise.

Commented [GT19]: Is this section relevant as I thought it was focussed on PIPP?

Commented [AZ-G20R19]: See previous comment in exec summary.

Procurement stage for purchase of PPE stockpile

In our opinion, there has been an absence of:

- **any upfront independent pre-purchase quality / safety controls conducted by the Department or those commissioned in respect of PIPP stockpile items.**
- **post purchase quality assurance controls.**

There was a critical missed opportunity for the Department to take early action - following an advisory groups report - to address risks associated with the stockpile and ensure that products are safe and appropriate for deployment to frontline staff.

Either there is no evidence, or incomplete or unclear evidence, that the products were tested (through any DHSC commissioning) to confirm that they met the required standard(s) before being procured. For any documents supplied, we found that the manufacturer name/product code did not always match what was stated on certificates/reports.

There are no records available to evidence that the products were tested once they had been procured and were delivered to the stockpile. Complete reliance is placed upon the manufacturer's testing (if/where available) and manufacturer's liability. For two of the products, where there was a Certificate of Conformity available, the identifying records did not match the product.

For five of the PPE products, quality standards cited were dated after the procurement of the products. It was unclear if these are errors in the records, retrospective changes, or if the standards were reviewed and updated (however, there are no records to indicate this).

In two cases, products which were not appropriate for the PPE stockpile were still retained within the stockpile. These two products (Type IIR Face Masks) had been procured for the swine flu pandemic. We question why the items were still kept in the stockpile and whether this is indicative of poor management of the stockpile as the Department may be paying for storage for this product.

A report from NERVTAG (The New and Emerging Respiratory Virus Threats Advisory Group) which advises the government on the threat posed by new and emerging respiratory viruses), dated June 2016, recommended the use of aprons and gloves for all close patient contact including social care settings. This increased the profiled stockpile requirement for aprons by 118m, however levels of aprons held were not increased to this level until 2019. It also mentions the good practice of conducting fit tests of equipment purchased at the procurement stage (rather than when deployed during a pandemic) to ensure that items are of an appropriate size and fit for end users. The report also mentions the likelihood of the eyes being a portal for transmission and the need to use protective visors or glasses (no detail on specification and standards).

Following the issue with the Tiger Eyewear product, newly initiated independent testing conducted for some products, once Covid 19 emerged, did not always support the results of earlier testing; some items (FFP3 respirators and facemasks) have had their use-by dates extended by significant margins via testing undertaken by the manufacturer, and some facemasks which had their use-by dates extended and were deployed have been subsequently withdrawn because of quality / degradation issues. This makes clear the importance of the Department not being wholly reliant on reports and certificates of conformity provided by suppliers or other third parties. This risk is exacerbated when extending the life of products, as it increases the likelihood of large scale product recalls being necessary when they have been deployed during a pandemic, and the Department having to go to market to source replacement PPE at a time when there is increased demand and other risks associated with the global supply chain for PPE.

A thorough quality checking regime for PPE products should be designed and implemented. See Recommendation 2.

Maintenance of products held in the stockpile

There has been an absence of any routine or periodic quality control check specified as part of the maintenance agreement to ensure the PPE products continue to meet quality standards and no replenishment strategy.

Manufacturer's storage instructions were not available, or no documentation retained for seven of the PPE products lines. However, as the PPE lines are not deemed to be perishable, they have been stored under ambient temperature controlled storage conditions meaning that the risk of them becoming 'spoilt' is extremely low.

Annual Perpetual Inventory (PI) checks had been carried out. These checks include the reporting of any physical damage to products and/or pallets. Records are available, but these only detail total counts at different points in time; and contain no detail of any reported damage or losses to the stockpile in terms of quality aspects.

Commented [GT21]: Useful to know precisely which products and the nature of the issue.

Commented [AZ-G22R21]: See line 8 in annex 4 for details

Commented [GT23]: It think this mixes up the overall stockpile of aprons and the subset required for social care which in total is 53m. Large scale procurements take significant time. That said I would have wanted this to have completed quicker but often procurements are prioritised based on available PHE resource.

Commented [AZ-G24R23]: Noted, we are stating what was in the NERVTAG report as we have not investigated stockpile issues.

no amendment required

Commented [GT25]: Not sure of the value of this comment given a mention is not a recommendation to DHSC Policy and indeed the latter organisation do not act on this which I would understand (as it was not a recommendation).

Commented [AZ-G26R25]: Included to set the context and raise the matter that issues were identified and not acted upon

Can discuss further

No amendment required

Commented [GT27]: It's not new and stock items had been subject to independent testing prior to the issue with the Tiger Eyeware.

Commented [AZ-G28R27]: To discuss as evidence indicates this testing was all post covid 19

No amendment required

Commented [SG-G29R27]: Agreed – only testing has been to extend shelf life

Commented [GT30]: I don't agree. It more likely points to limitations in the age-acceleration process and the variability of local storage conditions compared to those centrally. Worth discussing further as suggesting we can't rely on reports / certs would break any assurance regime.

Commented [AZ-G31R30]: Please refer to our previous comment above as in our opinion the assurance regime needs strengthening for example due to a high risk of fraudulent CE certs being provided

Commented [SG-G32R30]: Age acceleration process is done by manufacturers sometimes too though, so if there are flaws in this, there are potentially flaws in their original CE certifications. Given the nature of the products and materials they are manufactured out of it is unlikely that storage conditions in hospitals are the root cause of any issues. A lot of the issues have been around design and fit rather than degradation of materials

The only time quality checks are performed on items is when they are nearing the use-by date specified by the manufacturer. Items are subjected to accelerated aging tests to assess whether use-by dates can be extended. One product that was successfully re-tested by the manufacturer and had its use-by date extended, needed to be recalled following deployment because of quality / degradation. Other products nearing the end of their shelf life have been subjected to a limited testing regime agreed with HSE to enable them to be distributed during the current pandemic (there is no evidence to date that there have been any issues with these particular items). We are also aware that there has been some significant stock write offs in the past e.g. 8000 pallets of respirators were sent to landfill because they had exceeded use-by dates. We understand that replenishing of PPE stockpile products have in the last few years began to take place.

A stockpile replenishing strategy should be agreed, produced and implemented to ensure all items held in the stockpile have a defined durable lifespan and to ensure that there is no wastage. See Recommendation 4

Please refer to Annex 3 showing detailed audit findings per each product.

Annex 1 Management action plan

	Recommendation(s)	Priority	Action agreed	Implementation date	Owner
1	***GOVERNANCE*** *- The governance arrangements in respect of the DHSC PPE influenza pandemic stockpile should be reviewed and revised from a true end to end process perspective (specification, procurement, storage, ongoing quality assurance and distribution).* *As there is multi team and multi organisation involvement in addressing the risk that there are insufficient 'quality' supplies to deal with an influenza pandemic, greater clarity is needed regarding accountability / roles and responsibilities (especially where there are handoffs or third-party suppliers involved) as well as intelligence sharing protocols.* *Representation at governance forums needs to be revisited in light of the above recommendation and the various findings in our report.* *The accountability, purpose, remit and the membership of the Clinical Countermeasures Board (CCMB) should be clarified (and documented in the CCMB terms of reference) to ensure all quality aspects of the ~~PHE~~~~DHSC~~ PPE influenza pandemic stockpile are adequately monitored and reported to the CCMB.*	High	Yes - as per the recommendation	End November 2020	Emma Reed
2	***QUALITY CHECKS*** *- The end to end quality assurance regime for influenza pandemic stockpile items should be defined, documented and enacted (with appropriate consultation with specialists such as the Health and Safety Executive, Clinicians etc).* *Processes and practices should be introduced so that appropriate quality checks are undertaken across the lifecycle of the product from point of purchase to issue into use. Processes should*	High	Yes - - as per the recommendation	End November 2020	Peter Howitt

Commented [GT33]: This I understand but a limitation will relate to the reason for which the stock was purchased. So I think the first recommendation would be to establish the scope of the health risk being mitigated which was just influenza and does not take into account any supply chain failures. Definition of future health risk scope is required as a first foundation step to the other actions.

Commented [AZ-G34R33]: The above can be part of the actions to be undertaken, also need to ensure that influenza covers pandemics such as Covid.

	recognise that different testing regimes will be required for each product. *Regular assurance reports to be produced and shared with the appropriate governance forum on the quality of items held within any PPE stockpile.*				
3	***PRODUCT SPECIFICATION AND CERTIFICATES OF CONFORMITY*** – Responsibility for defining and updating product specification for products held in the influenza Pandemic stockpile should be formalised. There should be greater clarity of understanding regarding current product specification at procurement stage, following which clear protocols should be put in place to ensure certificates on conformity for PPE stockpile products clearly describe or link to the actual product which has been purchased (based on the agreed specification).	High	Yes - - as per the recommendation	End November 2020	Peter Howitt
4	***PPE STOCKPILE REPLENISHING STRATEGY*** – A PPE stockpile replenishing strategy should be agreed, produced and implemented to ensure all items held in the stockpile have a defined durable lifespan and to ensure that there is no wastage.	Medium	Yes - - as per the recommendation	End January 2021	Emma Reed
5	***DOCUMENTATION / AUDIT TRIAL*** – Retention protocols relating to documentation covering the procurement and up-keep of the influenza pandemic stockpile (including applicable quality standards/reports) should be reviewed and revised. A risk assessment of the destruction of contractual records should be undertaken to ensure that action taken is commensurate with accountabilities (per National Archives advice). Key documents should be retained until products have expired or have been used.	Medium	Yes - - as per the recommendation	End December 2020	Peter Howitt

Annex 2

Tiger eyewear issue: summary timeline, key dates

Tiger eyewear issue - detailed timeline

Identified based primarily on LOTUS notes email evidence obtained via the Management of Electronic Documents System (MEDS).

Date	What	Event details (wording paraphrased based on original email)	GIAA observations
4/5/09	Email from DH Pandemic Influenza Preparedness Team	Stating that the **order is still subject to checking the viability of Tiger Medical** (awaiting Dun & Bradsteet reports and assurance that the company have sufficient working capital to progress the order). *"If all is ok should be able to order 30.5m eye protection (would bring us up to target of 34m)".*	**Early issues existed re viability of the supplier** Tiger Medical, this was about a week before the order was placed
4/5/09	Response Email from NHS Supply Chain	Outlining Dun &Bradstreet report (noting Tiger Medical are not a UK registered business). Total order value expected to exceed £13m. **Recommendation to send a representative to China to "validate things are all in order** before the first shipment"	Department was advised that **some additional assurance over product standards would be prudent** as part of this procurement exercise
4/5/09	Response Email from DH Commercial	**Recognition of the degree of risk because of absence of trading history**. Email notes Tiger Medical have asked for advance payment, and the potential use of an Escrow account to mitigate any associated risks	Further evidence that there were **live concerns regarding the suitability of Tiger Medical** as a supplier

Date	What	Event details (wording paraphrased based on original email)	GIAA observations
4/5/09	Response email from DH Pandemic Influenza Preparedness Team	States unit prices are fine but **further clarification needed** on expected delivery dates and **the item's compatibility with other items in the PIPP PPE stockpile** (Cardinal and 3M respirators)	GIAA are awaiting documentation to determine whether this assurance was provided
4/5/09	Further email correspondence between DH Commercials and Pandemic Influenza Preparedness Team	Some discussion regarding **the compatibility question with FFP3s.** Agreement reached that because of the design of FFP3s ordered that **in principle the eye protectors should be ordered, but this is "*subject to DH seeing the samples, and this is a condition of the eye protection order going ahead with Tiger Medical*"**	GIAA are awaiting documentation and evidence to determine if the samples were ever received or tested as per these conditions prior to the order being placed
4/5/09	Email from NHS Supply Chain	**Confirming credit status of Tiger not fully investigated but still of concern**. Statement that advance payments will not be made, but because of this, further assurance over Tiger's ability to finance the transaction was needed. References to the need to urgently reserve production capacity with the requirement to confirm this with Tiger Medical by 5/5/09	Scenario emerging where the **need to obtain stock is becoming the overriding priority, despite legitimate concerns over lack of assurance of quality and the supplier's financial viability**.
4/5/09	Email from DH Commercial	Stating Tiger Medical have provisionally reserved production capacity on the proviso that DH will confirm the order 5/5/09. **Tiger will also provide further detail of how they will fund the order "on the basis that NHS Supply Chain (NHS SC) will pay promptly for compliant orders delivered"**	
5/5/09	Email from DH Pandemic Influenza Preparedness Team	Email states: *"In anticipation of the checks on Tiger Medical coming back satisfactory, attached to the email is the signed order (word document dated 4/5/09 with an embedded spreadsheet)".* Order spreadsheet states: • Goggles from Tiger Medical: **one size fits all eye protectors. Splash resistant.** Non assembled delivery. • *"We have visited the supplier in Shanghai and inspected a number of factories used by Tiger. **Tiger are an agent, not directly a manufacturer.** The order will be **placed subject to: Certificates of conformity to relevant EN standards".*** • *Approval of **samples** by Department of Health (samples would be urgently required in the UK).*	Early evidence to indicate the eye wear **should have been splash resistant** Tiger Medical was an agent, nothing to indicate any checks on the manufactures further down the supply chain Order **should** have been placed **subject to CE EN standards** Dun and Bradstreet report still outstanding at this stage

Date	What	Event details (wording paraphrased based on original email)	GIAA observations
		• *Confirmation that Tiger Medical will assume product **liability** and has appropriate **insurance** in place. Confirmation of product **shelf life**.* • *First container loads being available for shipping by end of May 2009, with a regular ongoing supply and all product being available no later than 31st March 2010.* • *NHS Supply Chain terms and conditions of order (a copy will be provided with the order).* • *We will also be reviewing a **Dun and Bradstreet report** and if necessary, seeking assurance that Tiger Medical has sufficient working capital to progress the order.*	
12/5/09	Email correspondence within DH Pandemic Influenza Preparedness Programme and relevant Commercial Directorate	*'We need to instruct NHS SC to process the order for eye protection from Tiger Medical - please can you confirm that **Policy Team happy for the order to go ahead based on the samples received yesterday**?'* *Please note, we have been advised that there is **no relevant EN standard for this product** (**our requirement is for splash resistance**, the **EN standards focus on impact resistance** for goggles) - so the **decision effectively needs to be based on the samples.***	Requirement stated was for splash resistance – **email incorrectly states that there is no standard for this** (EN166 has tests for splash resistance for both goggles and for visors) **EN standards do relate to impact resistance**, again the statement that this is only applicable to goggles is incorrect as the lenses of all protective eyewear are subject to impact resistant testing No evidence re policy decision as to what standard (and on what basis) it would be required for the eyewear re PPE PIPP stock **Lack of understanding of technical standards** relating to eye protectors and how they are applied. **Lack of clarity over the standards specified within the tender documentation.**
13/5/09	Email correspondence within DH PIPP and relevant Commercial Directorate	Clinical Countermeasures Manager, Pandemic Flu Team **approves order**: *Yes, please place the order*	Order approved – no evidence or references to state samples were received. No evidence to state how samples were tested and if they met splash resistant requirement

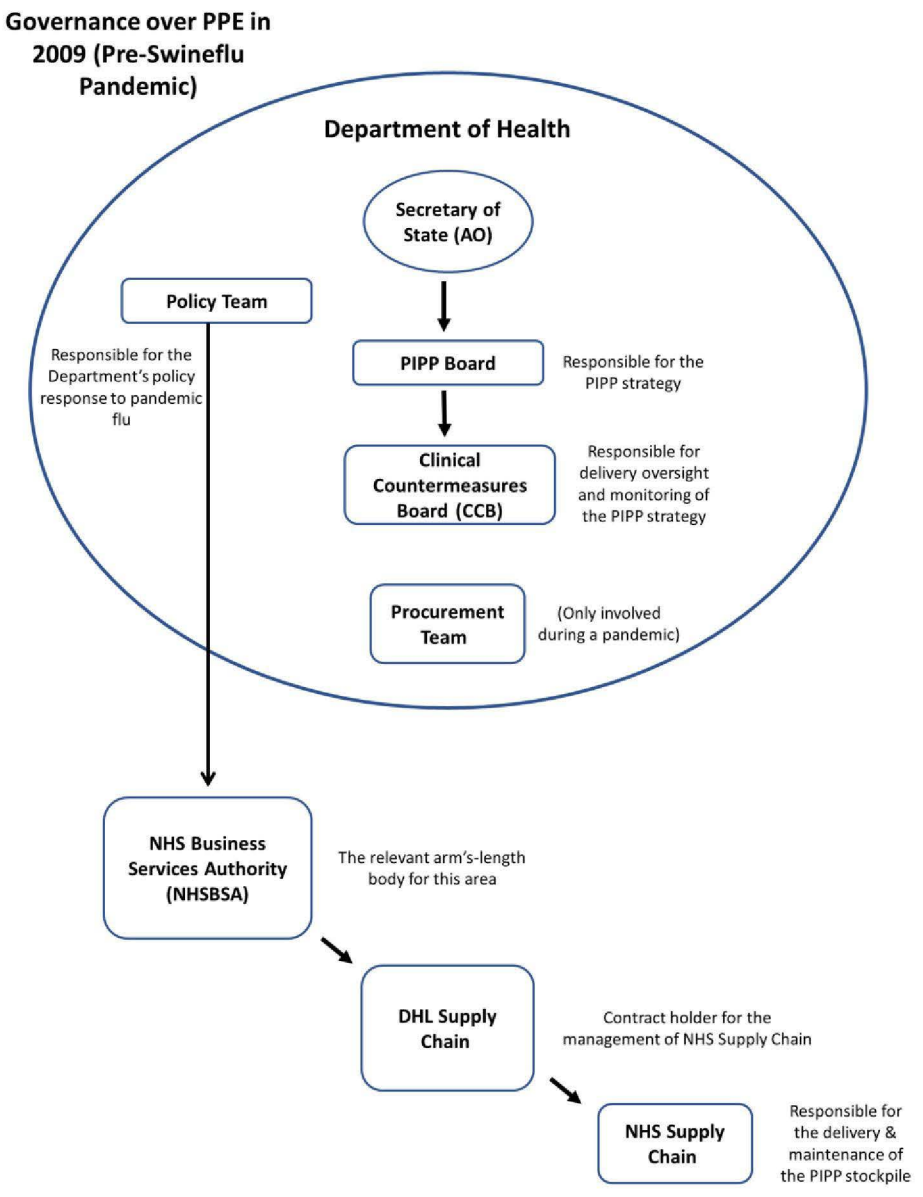
Date	What	Event details (wording paraphrased based on original email)	GIAA observations
13/5/09	Email correspondence within DH PIPP and relevant Commercial Directorate	DH Commercial informed NHS SC who will now advise Tiger Medical to **start production**.	Order placed
13/5/09	Email from DH PIPP CD to NHS SC	Confirms that "*the **policy team has now seen the samples of eye protection** and have asked for the PIPP order for this [the Tiger Medical] product to go ahead*"	**No evidence to outline what testing or evaluation was conducted by the Department to satisfy itself that the product was safe to use and fit for purpose**.
15/5/09	Commercial Directorate PIPP procurement dashboard spreadsheet	Entry re eye protection states: *Policy Team has reviewed samples from Tiger Medical and has agreed that production can go ahead. PIPP requirement will now be completed.*	No evidence to state how samples were tested and if they met splash resistant requirement
23/6/09	Email NHS Supply chain	Email refers to feedback on audit trail paper being produced: *an audit trail for the 2nd tranche of consumables ordered* in an attachment	GIAA attempting to access a file which is a zipped filed embedded in a pdf document (cannot be accessed at the moment)
No further relevant correspondence has been identified re Tiger Medical after June 2009			
2/9/11 and 6/9/11	Email correspondence between Commercial Director, NHS Supply Chain and Head of NHS BSA Supply Chain Management and DH Director, Supply Chain	Subject Email Re: CONFIDENTIAL -TIGER MEDICAL STOCKINETTES FOUND NOT TO BE STERILE!" Initial email from NHS SC confirming non-sterile goods had been identified and quarantined prior to distribution. **NHS BSA – highlighting risk of other Tiger Medical products in the supply chain and what assurances were available over quality standards. Noting that "*suspects that all the relevant prior upfront checks were not done, testing this late in the process, is too late*"** **NHS BSA – impressing the need for assurance and evidence to demonstrate appropriate QA framework in place within the Tiger Medical supply chain.** Reference to a DH review in May 2010 relating to NHS SC QA processes and an assurance framework they had introduced which included site visits and full evaluation of supporting quality documentation**. Clear steer to identify any other Tiger Medical products that could be compromised.** DH Director Supply Chain – **referencing discussion with MHRA where they have found**	Although the issue is unrelated to PPE stock, it does relate to the supplier Tiger Medical, throwing into doubt the credibility of what they will have supplied previously. These are **serious concerns not only about Tiger Medical as a supplier and the products that they have previously moved into the NHS supply chain, but also NHS SC and their supply chain assurance processes**. **This a clear missed opportunity to have identified and remedied issues highlighted subsequently found in 2020 with Tiger Eye Protectors**

Date	What	Event details (wording paraphrased based on original email)	GIAA observations
		"no systems governance or procedures at all" to support QA within the supply chain of the affected products.	
24/10/11	Email chain from NHS BSA to DHL	Issues highlighted relating to contractual agreements with Tiger Medical for the supply of the range of products for use across NHS. *"None of the frameworks provided include copies of schedule 1 product specifications. These would be useful in understanding how you defined product requirements. (Bit worried the product specs aren't an integral part of the framework package)* *Secondly, a number of the frameworks (87%) don't seem to have any contractual clauses relating to audit/access rights to test for product compliance to specs etc. nor is there any clause regarding agreed process for managing product changes /additions/deletions under the framework…* *Lastly, I need to know if NHSSC have any other agreements/MOU's or business arrangements with Tiger which are not covered within the frameworks but which can be directly or indirectly (linked) to execution of NHS Business".*	**Serious issues raised relating how robust commercial arrangements with Tiger Medical are.** Some further correspondence from DHL's legal team in response to the queries raised. No further information on this strand available at this point in time.
26/10/11	Draft letter from NHS BSA Supply Chain Management to CE of NHS SC	Letter outlines serious concerns / failings within the supply chain. Key points raised: • *"In the case of tiger products – tiger product and technical information files have been identified recently as having incorrect and incomplete info – which **brings into question whether tiger products are properly certified – even though a CE certificate may have been issued – is it genuine** and if so has it been issued against correct tiger technical files?.* • ***the weakness is in supplier evaluation, audit and lack of governance, risk and control testing regimes**. Further, the CE marking only provides a degree of assurance, it is not fully comprehensive"* • *NHS SC do not have to do the testing but "they need evidence and assurance from their suppliers that the test has been done by a bona fide test house and that formulas used are to European standards"*	**Despite failings in Tiger Medical QA / certification process, no evidence of a systemic review being initiated to identify any other suspect items within the NHS supply chain**
28/10/11	Draft Letter from DH Commercial to NHS SC	Letter outlines concerns following action taken by NHS SC following the identification of non-compliant products in supply chain procured from Tiger Medical. Key points:	

Date	What	Event details (wording paraphrased based on original email)	GIAA observations
		• Recognition that NHS SC has self-reported breaches • Concerns that further criminal offences may have arisen and that there may have been further breaches of patient safety. • Concerns that almost 6 months after the initial default notice relating to CE marking breaches (April 2011) a satisfactory action plan is not in place to remedy. • Further concerns raised around commercial arrangements and overarching governance between DH, NHS BSA and NHS SC.	
17/11/11	Letter from CEO NHS SC to CEO NHS BSA	Letter in response to contractual breaches relating to release of untested products into supply chain, originally procured via Tiger Medical. Outlines official response to each breach and the remedies put in place and the point that **all commercial relationships with Tiger Medical terminated.**	
25/11/11	Briefing from DH Commercial to Minister of State	Outlining breaches where non-compliant products were placed on the market and the legal position regarding terminating commercial relationship with NHS SC. Briefing assures that patient safety not compromised and that products have been recalled. Note highlights that NHS SC are **"terminating all Tiger Medical Supply contracts because of concerns about their supply chain"** Briefing concludes that terminating the contract with NHS SC would have unwanted consequences across the wider NHS and that recent senior management appointments within the organisation should result in more robust management in future	
28/11/11	Letter from NHS SC to DH Commercial	Letter relates to potential legal action and consequences as a result of Tiger Medical supplying non-compliant goods as part of the Choices for Health Programme. NHS SC looking to close the matter with any further investigations so that they can focus on delivery of core business.	
Issues re Tiger Eyewear - 2020			
27/4/20	Emails between Army and NHS E&I	Col Simon Smith confirmed **complaint on Tiger eyewear was first raised on 27 April 2020**, from Scotland about them being loose fitting. Initial investigations conducted on 28 March deemed them fit for purpose, but items subsequently quarantined on 29/03/20 after it became apparent that **no quality certification data sheets were available**	
30/4/20	Emails between Army and NHS E&I	NHS E & I informed of complaints and lack of documentation (data sheets) to support Tiger eye protectors.	

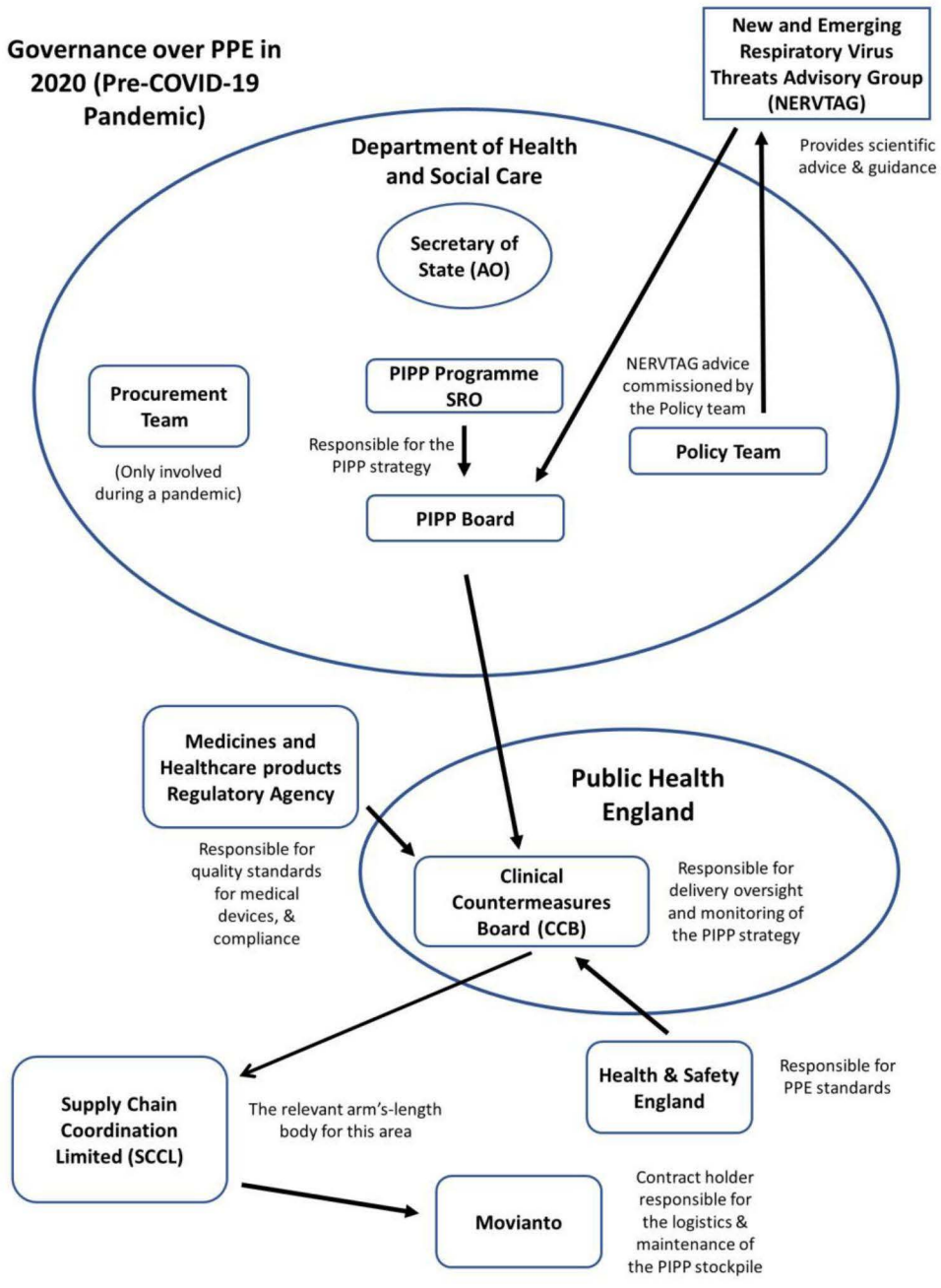
Date	What	Event details (wording paraphrased based on original email)	GIAA observations
		NHS E& I requested testing and further photographic evidence (received 30/04/20)	
1/5/20	Email from Army to NHS E&I	Confirmation that samples had been sent to BSI for urgent testing	
2/5/20	Emails between BSI, Army and NHS E&I	Confirmation that ***"the design of them [Tiger eye protectors] will not meet the BSI COVID-19 eyewear spec as this calls up a clause from the eyewear standard EN 166 requirements which offers protection against liquid splash. This requires the protector to have coverage illustrated by the rectangle A, B, C, D in the diagram on the right and is only really provided by face shield style eyewear"***	
7/5/20 – 8/5/20	Emails between Army, BSI, NHS E&I and DHSC	Queries to assess the degree to which the eye protectors did not meet requirements to assess level of risk to those who have used the product. BSI assessment "***In total, the spectacles need to be about 1cm taller, extend down over the nose portion not being covered (approx. 2 cm) and 3 cm further back around towards the ears."***	

Annex 3 – Governance Diagrams – PPE stockpile



Commented [AK35]: DN from TH: I believe this graphic is incorrect, I don't think NERVTAG existed in 2009 and the older PIPP ToR show a reporting link to the Departmental Board, not the Policy team (which should sit off to one side)

updated



Commented [AK36]: DN from TH: I don't believe this is correct. The PIPP programme SRO should be listed in place of the Policy Team (who sit below the SRO). NERVTAG advice should be shown as commissioned by the policy team.

updated

Annex 4 - Detailed results of audit findings on quality assurance for each PPE product held in the Pandemic InfluenzaFlu stockpile

We assessed whether the audit trail of documentation for purchased PPE in the PIPP stockpile was sufficient/adequate to demonstrate that expected quality controls had been met.

Item	PIPP Code	Year of Order and Receipt	Supplier	Commercial Route	Audit Findings
1. Eye Protectors	BTP083 (Frames) and BTP097 (Lens)	2009/10	Tiger Medical	Via NHS SC	• **No documents available related to this product line for audit** testing to be undertaken – **unable to confirm whether the standard required is correct, that any tests were performed after receipt of the product, or that it was checked for meeting the standard required.** • A picture of the box that the Tiger eye protectors came in was obtained - describes them as 'splash resistant', not splash-proof. This indicates that the **product was not appropriate for use in the COVID-19 pandemic.**
2. Safety glasses assembled	BTP012	2009/10	Bunzl	Via NHS SC	• A declaration of conformity letter was available which was on headed paper with the company name 'TIDI'. No mention of the supplier Bunzl. The letter is signed in June 2018, but items ordered/received in 2009/10 (no evidence available relating to the time of purchase); letter states it is based on a BSI certificate with an expiry June 2021, which is 3 years from when issued. It is unclear if this the duration of the actual product or if the reference to the BSI certificate covers the residual product shelf life. • **No evidence or link to the actual product on the documentation** or even if it relates to the conformity letter. • **No evidence of any quality checks post-delivery** to confirm that the product met the required standard.
3. Aprons	BTB272	2009	HPC Healthline UK Ltd	Via NHS SC	• A range of quality standards have been quoted within the specification and framework document. **The quality standard quoted (BS EN ISO IEC 17025:2005) is not specifically relevant to protective aprons**, it solely relates to a 'standard that specifies the general requirements for the competence of laboratories to carry out tests and/or calibrations, including sampling'. This quality standard therefore relates to accreditation of labs to undertake technical quality testing. • **Unclear if any specification was set for tear resistance** within the procurement framework, but size and thickness are specified and aprons meet these requirements
	BTB272A	2018/19 and 2019/20	Polyco Healthline	NHSSC Framework Polymer Product	

Commented [GT37]: Only relevant to the response which was for COVID. They were procured for influenza.

Commented [AZ-G38R37]: Noted and this is the point we have made, they were procured for influenza but subsequently deployed for use for Covid

Commented [SG-G39R37]: Regardless of where they were used, they did not meet the CE spec for splash resistance, and also failed impact testing, so they were never fit for purpose in any setting. The flu / COVID argument being used here is perhaps not relevant.

Item	PIPP Code	Year of Order and Receipt	Supplier	Commercial Route	Audit Findings
				(FAG000016 272)	• **No quality testing of items upon receipt.** • Business case dated April 2019 and was produced in advance of significant purchase of items in late 2019 therefore it does not relate to earlier purchase of item BTB272.
4. Clinical waste bags (orange)	MVN849	2019/20	British Polythene Ltd	NHSSC Framework Polymer Product (FAG000016 272)	• Same certificate of conformity provided for orange and yellow waste bags. • No reference on certificate to colour of the bag, therefore **unable to ascertain if the certificate relates to these bags as the size also differs** (on the certificate it states 711 x 865mm and on the product data sheet it states 711 x 695mm). • **Tender Specification states standard to be met is UN3291; however, the certificate states UN5H4Y11/S/GB/6978.** • The supplier data sheet states that the document relates to item MVN852 (which SCCL stated is the business as usual code) and that MVN849 or MVN850 are PIPP allocated in terms of product code, however, **none of these product codes correlate to the certificate of conformity**.
5. Clinical waste bags (yellow)	MVN850	2019/20	British Polythene Ltd	NHSSC Framework Polymer Product (FAG000016 272)	
6. Gloves (S, M, L)	BTM005A (Small) BTM006A (Medium) BTM007A (Large)	2019/20 (NHS SC swap out)	Medicare	NHS SC Framework	• **No evidence that gloves were quality tested pre/post-delivery,** sole reliance based on certificates supplied by the company.
7. FFP3 Respirators valved and unvalved	BTP081, BTP104, BTP011, BTP082, BTP102	2009/10	3M	NHS SC	• Test report was commissioned in March 2020 (post Covid 19) which tests a number of samples from the stockpile. These items appear to have exceeded their original use by dates and limited testing agreed between PHE and HSE have deemed items fit for purpose. ~~and SCCL have confirmed that PHE agreed with HSE to allow use for a further 12 months~~ • **No evidence provided of a business case or other document outlining technical specification required for the product** at the time of purchase. • **No evidence that quality checks performed on items as they entered the stockpile.**
	BTP077	2009/10	Medline	NHS SC	• As with 3M products (above) - Test report was commissioned in March 2020 (post Covid 19) which tests a number of samples from the stockpile. ~~testing conducted on products commissioned in March 2020. Testing results appear inconclusive, with **several of the tests not being fully met, even with products within shelf life**~~. Limited testing agreed between PHE and HSE have deemed items fit for purpose. • **No evidence of a business case with specification outlined, any testing of products on receipt etc. at the time of purchase**. Product data sheet is from 2019.
	BWM028	2009/10	Cardinal/ Medline	NHS SC	• **These masks that were withdrawn from circulation recently** because the foam on the nose part was disintegrating and some of the straps were breaking.

Commented [GT40]: There might be some confusion on this as the QA testing only enables confirmation that the product is still fit for consumption and no future expire date can be given without accelerated age testing.

Commented [AZ-G41R40]: To discuss

Amended

Commented [SG-G42R40]: The information we got was that the HSE testing re-lifed the products for 12 months. To discuss with Gareth if this is what he is saying that this is not the situation, in which case we are unsure how they can be deployed without accelerated age testing as he states here.

Commented [GT43]: Again something is confused here. The FFP3s were tested in March/April 20 and all batches passed.

Amended

Commented [SG-G44R43]:

Item	PIPP Code	Year of Order and Receipt	Supplier	Commercial Route	Audit Findings
8. Type IIR Face Masks					• Certificate of conformity provided, dated April 2009. The manufacturer is reported as priMED (not Cardinal/Medline). It states it is a class I surgical mask, but it does not state the product code on the testing sheet. It confirms that it meets 93/42/EEC or 98/79/EEC. • **No evidence of the expected specification of the product** or evidence of checks performed prior to procurement. • No evidence of manufacturer storage instructions. • **No evidence that they have been tested to the latest standards** (BS EN 14683:2019).

	BWM065 BWM069	2009/10	Tiger Medical	NHS SC	• 'Nelson' test reports for bacterial filtration efficiency and differential pressure and synthetic blood penetration resistance were provided, dated 2009. Stating that tested against requirements for EN14683:2005 as Type IIR. The results section stated that 'testing met the acceptance criteria previously stated in the report' and 'met the performance requirements of EN14683:2005 as Type IIR'. Test report does not include manufacturer name or product code.
					• Three test reports from MET which test against EN14683:2014 were provided. They do not state the manufacturer of the mask.
					  ○ Report 1 - Time zero test: dated June 2017 - bacterial filtration efficiency, airflow resistance, blood penetration resistance and tensile strength, **3 batches did not meet acceptance criteria** (higher than expected airflow resistance);
					  ○ Report 2 - One year accelerated test: dated June 2017 – **some samples did not meet blood penetration, tensile strength or breathing resistance requirements**; and,
					  ○ Report 3 - Two years accelerated test: dated 2017 – **4 batches did not meet requirements.**
					• **No evidence of the expected specification of the product** or checks performed prior to procurement.
					• No evidence of manufacturer storage instructions.
					• **No evidence that they have been tested to the latest standards** (BS EN 14683:2019).

	BWM036	2009/10	3M	NHS SC	• We were provided a copy of the pdf format datasheet, but it is inaccessible because when opened, an error message flagged, and the document was blank. • Formal PIPP Stockpile Shelf-life Extension letter from 3M provided was dated 2013. This approved the shelf life extension; however, the letter is not actually signed. It is not clear how they came to this conclusion i.e. what tests they conducted (if any). If the extended dates on the letter are the current expiry dates, then the product needs to be re-tested. • **No evidence of the expected specification of the product** at the time of procurement. • **No evidence to demonstrate that they met the standards pre-procurement** or at the time of procurement. • **No evidence that they have been tested to the latest standards** (BS EN 14683:2019).
	BWM014	2009/10	Bunzl – NB; Bunzl are the distributor	NHS SC	• **No evidence of the expected specification or of checks** performed prior to procurement. • No evidence of manufacturer storage instructions. • **No evidence that they have been tested to the latest standards** (BS EN 14683:2019).

Commented [GT45]: It works for us so happy to assist with getting sight?

Commented [AZ-G46R45]: PHE to send to GIAA, no real impact on the overall finding

Item	PIPP Code	Year of Order and Receipt	Supplier	Commercial Route	Audit Findings
			. The product is manufactured by Kimberley Clark and is the same product as BWM072		
	BWM072	2009/10	Kimberly Clark	NHS SC	• **No evidence of the expected specification of the product** or checks performed prior to procurement. • No evidence of manufacturer storage instructions. • **No evidence that they have been tested to the latest standards** (BS EN 14683:2019).
9. Alcohol Hand Sanitiser - Diversey Soft Care Med	MRB772	2012/13	Diversey	NHS SC	• **No issues identified. Comprehensive testing data records available**, although dated pre-procurement. Product has not been tested since procurement but expiry dates not yet reached; current stock expires September – November 2020. Continued purchasing the same model of alcohol hand sanitizer.
10. Liquid Hand Soap - Soft Care Lotionised	MRB773	2012/13	Diversey	NHS SC	• **No issues identified. Comprehensive testing data records available**, although dated pre-procurement. Product has not been tested since procurement but expiry dates not yet reached; current stock expires in 2022. Continued purchasing the same model of hand soap.

Annex 5: Objectives, scope and limitations

Objectives

The objective of this advisory review has been to identify how the issue with the protective equipment has arisen, and to determine why the inadequacy of the equipment was not identified before it was issued to front-line staff. We will also review the procurement and storage of the other PIPP PPE stockpile items.

Scope and Limitations

Our review covers the following areas:

- The procurement processes that were in place at the time that the Department of Health procured the items held in the PIPP PPE stockpile;
- Compliance with these procurement processes, including the creation of the tender specifications and quality standards set out for the protective equipment to be procured;
- Goods receipting processes at the time of the procurement, and any quality or safety checks that were carried out on the goods received;
- Standards in place for the appropriate storage of the product e.g. temperature, length of time in storage, expiry dates of the items;
- Periodic checks in place to ensure the products were being stored appropriately and were free from damage or degradation; and,
- Monitoring of the legislation, regulations or standards over the acceptable protective equipment for use in pandemics, and where applicable, the rechecking of products in storage where the applicable quality standards are amended, to ensure that the products stockpiled remain safe and fit for purpose.

Exclusions from the Scope:

- The Department's response to the issue; and,
- We will not undertake any investigations into the manufacturers of the protective equipment, or into the testing that the manufacturers may have conducted over the product, before or after the items were procured and acquired by DHSC (or by PHE on behalf of DHSC).

Distribution

David Williams Second Permanent Secretary – DHSC
Jonathan Marron Director General, PPE and Public Health – DHSC
Clara Swinson Director General for Public Health - DHSC
Peter Howitt Director of PPE Policy – DHSC
Melinda Johnson Commercial Director – DHSC
Andy Brittain~~Chris Young~~ Director of Finance – DHSC
Steve Oldfield Chief Commercial Officer - DHSC

Commented [AK47]: DQ from TH: is this correct or should it be reworded? Acquisitions between 01/01/2013 and the present we managed by PHE on behalf of SofS and his counterparts in the DAs

Commented [AZ-G48R47]: amended

Commented [AK49]: Request to add Clara Swinson DG for PublicHealth to this distribution list as PIPP sits within her portfolio.

Commented [AZ-G50R49]: amended

Annex 6: Our classification system

Recommendation

Priority	Definition	Action required
High	Significant weakness in governance, risk management and control that if unresolved exposes the organisation to an unacceptable level of residual risk.	Remedial action must be taken urgently and within an agreed timescale.
Medium	Weakness in governance, risk management and control that if unresolved exposes the organisation to a high level of residual risk.	Remedial action should be taken at the earliest opportunity and within an agreed timescale.
Low	Scope for improvement in governance, risk management and control.	Remedial action should be prioritised and undertaken within an agreed timescale.


Better insights, better outcomes