

## Future clinical countermeasures governance

### Introduction

1. This paper explores whether any changes to the governance for the clinical countermeasures programme should be introduced to support the recommended expansion of the clinical countermeasures programme scope and ongoing work to develop the PIPP programme.

### Current programme governance

2. Currently the clinical countermeasures programme is overseen by the Clinical Countermeasures Board (CCMB), whose purposes is *"to provide governance and oversight of the necessary maintenance and management of the clinical countermeasure UK stockpiles and the agreements required to ensure that the UK is well prepared to respond effectively to a pandemic"* (see Terms of Reference at **Annex A**). The Board:
  - a) ensures that all procurements are aligned to pandemic preparedness policy;
  - b) reviews break points in contracts and outlines key points at which there is scope for DHSC and the Devolved Governments to review and, if appropriate, propose changes to pandemic preparedness policy;
  - c) reviews procurement and approval timelines, to track progress of activities and ensure procurements are completed so that stock levels are maintained;
  - d) reviews risks and issues that relate to clinical countermeasures; tracks progress of actions and escalates where necessary;
  - e) disseminates and shares relevant and timely information.
3. The key exclusions from the scope of the CCMB are:
  - a) Setting and approving pandemic flu policy.
  - b) Development and revision of scientific and clinical advice and guidance.
  - c) The supply of routine medicines during a pandemic.
  - d) Advice on the appropriate use of countermeasures in the clinical setting.
  - e) Developing communications to support public understanding of and use of countermeasures.
  - f) The UK CBRN stockpile, which is governed by the UK Stockpile Deployment Group.
4. The CCMB is chaired by UKHSA Vaccines Countermeasures and Response (VCR) team; currently meets biannually; and reports in to the PIPP Board.
5. The Terms of Reference outline that a parallel Operational Management Board co-chaired by UKHSA and NHSE manages the National Pandemic 'Flu Service (NPFS). However, this board is not currently operational.

### Changes to countermeasures programme scope and PIPP governance changes

6. Recommendations from the Clinical Countermeasures Review Governance Subgroup so far include the expansion of countermeasures programme scope to include identification and coordination of R&D priorities across government, through a proposed new cross-government

working group; and coordination with other government owned or held stockpiles of clinical products.

7. In addition, the PIPP Board is currently re-scoping the PIPP work programme under several objectives. One of these is currently drafted as *"To procure, manufacture, store, distribute and support the research/development of clinical countermeasures designed to support the containment of a future infectious disease by treating or protecting the population."* Under this, several workstreams have been outlined (including the Clinical Countermeasures Review, its implementation, the review of the National Pandemic 'Flu Service, determining the long-term home for novel pandemic vaccine development as the Vaccines Taskforce winds down, and completion of ongoing procurements for influenza antivirals and a new advance purchase agreement), and a new reporting template is being developed.
8. Notably, the expanded elements of the countermeasures programme and several of the workstreams under the PIPP Board have an emphasis on policy review or generating scientific advice which fall outside of the existing operational delivery scope of the Clinical Countermeasures Board.

### Proposal

#### 9. We recommend that:

- a) The Clinical Countermeasures Board continues operating with its existing remit and UKHSA in the chair, covering the clinical countermeasure UK stockpiles and the agreements required to ensure that the UK is well prepared to respond effectively to a pandemic.
- b) That in future this scope includes any stockpiles and related agreements developed for other pandemic, emerging infectious disease or HCID risks (e.g. Imvanex); and the National Pandemic 'Flu Service (NPFS).
- c) That meetings move to quarterly frequency.
- d) Meetings should have standing agenda items, commissioned where necessary by UKHSA secretariat, covering:
  - Stockholdings vs target volumes (and any projected changes) of products held for pandemic, HICD, and emerging infectious disease risks.
  - Reporting on ongoing procurements and re-procurements and other projects (noting that in some cases, project-specific boards may also be established)
  - Forward look on upcoming procurements, break points, or other points where scientific advice or policy may need or could be reviewed.
  - Relevant updates from the stockpile coordination group (the proposed group providing coordination between government-owned clinical stockpiles) and clinical countermeasures research and development coordination group. These are both working coordination groups to support the clinical countermeasures programme rather than formal governance structures, so updates are to support coordination rather than as formal programme reporting.
  - Short updates from any ongoing relevant policy initiatives, though these will be governed separately (see below).

- e) UKHSA should update the terms of reference to reflect these changes; to update organisational and individual membership for accuracy given changes to organisation names and structures etc.; and to accurately reflect the status of any other boards which may no longer exist or have changed (e.g. Operational Management Board).
- 10. CCMB continues to sit below PIPP and will provide high-level updates to PIPP and may escalate significant risks, issues, or decisions.
- 11. Workstreams relating to clinical countermeasures which falls outside of the scope of the CCMB (i.e. relates to development or review of policy or scientific advice) shall be agreed by the PIPP Board or PIPP Senior Responsible Officer (SRO), captured in the PIPP work programme, and sit directly under and report to the PIPP Board. If a workstream is significant enough, then an additional governance sub-structure or process may be put in place beneath PIPP to manage the work. As well as reviews relating to specific clinical countermeasures, the PIPP Board is expected to commission a cross-system review of clinical countermeasures approximately every 3-5 years to ensure our approach remains fit for purpose and aligned with wider government and sector activity.
- 12. Policy development and reviews shall be led by the lead policy team in collaboration with colleagues on the CCMB. While not members of the PIPP Board, Devolved Governments should be engaged in this work on the basis that clinical countermeasures are an area where the four nations aim to coordinate. Following agreement of any new clinical countermeasures policy or changes to existing policy by ministers, its operationalisation shall fall under the CCMB.
- 13. Deployment of countermeasures shall be governed separately under incident and emergency response structures, as outlined in **Paper C**.
- 14. Preparation of Spending Review bids should be led by the responsible policy teams, working with other members of the CCMB.

***Does the Subgroup agree with these proposals?***

**Next steps**

- 15. If the Subgroup and Advisory Board agree these proposals, they should be implemented immediately and serve as the basis for ongoing governance of the clinical countermeasures programme.
- 16. Following the conclusion of the Clinical Countermeasures Review, approved recommendations from the various Subgroups will be collated and actions to implement them will be captured under the PIPP objectives framework, to be monitored and reported under the CCMB or PIPP Board as appropriate.

## Annex A

### Terms of Reference

#### Clinical Countermeasures Board Pandemic Influenza Preparedness Programme

##### Overview

Access to the following range of countermeasures is essential to planning and delivering a response to an influenza pandemic:

- pre-pandemic and pandemic-specific vaccines
- antibiotics
- antivirals
- consumables (including hygiene and protective equipment).

The purpose of the Clinical Countermeasures Board (CCMB) is to provide governance and oversight of the necessary maintenance and management of the clinical countermeasure UK stockpiles and the agreements required to ensure that the UK is well prepared to respond effectively to a pandemic.

The Clinical Countermeasures Board will

- ensure that all procurements are aligned to pandemic preparedness policy;
- review break points in contracts and outline key points at which there is scope for the Department of Health to review and change pandemic preparedness policy;
- review procurement and approval timelines, to track progress of activities and ensure procurements are completed so that stock levels are maintained;
- review risks and issues that relate to clinical countermeasures; track progress of actions and escalate where necessary;
- disseminate and share relevant and timely information to the UKCs and including to NHS England.

##### Out of Scope

The key exclusions from the scope of the Clinical Countermeasures Board:

- Setting and approving pandemic flu policy is the responsibility of the Department.
- Development and revision of scientific and clinical advice and guidance. This is now the responsibility of the Department to arrange with the appropriate expert group eg. New and Emerging Respiratory Virus Threats Advisory Groups (NERVTAG) and the Joint Committee on Vaccination and Immunisation (JCVI).
- The supply of routine medicines during a pandemic is not included. This is the responsibility of the DH Medicines, Pharmacy and Industry (MPI).
- Advice on the appropriate use of countermeasures in the clinical setting, e.g.

use of facemasks in a hospital can be referred to through existing guidance issued on the Gov.UK website.

- Developing communications to support public understanding of and use of countermeasures is the responsibility of DH, PHE and Cabinet Office Communication teams.
- The UK CBRN stockpile. This is covered by the UK Stockpile Deployment Group.

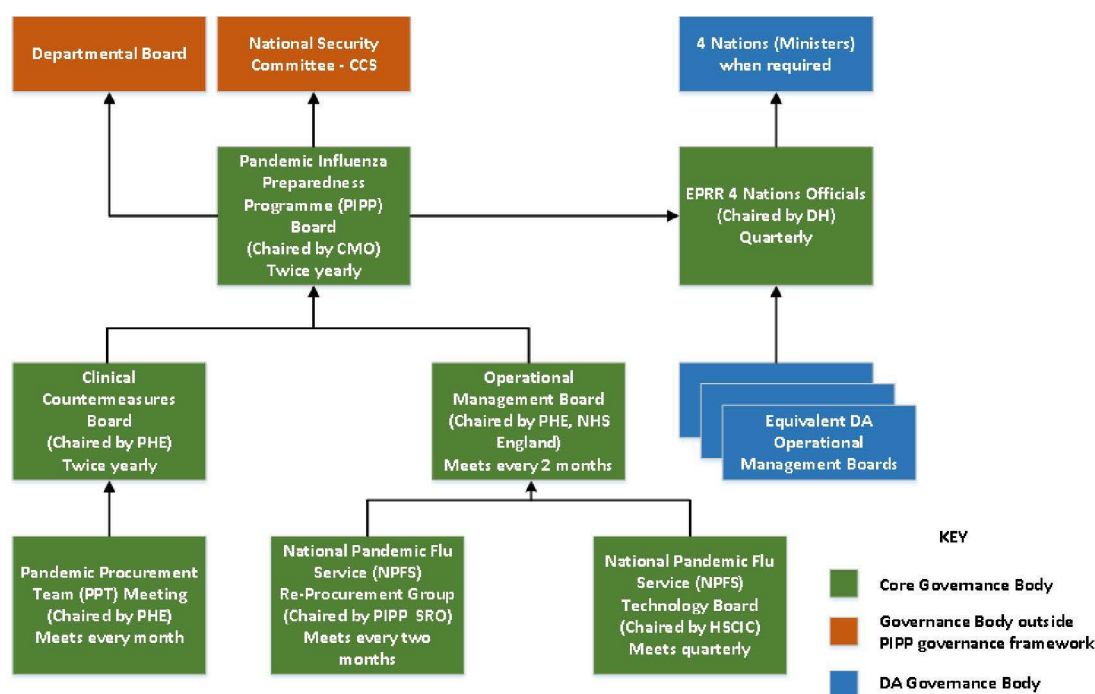
## Governance

The Board is accountable to the Pandemic Flu Programme Board for the leadership and management of clinical countermeasures required for pandemic influenza preparedness and to their internal organisation's governance arrangements.

The Board is responsible for the consideration of pandemic policy decisions, and to seek approval from the Programme Board when necessary.

The Board is responsible for escalating to the Programme Board those decisions that impact adversely on the Pandemic Influenza Preparedness Programme's aims

The governance arrangements for the Pandemic Influenza Preparedness Programme are as follows:



PIPP Governance Structure

## Membership

Public Health England will chair and provide secretariat for the Board.  
The Board will consist of representatives and/or specialists from the following:

Public Health England
DH Pandemic Influenza Preparedness Policy
Commercial Medicines Unit
DH Medicines, Pharmacist and Industry
DH Financial Controls Branch (Investment Approvals)
NHS Business Services Authority
NHS England
Welsh Assembly Government (Health Emergency Preparedness Unit,)
Scottish Government (Health Delivery: Pandemic Flu Team)
Northern Ireland (DHSSPS Pandemic Flu Team)

Names of members are at Annex A

Additional members may be invited, either on a temporary or permanent basis, to attend as representatives or specialists who will contribute to the objectives of the Board.

## Meetings

The CCB will normally meet every 6 months in London, usually in March and October each year.

Teleconference arrangements will be made available. Meetings are usually held for no more than 2 hours.

## Annex 1: Membership/Representation

Gareth Thomas	PHE	Interim Chair
Krishna Patel	PHE	Secretariat
Mark Thomas	PHE	Head of Business Management
Martyn Underdown	PHE	Head of Clinical Countermeasures
Judith Field	PHE	UK National Countermeasures Manager
Alan Russell	DH (CMU)	Technical Pharmacist
	DH (Policy)	Head of Flu Preparedness
<b>Name Redacted</b>	DH (CMU)	Category Manager
<b>NR</b>	DH (MPI)	Principal Pharmacist
<b>NR</b>	DH (Approvals)	Investment Approvals
Martin Hall	SCCL	Supplier and Contract Management
Chloe Sellwood	NHS England	Pandemic Influenza Resilience

NR		Scottish Government	Representative for Scotland
NR		DHSSPS	Representative for Northern Ireland
David Goulding		Welsh Assembly Government	Representative for Wales