

Use of FFP3 Respirators held in the Pandemic Influenza Preparedness (PIPP) stockpile in a response to the COVID-19 incident

Background

1. Public Health England (PHE) coordinates the purchase of a number of Pharmaceutical and Consumable products for inclusion in the Pandemic Influenza Preparedness Programme (PIPP) stockpile for use in the event of Pandemic Influenza outbreak.
2. These procurements are open to participation from all four nations of the UK (England, Scotland, Wales, Northern Ireland).
3. Due to the volume and expiry profile of product, the need to achieve best value for money, and taking in to account specifications within clinical guidance (where appropriate), it is possible that products procured will be across a range of manufacturers.
4. FFP3 respirators held within the PIPP stockpile are manufactured by 3M and Cardinal (now Medline).
5. This strategy outlines the situation within the UK for FFP3 respirators and outlines principles associated with the use of the PIPP stockpiles of FFP3 respirators in response to the COVID-19 outbreak.

Current Situation within UK countries

6. England has provided each DA with a volume of 100k eaches of in date 3M in stock with an end-June 2020 expiry under Mutual Aid arrangements in February 2020. This has been provided with the understanding that the DAs will reimburse England for any stocks used, and that they will dispose of any remaining stocks at the end of their shelf-life. See Annex A.

England - PIPP Stockpile

7. The PIPP stockpile within England contains FFP3 respirators from two manufacturers.
8. The volumes of in date 3M respirators is approx. 1.5 million eaches, however by end-April 2020 this figure drops to less than 500k eaches. By end-June 2020 there is circa 206k eaches left in date.
9. The volumes of in date Cardinal (now Medline) respirators is approx. 390k eaches. These expire by end-March 2020.
10. In addition, there is approx. 6.4 million eaches of Cardinal (Medline) respirators that have now passed their three-year accelerated ageing process with Medline (See 'Cardinal (Medline) product tested by Medline')

England – PIPP stockpile storage conditions

Commented [RC1]: Storage Conditions (only limited information was provided)

The storage requirements advised by the manufacturers to ensure shelf life are temperature, relative humidity and original packaging.

The main document only refers to temperature but with reference to packaging for some nations. Relative humidity is not mentioned, however in our experience of monitoring relative humidity in indoor environments, and acknowledging the climatic conditions of the UK, it would be highly unlikely to exceed 80%.

Where details of original packing are not stated the main concern, here would be exposure to excessive humidity, sunlight, and contaminants. A visual inspection of the respirator prior to use (as detailed in para 55) may identify visible physical damage and supported by the QA testing undertaken.

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11. These products have always been stored under aAmbient conditions in both temperature monitored, and temperature controlled facilities.
12. Monthly temperature reporting is a KPI feature of the contract with all reportable excursions and effect on stock being commented on. Temperature records are available.
13. There have been no temperature excursions that have affected or compromised the stability of the product.

England - BAU Usage

14. Acute Trusts within England use a variety of manufacturer products including (by order of highest volumes used over a 12-week period);
 - Full Support
 - 3M
 - Medline
 - Valmy

Scotland - PIPP Stockpile

15. The PIPP stockpile within Scotland contains FFP3 respirators from four manufacturers. However, products from Gerson and Arco have expired >10 years ago and are being held for use in-extremis.
16. The volumes of in date 3M respirators is approx. 13k eaches, with the first of these products expiring in January 2021.
17. In addition there is a quantity of 100k eaches of 3M respirators as supplied from the England PIPP stockpile under mutual aid (any consumed product to be reimbursed to England). These expire by end-June 2020.

Scotland – PIPP stockpile storage conditions

18. Product has been stored in ambient controlled environments; therefore, the masks have not been subject to any adverse temperatures.
19. All stock has been visually checked bi-annually and the ti/hi layers of the pallets rotated to ensure integrity of all outer boxes within the holding pallets. Note, both storage locations are ISO accredited and have been audited by NSS Quality Control and Audit Scotland without any non-conformances reported.

Scotland - BAU Usage

20. Health Boards within Scotland would appear to use only 3M manufactured FFP3 respirators in BAU.

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Wales - PIPP Stockpile

21. The PIPP stockpile within Wales contains FFP3 respirators from one manufacturer only.
22. All 3M respirators within the Wales stockpile have expired, except for circa 10k remaining from the 100k eaches of 3M respirators, as supplied from the England PIPP stockpile under mutual aid. These expire by end-June 2020.

Wales – PIPP stockpile storage conditions

23. Product has been held in a temperature-controlled environment for the last 3 years and prior to that it was in a normal store. Both locations had the respective ISO accreditations for the environment and health and safety.

Wales - BAU Usage

24. Wales NHS Trusts use a variety of manufacturer products including:
 - Four Health Boards use 3M products exclusively
 - Two Health Boards use a mixture of 3M and Full Support products
 - One Health Board uses a mix of 3M and Arco products.
 - Data for one trust was not available though they have now been provided with 3M product.

Northern Ireland - PIPP Stockpile

25. The PIPP stockpile within Northern Ireland contains FFP3 respirators from one manufacturer only.
26. All 3M respirators within the Northern Ireland stockpile have expired, except for circa 99k remaining from the 100k eaches of 3M respirators, as supplied from the England PIPP stockpile under Mutual Aid (any consumed product to be reimbursed to England). These expire by end-June 2020.

Northern Ireland – PIPP stockpile storage conditions

27. Product has been stored in a clean, dry ambient warehouse within the temperature range -20 - +25 degrees C. The product is still in its original packing, as received from the manufacturer.

Northern Ireland - BAU Usage

28. No data is available for product usage by manufacturer for Northern Ireland

QA and accelerated age testing

Cardinal (Medline) product tested by Medline

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29. Within the England stockpile of FFP3 respirators there is circa 6.4 million eaches of Cardinal (now Medline) respirators that have expired.
30. From data provided by Scotland it would appear that they also have circa 129k eaches of this product held locally.
31. Associated batches of these products were sent to Medline for QA / fit for purpose testing and accelerated ageing of 3 and 5 years with a view to extending the shelf-life of these products and giving assurance that they can be utilised for a COVID-19 response.
32. All batches of these products have now passed the three-year accelerated ageing and have now progressed to the five-year ageing process.
33. These Cardinal (Medline) masks are now undergoing a re-labelling exercise by Movianto UK with the expectation that the first volumes of this product will become available for use by week commencing 16th March 2020.
34. Medline hold liability for the use of these products.
35. Medline were approached to determine whether there would be a requirement for completion of Fit-Testing against these products once distributed or if a fit-test result against the current Medline FFP3 respirators would suffice. Despite an initial suggestion from Medline that this would not be required, it is the opinion of PHE that the written confirmation to support this does not provide enough evidence and thus we recommend fit testing is undertaken within Trusts against this re-labelled product.

3M product tested by Medline and INSPEC International

36. Wales have had a small number of 3M FFP3 respirators tested for QA / fit for purpose testing via Surgical Material Testing Laboratory (SMTL) with encouraging results across the samples tested. See Annex B.
37. All four nations of the UK hold a stockpile of 3M FFP3 respirators that have now expired.
38. England approached a number of testing houses to determine who could undertake QA / fit for purpose testing and accelerated ageing testing on their volume of circa 19.3 million eaches.
39. 3M had suggested they may be able to offer support to England for this work but subsequently withdrew this offer following two weeks of internal discussions within 3M. Instead they suggested that an independent testing house be approached to complete this work.
40. At this time 3M confirmed they would be happy for their product to be re-labelled with a new expiry noting that they would NOT hold the liability. This liability of use passes to the UK Government.

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41. Medline, INSPEC International, and MET UK were approached to undertake this testing regime however only Medline were able to offer accelerated ageing. They were thus engaged to complete both QA / fit for purpose testing and a one year accelerated ageing shelf-life extension.
42. Whilst both MET UK and INSPEC International could complete the QA testing, it was INSPEC International whom would return results in the shortest timescales and thus they were selected in addition to Medline to provide additional confidence that the associated product has passed a QA /fit for purpose should it need to be used prior to receiving a one year shelf-life extension.
43. The Devolved Administrations (DAs) and Supply Chain Coordination Limited (SCCL) completed a reconciliation of batch numbers across all 4 nations to ensure that full batch coverage across each country was included in this testing work.
44. In total circa 21.1 million eaches of 3M product will begin QA / fit for purpose and accelerated ageing testing week commencing 9th March 2020.
45. It is expected that INSPEC International will report back a limited QA / ft for purpose result on this 3M product by end-March 2020. See Annex C.
46. A further QA result to provide additional reassurance of the products usability is expected from Medline by mid-April 2020.
47. The results of the accelerated ageing process with Medline for a one year accelerated ageing shelf-life extension for this 3M product is expected by June 2020 (best case). See Annex D.
48. Assuming that this product passes its one-year ageing process the product will then be subject to a re-labelling exercise subject to discussions with HSE (this re-labelling will be undertaken by Movianto UK for England) resulting in product availability in to the NHS Supply Chain (NHS SC) in July 2020.

Commented [RC2]: What further discussions do you need to have on this?

Principles of PIPP FFP3 respirator usage.

Short dated Stocks

49. For use to support;
 - a. Community swabbing activities
 - b. Fit testing of particular manufacturer's mask if a switch for BAU is required
 - c. Supply acute trusts that use the specific manufacturers product

Commented [VP3]: What is the level of control here in terms of FFP3 usage? E.g. does this include drive through test sites – in an effort to conserve stocks it may be worth considering how this is managed.

In-date Stocks

50. For use to support
 - a. Utilising data from trusts on BAU products, distribute in date stocks for BAU usage in acute trusts.