

Coordination across the Devolved Governments, Crown Dependencies and Overseas Territories on clinical countermeasures for pandemic and high-consequence infectious disease preparedness

1. Introduction

- 1.1. The purpose of this paper is to summarise and re-affirm how the four nations of the UK work together on the pandemic and high-consequence infectious disease (HCID) preparedness stockpiles that are under the remit of the Pandemic Influenza Preparedness Programme (PIPP). Stockpiles currently exist for pandemic influenza, with the potential to expand to include other pandemic and HCID risks in the future. Stocks of Imvanex/Jynneos and Tecovirimat have recently been procured specifically for monkeypox.
- 1.2. The paper notes the role of the UK government and the Devolved Governments in the procurement and management of these stockpiles. The paper also briefly covers the coordination and deployment arrangements of countermeasures to Crown dependencies (CD) and Overseas Territories (OT) for COVID-19 and monkeypox, and implications for the pandemic preparedness clinical countermeasures programme.
- 1.3. The paper highlights the various stages of the countermeasures procurement and management programme and notes the involvement of the Devolved Governments at each stage.

2. Action required

- 2.1. Note and review the status and arrangements of the stockpiles listed.
- 2.2. Note and confirm the recommendations provided.

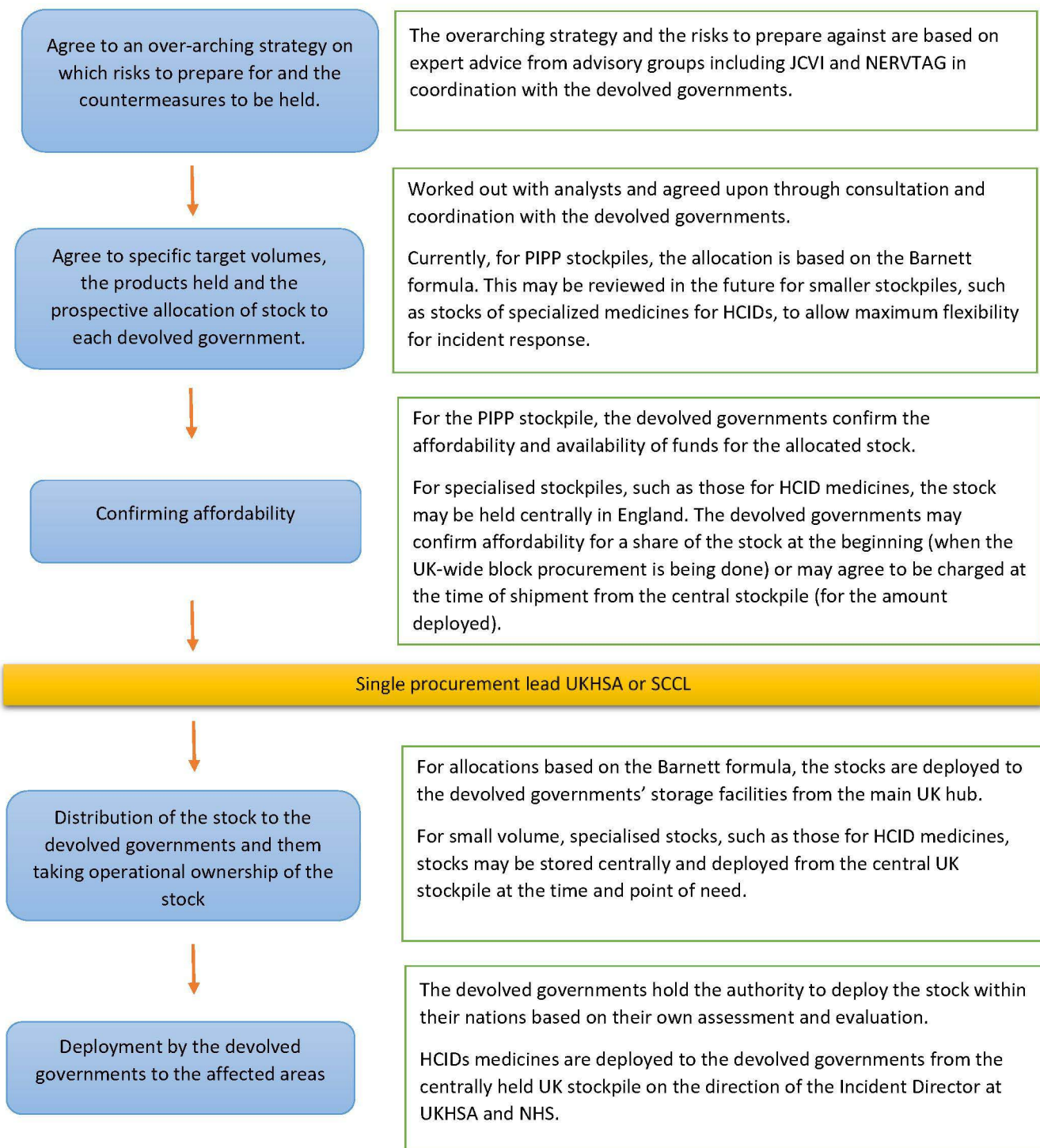
3. Context

- 3.1. The countermeasures held go through a number of phases, from the point of being envisaged to being deployed to the Devolved Governments. The flow chart below outlines the various stages of the process and highlights the role of the Devolved Governments at each stage.
- 3.2. The phases through which the countermeasures are established and managed are broadly as follows:
 - Agreeing to an overarching strategy on which risks to prepare for and the countermeasures to be held in response to those risks. The Pandemic 'Flu Strategy of 2011 was the current over-arching strategy for pandemic flu preparedness, but the preparedness programme is now being expanded to include a wider range of pandemic, emerging infectious disease and HCID risks. This will be reflected in an updated strategy in due course.
 - Agreeing the specific products and target volumes to be held within the stocks and determining the prospective allocation to each Devolved Government

(typically done through the Barnett Formula – additional consultation/work may be needed to determine allocation of some specific products).

- Confirming the affordability for each Devolved Government.
- Procurement, which has a single lead (UKHSA for medicines, consumables, and pandemic-specific vaccine Advance Purchase Agreement (APA) and, historically, PPE; PPE lead may transfer to SCCL in future), unless a Devolved Government wishes to procure the product on its own.
- Distribution of the products to the Devolved Governments and them taking ownership of the storage and distribution of the products.
- Deployment by the Devolved Governments to the affected areas in an incident or pandemic based on each Devolved Government's individual assessment and evaluation.

Phases of the countermeasures programme



4. Countermeasures held for pandemic and HCID risks and the relationship with the Devolved Governments in the management of those countermeasures:

PIPP

4.1. The PIPP stock consists of:

- Antivirals
- Antibiotics
- APA for pandemic-specific 'flu vaccine
- Clinical consumables (related to medicines deployment and infection, prevention, and control)
- PPE

4.2. UKHSA procures and supplies medicines and consumables for the UK PIPP stockpiles on behalf of DHSC and the Devolved Governments. Specifically, UKHSA's Vaccines, Countermeasure and Response (VCR) team manages all aspects (including procurement) of the PIPP stockpiles. The Devolved Governments can opt in or out of the PIPP procurements. This arrangement is expected to continue going forward.

4.3. Products are allocated to the nations based on the Barnett formula. The products are held in England on delivery following procurement. These are delivered to the Devolved Governments in Q4 (Jan-Mar) at which time the Devolved Governments take ownership and responsibility for their allocations. Ownership of the England volume remains with UKHSA.

4.4. Each Devolved Government holds responsibility for the storage, distribution, and stock management of its own PIPP stockpile products. At the time of a pandemic, each country independently manages its stockpiles using its stockpile allocation. Any additional needs for stock are met by mutual aid between nations and deployment from the stockpile hub held in England.

4.5. The storage and distribution services for the PIPP stock in England is managed by Movianto UK. The contracting authority for these services is SCCL. Memorandums of Understanding (MOUs) between PHE (to be novated to UKHSA) and each of the Devolved Governments are in place for each of the following:

- Storage and distribution, and procurement services
- Antivirals
- Antibiotics
- Advanced Purchase Agreement

4.6. The APA arrangements for stock allocation and the corresponding costs for the Devolved Government are based on the Barnett formula. Once the advanced purchased vaccines are received by the UK, deployment to the Devolved Governments would also follow the Barnett determined allocation. There may be

some flexibility in the volumes allocated and deployed, based on each government's need. This would be done through mutual agreement and collaboration with the four governments.

- 4.7. Historically, PPE for pandemic preparedness has been held within the PIPP stockpile. That stock diminished early into the COVID-19 pandemic and currently stands at near zero stock holding. A DHSC-NHSE COVID-19 PPE cell was set up early into the COVID-19 pandemic to manage and cater to the PPE demands for the whole of UK. As of 1 April 2022, the management of the COVID-19 PPE stock transitioned from the PPE Cell to SCCL.
- 4.8. The intention is that this safety stock will transition to cover wider pandemic preparedness requirements on a UK wide basis from April 2023; and this subgroup has provisionally agreed that the SCCL will take over the responsibility of the procurement and management of PPE for pandemic preparedness from UKHSA.
- 4.9. These arrangements are currently being worked through, with the intention that the arrangements for pandemic preparedness PPE would continue to be on the same four nations basis as historically, and still exist for the rest of the PIPP stockpiles. The possible exception is the Scottish Government, who are exploring setting up separate procurement routes for their PPE, potentially commencing the financial year 2023/24.

Other pandemic clinical countermeasures

- 4.10. Currently there are no clinical countermeasures for pandemic risks other than influenza, but these are now in scope of the programme and being considered under the Clinical Countermeasures Review. We propose that the same UK-wide arrangements would be applied to these as to the PIPP stockpiles.

HCID stockpiles

- 4.11. Small, centralised stockpiles of Imvanex/Jynneos and Tecovirimat have recently been procured in response to the ongoing monkeypox incident in the UK. Other than this there are no HCID clinical countermeasures currently in place, but these are also now under the scope of the programme and are being considered under the Clinical Countermeasures Review so may be developed in future.
- 4.12. HCID medicines stockpiles will vary depending on the type and category of medicines held and the incidents being prepared for. They will generally be significantly smaller than pandemic stockpiles; be deployed at very short notice in response to an incident, but in small numbers and on a localised basis through specialised routes. As such, they may require a slightly different approach to storage and deployment than stocks held for pandemic preparedness.
- 4.13. Like pandemic preparedness countermeasures, HCID countermeasures will likely benefit from block procurements for the whole of the UK to take advantage of negotiating power and efficiencies.
- 4.14. However, reasons for considering a different model to the Barnett formula volume allocations and distribution to each nation include:

- The timing and location of HCID incidents – and by extension demand for clinical countermeasures – is unpredictable. Over the shelf life of a countermeasure, volume demand for each nation is unlikely to follow Barnett formula or respective population proportions.
 - Such medicines may also require specialist storage facilities and capabilities that aren't readily available.
- 4.15. As such, with collective agreement HCID countermeasures may be stored centrally as long as delivery to point of need anywhere in the UK within 24 hours can be assured. Under this model, two cost-sharing approaches can be taken:
- Devolved Governments may still contribute upfront to a share of the procurement costs based on the Barnett formula. Product volumes up to the respective Barnett proportions may then be deployed free of charge to the Devolved Governments at the time of need.
 - Alternatively, there may be no upfront costs for the Devolved Governments, but a charge may be made instead at the time of deployment to the Devolved Governments during an incident for the amount deployed.
- 4.16. Alternatively, it could be decided that HCID countermeasures are managed in line with PIPP pandemic stocks, with distribution after procurement to each Devolved Government to store and manage respective volumes determined by the Barnett formula; with proportionate financial contributions from the Devolved Governments.
- 4.17. The choice between these two models will depend on a number of factors, including:
- Importance of speed of supply;
 - Resilience of delivery routes across UK;
 - Forecasted frequency and geography of incidents.
- 4.18. As such, it is proposed that the specific storage and management model for HCID countermeasures is decided upon by collective agreement on a case-by-case basis.

5. Coordination and deployment of countermeasures to Overseas Territories and Crown Dependencies

- 5.1. The UK government does not have a binding duty to assist the Overseas Territories (OTs) and Crown Dependencies (CDs) with countermeasures for pandemics or HCID related incidents. The PIPP stockpiles have historically been established solely to serve the four nations.
- 5.2. The UK Government has, however, in the past provided assistance to the CDs and OTs (especially those in need) as a gesture of support.
- 5.3. In response to the COVID-19 pandemic response, the UK government provided the OTs and CDs with vaccines, test kits, PPE, and therapeutics, amongst other urgent supplies. More recently UK Government ministers agreed to supplying the OTs and CDs with the monkeypox vaccine in response to rising cases of monkeypox.

- 5.4. In terms of stock coordination and arrangement, the FCDO holds the constitutional relationship with the OTs and is closely involved in the logistical process of transporting and distributing the countermeasures. UKHSA's OT Programme team holds fortnightly meetings with the Chief Medical Officers of the OTs and engages with them on the details of what is required by the OT. The DHSC Devolution and Union team also joins those meetings and will update DHSC Ministers as required.
- 5.5. The MoJ holds the constitutional relationship with the CDs. The MoJ chairs regular meetings that facilitate direct consultation between DHSC policy teams and the CD External Engagement teams on CD requirements.
- 5.6. The amount allocated to the OTs and CDs is very much dependent on what is being supplied and the circumstances. Vaccines for COVID-19 have been committed to be supplied to all OTs and CDs free of charge until 2023/24. This has been agreed by DHSC ministers and signed off by the HMT. For antivirals and therapeutics, the ministers have signed off to a 1% allocation of stock to the OTs and CDs, applying Barnett Consequentials. For the monkeypox vaccine, 40 doses of the vaccine were supplied to the CDs and 20 doses of the vaccine were supplied to Gibraltar.
- 5.7. As an exceptional gesture of support, COVID-19 vaccines and their transport to the OTs has been funded entirely by the UK Government. The monkeypox vaccine has been provided free of charge, but the cost of storage and transport has been covered by the OTs and CDs themselves. As a general principle, the OTs and CDs are expected to cover the cost of transport and storage of the product unless the territory is in receipt of Official Development Aid (ODA). In the case of an OT in receipt of ODA, FCDO may look to cover the cost of transport and storage for the countermeasures. Expectations on cost recovery of the stock in emergencies has been a decision for UK Government Ministers.
- 5.8. For non-pandemic scenarios the OTs and CDs are expected to pay for their own stock and the transport of that stock, with the exception of four OTs that are in receipt of ODA; and there is a general expectation that they only come to UK Government for items that they cannot procure themselves. Support from the UK government in the provision of countermeasures even at cost is appreciated as it is often hard for the OTs and CDs to secure contracts with suppliers on their own due to the small size of the orders and the difficult international markets.
- 5.9. Upon receiving the stock, the CDs are able to manage, store and distribute the items effectively and independently. The OTs have previously required assistance from the FCDO in ensuring that the correct set up is in place on the island, e.g., in locating the correct type of freezer for vaccine storage. UKHSA colleagues with clinical backgrounds may also offer further conversations and guidance to the OTs on management and distribution as required.
- 5.10. Deploying stock to the CDs is fairly straightforward and fast but for some OTs this can be difficult and take a significant amount of time. Temperature controlled deliveries are possible but challenging, and most shipments usually require a good lead time to organise. Consideration has been given to the establishment of a small stock supply on one of the central overseas Caribbean islands, such as Anguilla.

This (if actioned) is expected to reduce the lead-in time considerably and provide quicker access to time sensitive vaccines.

6. We propose the following recommendations:

- 6.1. **A continuation of current arrangements** for coordination amongst the four nations on pandemic countermeasures, under which:
- All four nations coordinate and agree on the risks to prepare against and the broader countermeasures within those preparedness and response policies.
 - All four nation continue to agree upon the target volumes and products held based on expert advice.
 - UKHSA (and potentially SCCL) continue to procure all pandemic related countermeasures on behalf of all four nations, with the four nations having the option to opt in or out of individual procurements.
 - Devolved Governments continue to take ownership of storage and management responsibilities of the countermeasures stock upon receiving them (with the exception of primary care antibiotics which are held in England on behalf of all four nations).
- 6.2. Noting that the Scottish Government is exploring its own procurement routes for PPE, **we recommend that the four nations continue to coordinate on the planning assumptions underpinning this**, i.e. on the specific PPE products and volumes held for different risks.
- 6.3. Noting the potential for HCID countermeasure arrangements to be made in future, **we recommend that:**
- HCID and other emerging infectious disease risks and the products and volumes held in response to those risks are agreed upon on four nations basis;
 - The management, storage, and financing models for specialized stockpiles should be agreed on a case-by-case according to requirements. They may include a single stockpile covering all four nations, and volume allocations and funding contributions which do not follow the Barnett formula.
- 6.4. With regards to the OTs and CDs, we are not currently in a position to make definitive recommendations as to their inclusion or exclusion from future arrangements; but we do recommend that, in light of the precedent and ministerial preferences shown by the assistance and support provided during COVID-19, further conversations between the FCDO, MoJ, UKHSA's OT programme team and VCR team and DHSC's Devolution and Union team are held to explore possibilities of including OTs and CDs in countermeasures preparedness arrangements in future. This may involve setting the scope of the work, the population requirements, additional costs, and feasibility of operations, etc.