REVIEW OF COUNTERMEASURES FOR PANDEMIC INFLUENZA AND INFECTIOUS DISEASES

Issue

1. The COVID-19 pandemic has shown clinical countermeasures held for an influenza pandemic have limited applicability to non-influenza pandemic threats. The existing model of stockpile procurement, maintenance and delivery – such as a reliance on just-in-time supply contracts to augment stocks – has also experienced challenges in this pandemic.

2. It is proposed that the opportunity should be taken to learn the lessons from the current COVID-19 pandemic and undertake an evidence led review of current policies for the PIPP stockpiles. This would enable thorough consideration of stockpile contents and governance systems to ensure the UK has a resilient and flexible system to respond to the RWCS for a range of risks including, but not limited to, pandemic influenza.

Action required

3. Board members are asked to:

    - **agree** to the proposed scope, including expansion beyond influenza, and governance of the review; and
    - **note** the intention (where possible and in-line with existing expert advice) to repopulate PIPP stockpiles using available surplus COVID-19 stocks.

Background

4. Prior to COVID-19 the health departments of the four UK nations, working with Public Health England (PHE) as lead purchasing authority, only held central stockpiles for an influenza pandemic and CBRN incidents (out of scope for this proposal).

5. PHE managed Pandemic Influenza Preparedness Programme (PIPP) stockpiles usually hold medicines, personal protective equipment (PPE) and clinical consumables sufficient to respond to the Reasonable Worst Case Scenario (RWCS) influenza pandemic where 50 per cent of the population fall ill (see Annex A for details of current RWCS).

6. The PIPP stockpiles have been used to support the response to COVID-19, this had led to:

    - the complete depletion of the PPE stockpile;
    - significant use of other materials held (e.g. hygiene products); and
    - a possible need to deploy antibiotic stocks to mitigate shortages during the winter of 2020/21 (subject to separate policy considerations).

7. Beyond pandemic influenza the current position regarding stockpiles for HCIDs and other diseases is fragmented, with materials either purchased on an ad-hoc

basis not held centrally. An overview of the currently understood stockpile situation is included as Annex B.

Aims and scope of review

8. It is proposed that a review committee will be convened to advise on clinical countermeasures for all human disease risks within the National Security Risk Assessment (NSRA), with the following set aims:

   A. To advise the Secretary of State for Health and Social Care (SofS) on options for stockpile contents in the context of the current funding envelope, and additional options for increased capability which could be explored in a future multi-year Spending Review in 2021/22.
   B. To consider value-for-money and flexibility of stockpiles to respond to a variety of human disease and related biological risks, while advising on risks associated with concurrent disease outbreaks.
   C. To advise SofS and senior policy officials on appropriate governance arrangements for pandemic preparedness stockpiles and related activity in light of lessons learned from COVID-19.

9. In fulfilling these aims, The Review will investigate:

   - the types and quantities of PPE held for all infectious disease risks;
   - the medicines (types, presentations and quanitities) that should be held for all infectious disease risks;
   - the types and quantities of clinical consumables and hygiene products needed to support the response to a pandemic or large scale HCID outbreak; and
   - the models for stockpile procurement, maintenance, storage locations And response times.

10. The purpose of the review is advisory. Final decisions regarding stockpiling policy are reserved to the SofS. A full breakdown of areas where the advice of The Review will be sought is set out in Annex C alongside a summary of inputs and organisations likely to be engaged.

Wider considerations

11. The current personal protective equipment (PPE) stockpile depletion means the UK is at increased risk should an influenza pandemic occur prior to the completion of any review and subsequent procurement activity, as such there is an argument for initiating procurement activity as soon as possible to minimise gaps in UK preparedness.

12. The risk to the UK from the current stockpile depletion is is mitigated by the potential to draw on materials procured for the COVID-19 response in the interim if required. PPE is the most depleted stockpile but discussions with colleagues managing PPE supplies for COVID-19 indicate that, should a concurrent influenza pandemic occur, there is sufficient PPE available to support a response and additional resilience is provided by current contracts for manufacture within the UK.

13. An alternative approach would be to make some stockpile replenishment decisions in advance of the review completing. This could include incorporation of COVID-19 surplus into PIPP stockpiles (where the surplus stocks available meet the previous scientific, clinical and operational advice on what should be held).However, the long shelf-life of stockpiled products (e.g. PPE) would mean this approach may risk divergence between actual stockpile composition any recommendations from this review. Consequences of this could mean acceptance of lower levels of preparedness (or protection if PPE) or the need for additional procurement at extra cost. These risks would however have to be balanced against cost and operational benefits of using any available COVID-19 surplus.

Proposed structure and governance

14. For efficiency, the review will be carried out within existing governance structures. On this basis is it proposed that:

A. The Senior Responsible Owner (SRO) and chair for the review will be Emma Reed, Director for Enhanced Emergency Health Protection.
B. The review will be established as a sub-committee of this Board. The Chair of the proposed review will report findings to the PIPP Board.
C. the review will be led by a main committee, containing representation from DHSC, PHE, NHS England, Other Government Departments, expert advisors and the Devolved Administrations. The expert advisors on the group will lead Task-and-Finish groups on specific elements.

15. As per normal processes for countermeasures policy, any changes to policy that could potentially impact the degree of risk to the UK population will be put to Ministers for approval. The full proposals for governance and membership of the review are set out in Annex D and E respectively.

Recommendation

16. It is recommended that you agree the scope of the review as proposed, subject to the advice of the Board regarding the use of available COVID-19 stocks.

Name Redacted, *Policy Manager*
DHSC
14 December 2020

ANNEX A

BACKGROUND AND REASONABLE WORST CASE SCENARIOS FOR AN INFLUENZA PANDEMIC AND HCID OUTBREAK

1. Infectious diseases in humans take a variety of forms, some of which have the potential to cause significant public health impacts due to the number of people they might affect in a short space of time, and the severity of their symptoms. Possible scenarios range from significant outbreaks of 'containable' infectious diseases (which spread slowly and/or can be more easily delayed and stopped) but with a high fatality rate, through to pandemics such as the current COVID-19 pandemic, where the whole population is at risk from a highly infectious virus, which can cause large numbers of fatalities in some groups of the population.

2. Pandemics are the result of a new human virus emerging and spreading around the world and have occurred at infrequent and unpredictable intervals throughout human history. Their global impact has ranged from severe (influenza 1918 and COVID-19) to mild (influenza 2009).

3. It is difficult to forecast the spread and impact of a new disease until it arrives in the UK and starts circulating. As such, planning is undertaken on the basis of mitigating a Reasonable Worst Case Scenario (RWCS). Estimates of impacts from human diseases include:

Pandemics (RWCS based on influenza)

Health impacts

- up to half of the population may fall ill during an influenza (or influenza like illness) pandemic.
- Potentially up to 820,000 deaths across the UK (based on a case fatality ratio of 2.5%).
- Over 9,800,000 persons requiring assessment by the health services.
- Up to 4% of symptomatic individuals (1,312,000 persons) will require hospital care, of which 25% (328,000 persons) are expected to require the highest level of critical care.

Societal and economic impacts

- Significant disruption to all sectors of society (e.g. education and businesses).
- Workplace absence rates of up to 20% of the workforce during the peak of the pandemic.
- It is estimated that the economic impact to UK society from a future influenza pandemic may be as high as £2,355 billion (based on a centrally developed Cabinet Office methodology).

High Consequence Infectious Diseases

Health impacts

- Two thousand people experiencing symptoms
- Potentially up to 200 deaths across the UK.
- Increased demand on specialist intensive care and infectious diseases facilities as all symptomatic persons would require isolation and specialist care.

Societal impacts

- Some disruption to essential services, including health and education.
- Large numbers of possible contacts of infected persons being placed under surveillance.
- Public concern about travel, within and beyond the UK and possible international travel restriction advice.

ANNEX B

SUMMARY OF STOCKPILE SITUATION AS CURRENTLY UNDERSTOOD

1. Prior to COVID-19 DHSC, working with Public Health England (PHE), only centrally stockpiled for an influenza pandemic or CBRN incidents (out of scope for this project).

2. The current position regarding stockpiles for pandemic influenza and HCIDs is fragmented, but can be summarised as follows:

Pandemic influenza

A. Pandemic Influenza Preparedness Programme (PIPP) stockpiles usually hold medicines (antivirals and antibiotics), personal protective equipment (PPE), clinical consumables (needles etc.) and hygiene products (disinfectants etc.) sufficient for the RWCS.
B. The PIPP stockpile programme is comprised of a mix of Just-in-Case (JIC) stockpiles and Just-in-Time (JIT) contracts for delivery during a pandemic.
C. PIPP PPE stockpiles are completely depleted following the response to the first wave of COVID-19. However, contracts placed for PPE in response to COVID-19 may result in a significant quantity left post-pandemic which may meet the advised requirements for influenza and other infectious diseases.
D. PIPP antibiotic stockpiles may be drawn down during the winter of 2020/21 if difficulties in securing required supplies for COVID-19 on the open market result in in shortages and no other mitigations are possible.

HCIDs

E. No significant stocks of HCID countermeasures are held centrally by PHE and/or DHSC. Some experimental medicines (e.g. Ebola vaccine) are held by the Royal Free Hospital on behalf of the UK, but most materials are sourced if required.
F. Many HCIDs do not have recognised treatments and for those that do, because of limited demand, treatments may not always be available on the global pharmaceutical market. An example being a third-generation vaccine for Smallpox which was held for post-exposure prophylaxis. When last investigated, the manufacturer had plans to cease production.
G. Specialist PPE for HCIDs is held local locally within the NHS and sourced through NHS Supply Chain.
H. There is some overlap to CBRN stockpiles as some of the antibiotics for malicious biological incidents would be effective against a large-scale bacterial infection outbreak (e.g. Bubonic Plague). There may also be other overlaps requiring exploration at higher levels of classification.

ANNEX C

DETAILED INPUTS AND OUTPUTS OF PIPP STOCKPILE REVIEW

Outputs

On types of countermeasure, it is proposed that The Review will advise on:

1. The types and quantities of PPE held for a future influenza pandemic (unless there is a desire to re-procure to current levels given current stockpile status and delay decisions around changes to the influenza stockpile until the next Spending Review period).

2. The types and quantities of PPE that should be held to respond to a pandemic caused by a virus other than influenza, and whether this should be a separate PPE stock or additional items to enhance/augment stocks held for influenza.

3. The types of PPE items that could be added to the standard PPE ensemble held for an influenza pandemic to provide an enhanced level of protection in the event of a HCID outbreak; and, the quantities of these items that should be held.

4. The medicines that should be held for a future influenza (or other) pandemic and the quantities/mix of these medicines that should be held.

5. The medicines (including pre/post-exposure prophylaxis and treatments) that should be held for persons infected in a large scale (RWCS) HCID outbreak and their close contacts.

6. The types/quantities of clinical consumables (e.g. needles and syringes) needed to support the response to a pandemic (influenza or other virus of pandemic potential) or large RWCS scale HCID outbreak.

7. The types/quantities of hygiene products (e.g. clinical waste bags/containers and cleaning products) needed to support the response to a pandemic (influenza or other virus of pandemic potential) or large RWCS scale HCID outbreak.

When investigating the mix of countermeasures held and the target volumes required to mitigate the RWCS for each human disease risk, it is proposed that The Review will also consider:

8. The desired format in which to store countermeasures, e.g. vials or pre-filled syringes for HCID vaccines.

9. The balance of desirability between physical stockpiling on a JIC basis and contracts to provide materials on a JIT basis during a pandemic.

10. Response time requirements, if any, for HCID countermeasures (it is envisaged that pandemic stockpiles will be fed into the supply chain on a large scale).

11. The desirability of a distributed regional storage model to increase resilience and flexibility of deployment (this may be informed by any response time requirements).

12. The balance between efficiency of investment and risk mitigation (e.g. the desirability to hold one medicine for two concurrent risks).

Inputs

While advising on the preferred mix of stockpiles The Review will draw on a range of expert advice and evidence including, but not limited to:

13. Scientific advice – drawn from standing expert advisory groups and PHE.

14. Clinical advice on the models of care likely to be employed in a pandemic or infectious disease outbreak – drawn from NHS England and the NHS HCID Network.

15. Operational advice – drawn from PHE, NHS England and the NHS HCID Network.

16. Advice on differences between UK health systems – provided by representatives from the Devolved Administrations (DAs).

17. Analytical and economist support (including experts on time and motion analysis to base PPE usage on) – drawn from DHSC and PHE.

18. Learning from the COVID-19 response.

19. Policy advisors – drawn from DHSC (and other Government Departments as appropriate).

ANNEX D

FULL GOVERNANCE STRUCTURE PROPOSAL FOR PIPP STOCKPILE REVIEW

It is proposed that, for efficiency, the review of PIPP and HCID stockpiles ("The Review") will build on existing roles, governance structures (which may themselves be subject to review) and expert advisory functions.

On this basis, it is recommended that:

1. The Senior Responsible Owner (SRO) for The Review will be Emma Reed, Director for Enhanced Emergency Health Protection.

2. The Review will be established as a sub-committee of a reconstituted Pandemic Influenza Preparedness Programme Board (PIPPB), or a similar board fulfilling this function but reflecting the lessons learned from COVID-19 if structural changes are made to the programme. The Chair of the proposed Review will report findings to the PIPPB (or its successor).

3. It is proposed that the Review will be led by a main committee, containing representation from DHSC, PHE, NHS England, Other Government Departments, expert advisors and the Devolved Administrations. The expert advisors on the group will lead Task-and-Finish groups on specific elements.

4. Where possible, and subject to agreement, existing expert advisory groups will be used to provide Task-and-Finish groups, with their chairs being invited to sit on The Review. Where responsibility for an area of advice sits across two standing advisory groups (e.g. influenza vaccination) and no joint committee exists to support this review, members of standing advisory committees will be co-opted onto the proposed Task-and-Finish groups.

5. Where recommendations on the Review relate to governance functions and sub-committees of PIPPB, the chair of the PIPPB will consider and (if the Board agrees) implement those recommendations as appropriate. All other recommendations, once agreed by PIPPB, will be costed, incorporated into relevant spending plans and put to Ministers.

6. As per agreed processes for countermeasures, any changes to policy that impact the degree of risk to the UK population must be approved by a Minister.

ANNEX D

PROPOSED MEMBERSHIP OF THE REVIEW OF COUNTERMEASURES FOR PANDEMIC INFLUENZA AND INFECTIOUS DISEASES

Chair	SRO
Secretariat	DHSC UKHS
Policy	DHSC UKHS (*member*) DHSC EPRR (*member*) DHSC PPE S and BM (*as required*)
OGDs	CCS (*member*) MOD (*member*) DEFRA (*member*)
DAs	Scotland (*member*) Wales (*member*) Northern Ireland (*member*)
Experts: Scientific/Operational/ Commercial	DCMO DHSC Commercial (*as required*) DHSC Medicines (*member*) DHSC Finance (*as required*) PHE Vaccines and Countermeasures Team (*member*) NHS England (*member*) NERVTAG (*member*) ACDP (*member*) JCVI (*member*) SPI-M (*member*) PHE National Infections Service (*member*) PHE ERD (*as required*) HCID Network (*member*) DHSC Statistician (*as required*) DHSC Economist (*as required*) NICE (*as required*) MHRA (*as required*) HSE (*as required*)

- Additional organisations and further members from these bodies may be co-opted onto Task-and-Finish groups.

- Organisations marked “as required” will be asked to join Task-and-Finish groups and may be invited to attend the main committee meeting based on the requirements of the programme.