

UK VACCINES, THERAPEUTICS AND DIAGNOSTICS MANUFACTURING LANDSCAPE

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[DN: header to be updated by PPSP to match Strategy Board agenda requirements]

Summary

- ∞ Significant investment decisions have been and are being taken across government to develop and maintain UK capability and capacity to manufacture vaccines, therapeutics and diagnostics (VTD).
- ∞ These decisions need to be considered in the wider context of the domestic manufacturing landscape for VTD, and its contributions to the Government's Growth Mission and to the UK's pandemic preparedness and resilience.
- ∞ Effective investment in R&D and through related missions and strategies, e.g. Life Sciences Sector Plan, Biological Security Strategy, etc. make important contributions to the Government's Growth Mission, including the infrastructure, place, industrial strategy, and innovation pillars.
- ∞ This paper introduces a workstream led by DHSC in partnership with OLS and UKHSA, with support from UKRI – Innovate UK and other partners, to analyse the domestic manufacturing capacity and capability for VTD and produce a framework to inform strategic decisions.

Points for discussion

Board members are asked to note this workstream and reflect on the following questions in the meeting:

- ∞ Upcoming strategic and investment decisions: Are there any other high-profile / spend / long-term horizon decisions not currently listed (see paragraph 2), which should also be informed by the output of this work, and when do we expect those to happen?
- ∞ Scope: What types of capabilities and facilities should be in scope (e.g. should the framework also cover non-commercial manufacturers that have key roles in production for clinical trial purposes)?
- ∞ Structure and next steps: Which other organisations (beyond UKHSA, OLS, Innovate UK and DBT) might hold more information relevant to complete a comprehensive assessment of the baseline landscape? Is the approach set out the right way to think about the target/ideal manufacturing landscape?
- ∞ Governance: Is the proposed approach appropriate and proportionate?

Context and upcoming strategic decisions

1. Decisions are being taken across government to develop capability and capacity to manufacture VTD in the UK. These include policy and spend across:
 - ∞ Upcoming CCM procurements to maintain and/or enhance pandemic and emerging infectious disease stockpile resilience.

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- ∞ Potential targeting of R&D investment into priority pathogens and other incentives in the CCM development pipeline.
 - ∞ Decisions about other contractual arrangements including the Moderna Strategic Partnership and the future of the Advance Purchase Agreement (APA) contract with CSL Seqirus.
 - ∞ The Life Sciences Innovation Manufacturing Fund (LSIMF), a fund of up to £520m, which aims to drive economic growth and build resilience for future health emergencies by incentivising UK manufacturing investments. Scoring of LSIMF bids happens on a quarterly basis with the next round of bids due in March 2025. The fund has a Life Sciences wide scope, including vaccines, therapeutics, and diagnostics.
 - ∞ Investments in existing facilities that can play a role in supporting preparedness and resilience – discussions are taking place about how to maximise the contribution of existing assets (such as the RNA Centre of Excellence, Darlington, and Braintree Manufacturing Innovation Centre) to resilience and our response to any future health emergency.
 - ∞ Wider government support for the life sciences sector.
2. These, and other future decisions, need to be considered in the wider context of the current and evolving domestic manufacturing landscape for vaccines, therapeutics, and diagnostics and our requirements to maintain and enhance our pandemic preparedness.
 3. A robust and comprehensive assessment of the landscape is also critical for maximising the contribution of life sciences investments to the Government's Growth Mission, including the infrastructure, place, industrial strategy, and innovation pillars. An identification of the specific gaps in VTD capability and capacity in the landscape will help ensure that government support for the life sciences sector continues to be resilient and efficient.

Project scope and structure

4. This work acknowledges the range of information that is already held across government about the domestic manufacturing landscape and aims to make it more accessible for decision-makers.
5. Building on that information, since December 2024, DHSC, OLS and UKHSA have coordinated efforts to develop a comprehensive understanding of the UK CCM and diagnostics manufacturing landscape, to identify gaps in the ability to access appropriate volumes and types of products to respond to a pandemic or emerging outbreak, and therefore inform strategic decisions on manufacturing capacity and resilience.
6. Medical devices, MedTech and PPE are currently excluded from the scope of this project. Whilst some are also products required for pandemic preparedness, their core development is less specific to pandemics and, for MedTech in particular, this is a more complex landscape to map. Extending the framework to consider these products, or the ability to scale up domestic manufacturing for them, may be a longer-term consideration.
7. The infrastructure/facilities currently under consideration within the scope of manufacturing include those that:
 - ∞ Make drug substances or components relevant for VTD production (even if production output is not routinely used for that purpose) and/or make finished

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drug products (VTDs themselves). This should cover both disease specific VTD and also for, e.g. supportive medicines routinely used where specific therapeutics are not available (such as NSAIDs).

- ∞ Are GMP compliant.
 - ∞ Can manufacture at commercial-level scale or can rapidly increase production capacity within 3 months in an emergency scenario.
 - ∞ In the event of a pandemic, the government has priority access (including step-in rights) to call on their capacity for appropriate production as needed or has a reasonable assumption (based on previous experience or any existing contractual arrangements) that they would be open to make their capacity available to the UK's pandemic response.
8. This scope aligns with the ambition of the 100 Days Mission (100DM) and contributes to the delivery of medium-term commitments under Outcome 14 of the Biological Security Strategy (BSS) (*Capability to scale up discovery and development of therapeutics and vaccines within 100 days underpinned by targeted R&D programmes across the range of biological threats*).
 9. The output framework being considered is specific to decisions relating to pandemic preparedness and emerging infectious disease outbreak planning and ensuring breadth of manufacturing across the full range of priority pathogens of pandemic concern, although this work will have wider interest.

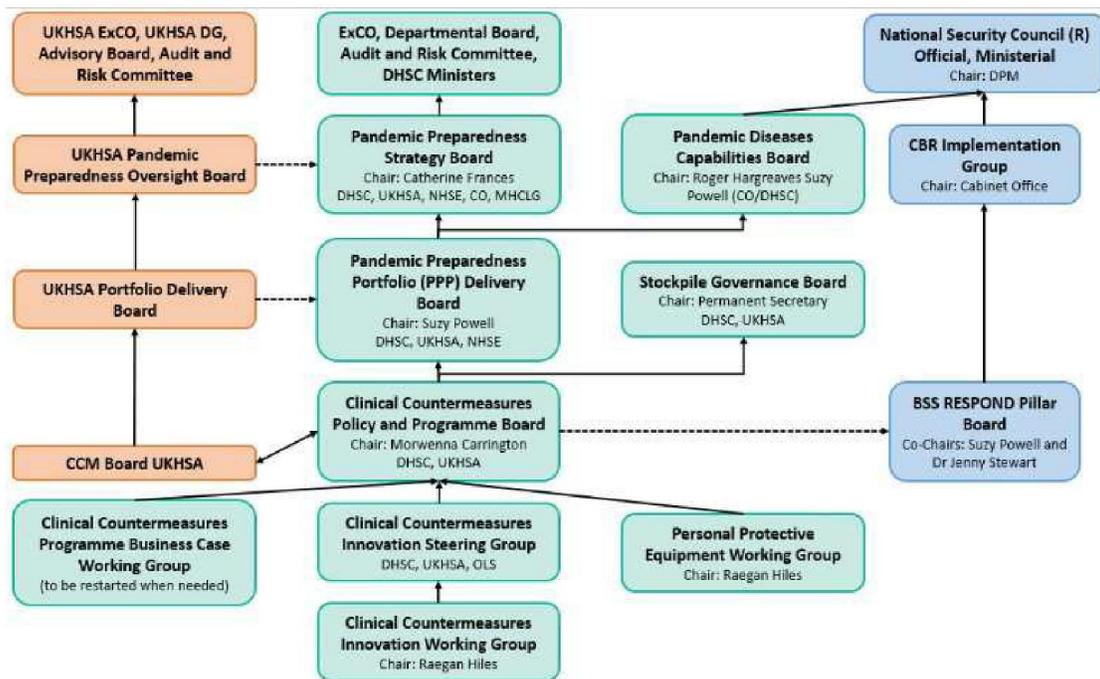
Initial inputs

10. To understand the current status of the manufacturing landscape, DHSC commissioned UKHSA Commercial to develop, with OLS, a first draft of a baseline report outlining the existing onshore capabilities by manufacturer, associated government efforts at supporting these, and key challenges. This will be updated with additional data and analysis before wider circulation of a full draft.
11. In parallel, to understand what the target/desired state of the landscape should be to ensure resilience for health emergencies, DHSC is using the reasonable worst-case scenario (RWCS) for the NSRA pandemic risk and the list of UKHSA priority pathogens and their associated VTD (either available or promising ones in development) to develop a preliminary understanding of what the ideal target manufacturing landscape might look like. This is currently based on the influenza and coronavirus scenarios set out in the 2024 NSRA, as well as scenarios extrapolated from literature concerning high and moderate pandemic risk pathogens. The 100DM resources, e.g. from annual stocktakes, workshops and engagement with industry, will also inform development of the desired landscape.
12. These inputs will be combined and developed into a framework outlining any gaps in the UK manufacturing landscape that impede the access to appropriate volumes and types of vaccines, therapeutics, and diagnostics in the event of a future health emergency. This will have implications not just to guide decisions on policy and spending about onshoring of manufacturing capacity and capability, but also on “how” those might be made available and used (informing questions including about government vs. market ownership of facilities and step-in rights for resilience).
13. A timeline outlining next steps is included at Annex B.

Governance

14. This project is being led by DHSC’s UK Health Security Team in partnership with the Office for Life Sciences (OLS) and UKHSA. Innovate UK – UKRI is also a critical partner and has been supporting early discussions. MHRA is involved particularly for advice on how we reflect the requirements for Good Manufacturing Practice (GMP) compliance.
15. There will be a time-limited SCS-level steering group chaired by DHSC, providing direction for the work and reporting into the DHSC Clinical Countermeasures Policy and Programme Board, and upwards into related pandemic preparedness governance, noting the outputs will also be used to inform reporting into the 100DM and the Biological Security Strategy. The overarching pandemic preparedness governance is detailed in Figure A.

Figure A - Governance map



Annex A: Slides giving an overview of VTD Manufacturing Landscape products and governance -

VTD Manufacturing Landscape

Baseline – Current UK VTD Manufacturing Landscape

- DHSC & OLS commissioned UKHSA Commercial to provide information on the current UK manufacturing capacity to set a baseline for the landscape analysis.
- UKHSA returned a first draft, and DHSC and OLS are engaging with other holders of information to feed towards a second version that can also incorporate diagnostics.

Target – Desired UK VTD Manufacturing Landscape

- In parallel, DHSC is considering the manufacturing capacity and capabilities required in the event of a pandemic.
- A preliminary draft of an analysis of the target manufacturing landscape is in progress and to be QA'd with analysts, ahead of wider circulation for contribution.

Our Ambition – UK VTD Manufacturing Strategic Framework

- The two workstreams above will be refined in March to develop a report outlining any gaps in the UK manufacturing landscape for ensuring access to appropriate volumes and types of VTD to respond to an outbreak or pandemic.
- The aim is for this work to provide a framework for making strategic decisions on UK manufacturing capacity and capability, to be ready in late May / early June.

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Baseline Manufacturing Landscape

Work so far

UKHSA Commercial proof-of-concept paper sets out:

- The paper includes information around the current UK manufacturing landscape highlighting the roles of CSL Seqirus (APA), Moderna (MSP), and AstraZeneca in particular, as well as an initial review of capacity and capability per manufacturer.
- The paper also includes an initial view on the gaps present in the landscape and of current government efforts to address them.

OLS have provided additional information on the capabilities per manufacturer
DHSC & OLS are engaging with other potential holders of baseline information (Innovate UK, Diagnostics Accelerator, DBT)

Next Steps

- Second draft will be circulated with this WG for wider contribution and challenge.
- Baseline landscape assessment to inform framework
- Agreement on how to maintain baseline information current

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Target/Ideal Manufacturing Landscape

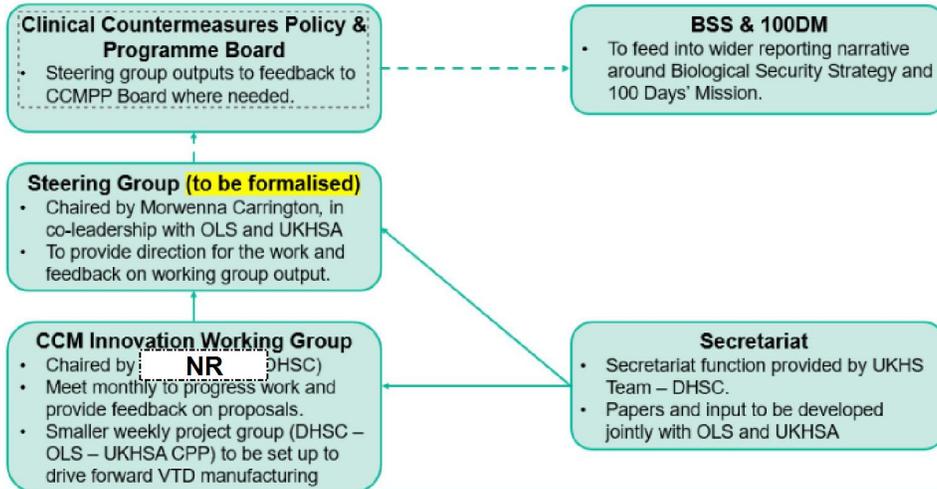
In parallel, DHSC has started developing an understanding of the target manufacturing landscape, which considers the manufacturing capacity required in the event of a pandemic. This draft 'target landscape' considers:

- The manufacturing capacity and capability required to respond to flu and coronavirus scenarios based on the NSRA 2023 Pandemic Risk.
- The manufacturing capacity and capability estimated to be required to respond to potential health emergencies based on 'high' and 'moderate' pandemic risk pathogens according to the priority pathogen list, with available CCMs.

At this stage, the work is largely illustrative and is based on assumptions and extrapolations from established NSRA scenarios and available literature. As such, this work will require robust challenge and subsequent refinement based on feedback from analysts and subject-matter experts.

Next Steps – Analytical QA of an initial draft, ahead of wider circulation with OLS and UKHSA and this WG

VTD Manufacturing Landscape Governance



Annex B: Timeline to show next steps on VTD Manufacturing Landscape project -

2025	Jan	Feb	Mar	Apr	May	Jun
Governance	Drafting ToR for WG/SG	Working Group Meetings				
	Drafting PDCB Paper & note to seniors	Steering Group Meetings				
		Present Paper at PDCB	Circulate Note to Seniors			June CCMPB Meeting
		Drafting Note to Seniors and Strategy Board Papers	Present Paper at Strategy Board			
			March CCMPB Meeting			
Manufacturing Landscape Analysis	Collate baseline landscape information	Refine Manufacturing Landscape Analysis (UKHSA)			Address Steering Group final Comments and Refine Paper	
	QA and continue to develop Target Manufacturing Landscape (DHSC & OLS)			Combine into a Strategic Framework		Present Paper at CCMPB