

ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Meeting date: 22 March 2023

Paper Title: The Government's medical technology strategy: implications for the Accelerated Access Collaborative

Agenda item: 4

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Paper type: For approval

AAC Priority Area:

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|--|-------------------------------------|---|-------------------------------------|
| Research | <input checked="" type="checkbox"/> | Building innovation capacity | <input checked="" type="checkbox"/> |
| Demand signalling and horizon scanning | <input type="checkbox"/> | Innovator support | <input type="checkbox"/> |
| Uptake of proven innovation | <input checked="" type="checkbox"/> | Cross-cutting (Health Inequalities, Net Zero, Life Sciences Vision) | <input type="checkbox"/> |
| Other (statutory, governance) | <input type="checkbox"/> | | |

Ask of the AAC Board:

- Discuss and comment on the AAC's strategic alignment with the government's medical technology strategy.
- Endorse the AAC as the implementation lead for the end-to-end innovation pipeline initiative under the proposed MedTech strategy implementation plan.
- Support a specific recommendation to establish a joint industry working group under the Health Technology Partnership to develop early proposals to improve the reimbursement process for innovation.

Executive summary:

The new medtech strategy was published in February with a target to launch an implementation plan by June (see attachment). The strategy sets out a vision of right product, right price, right place and identifies four areas of priority including creating clear, streamlined pathways for innovation. The proposed implementation plan is intended to be multi-agency in delivery with the AAC leading on putting in place an end-to-end innovation pipeline to help address the slow adoption of innovation.

A range of initiatives are already in place which strongly align with the medtech strategy including the NHS Innovation Service and Commercial Innovation Pipeline. However, we need to go further to simplify an over complex process and address the recurrent challenge from industry of reimbursement, which is fragmented, subject to cliff-edge hard stops and has created a market that is congested with too many products available taking away potential funding from the most effective innovations. A joint industry working group is proposed to develop early recommendations that can be taking forward to unlock the full potential of medtech to transform patient pathways.

Background

1. The medtech strategy was developed to establish and communicate the UK's strategic priorities for medical technology and ensure alignment across the health and care system. The strategy was published on 3 February 2023, and we are now working towards development of an implementation plan with a target publication by June 2023.
2. The intention is that different organisations will be asked to lead and be accountable for the delivery of specific initiatives to support a joined-up approach across the system (see Annex A). We have provisionally assigned the AAC to lead on enabling an **end-to-end innovation pipeline** (from regulation, assessment, reimbursement, to commercial), subject to agreement.

The Medtech Strategy

3. There are many delivery partners with roles and responsibilities in medtech. A strategy ensures a joined-up approach to achieve system wide improvement. Significantly to ensure:
 - a) The **right product** is used that delivers the most impact in terms of patient outcomes and efficiency based on clinical need and evidence base.
 - b) The **right price** is secured by adopting a data driven approach and understanding the value across the entire patient pathway.
 - c) Products are in the **right place** by addressing health inequalities in the adoption of innovation and protecting patient safety by ensuring the supply chain is resilient.
4. The strategy identifies four areas of priority:
 - a) **Resilience and Continuity of Supply:** Working with industry to achieve our shared goal of greater resilience will help to ensure the delivery of safe, high-quality care to patients.
 - b) **Innovation and Dynamic Markets:** Creating clear, streamlined pathways to market will support industry in turning innovative ideas into widely adopted best in class medtech products with tangible benefits for patients.
 - c) **Enabling Infrastructure:** Establishing and expanding our enabling infrastructure across data and industry partnership will increase the visibility of information and create channels for industry and government to engage in an open and collaborative way on joint priorities.
 - d) **Specific Market Focuses:** Specific market focuses that recognise the complexity of the MedTech landscape will allow us to work closely with industry on specific topics within the sector, in a bespoke, tailored way.

5. A key challenge across the strategy is the need to tackle the slow adoption of innovation. Unless we address, we will continue to not take full advantage of available system improvements while wasting resource on less effective solutions. In this context it is essential that we ensure a joined up end-to-end innovation pipeline is in place.

End-to-End Innovation Pipeline

6. A range of initiatives are already working to address current barriers within and across the pipeline:

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| Regulation | Assessment | Reimbursement | Commercial |
| MHRA Medical Devices Reform Group | NICE Early Value Assessments | NHSE AAC MedTech Funding Mandate | NHSE CCF Commercial Innovation Pipeline |
| NHSE AAC NHS Innovation Service | | | |

7. The above initiatives strongly align to the medtech strategy. However, we need to go further. Consistent feedback from industry is that the current pipeline is over complex, slow and not sufficiently joined up. In particular, reimbursement is seen as a missing link between assessment and adoption. Key challenges for reimbursement include:

- a) *Fragmented*: Although an array of different funding programmes is available across different agencies these are arguably sub-scale and reinforce a fragmented approach compared to medicines which has the medicine innovation fund (see Annex B). A single medtech innovation fund would simplify the process for industry, allow for better prioritisation, enable greater collaboration between different stakeholders, and as a result improve patient outcomes. Would it be more effective to have a single consolidated fund for medtech and / or mandated funding for certain categories of NICE-approved medtech?
- b) *Cliff-edge*: Innovations that do secure funding can hit a cliff edge when the funding ends resulting in investment loss and in some cases, products that were developed with UK funding moving exclusively outside the UK market. Would it be more effective to have a reimbursement decision point as part of a funding programme – with the ability to provide ongoing funding for those innovations that are able to help transform a patient pathway?
- c) *Congestion*: Too many products continue to be available on the market even if they are less effective making it more difficult for the right products to be adopted at scale. Would it be more effective to pro-actively withdraw

reimbursement and de-list poor value medical devices (recognising the need for and importance for clinical and patient input) to make room to invest and scale up adoption of the right innovation?

Recommendations

8. Reimbursement and innovation adoption is a complex area which needs careful consideration. It is recommended that a joint industry working group is established under the Health Technology Partnership to properly scope a review of the different reimbursement routes for medtech and develops a set of recommendations for the AAC Board to consider. Subject to approval, recommendations would be presented to ministers for consideration.
9. In 2021 the Health Technology Partnership proposed an Accelerated Transitional Adoption Scheme (ATAS) to provide a structured pathway for patient access to promising technologies that have regulatory approval/ conditional approval before they have received a NICE recommendation. A joint industry working group could revisit this proposal as part of a new review.
10. In the 2022 Autumn Statement the Chancellor announced the appointment of Sir Patrick Vallance to lead work to consider how the UK can better regulate emerging technologies, enabling their rapid and safe introduction and in this Month's Budget new investment was announced to support MHRA fast track approval of new innovation. This may provide an opportunity to explore options with HMT to consolidate and build funding programmes into a single medtech fund alongside the existing medicines innovation fund to enable innovation adoption.
11. NHS Supply Chain is reviewing current operating arrangements, which provides opportunity for a joint industry working group to inform the approach NHS Supply Chain apply going forward to support innovation adoption and, how best to de-list poor value medical devices. It is important that any removal of products from the market is undertaken with full clinical and patient involvement to avoid the risk of de-listing been used as simple cost reduction exercise and drive to the lowest cost option. A joint industry working group could help support the development of a balanced approach.





Next steps

12. We are beginning to engage ministers on our initial thinking for the implementation plan, including monthly progress updates to minister Quince.

Board members are asked to:

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Annex A: Draft MedTech Implementation Plan

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| | | MedTech Comparison Tool | <div style="border: 1px solid black; padding: 5px;"> DHSC Led ■ NHSE Led ■ MHRA Host ■ NICE Host ■ </div> |
| Design for Life Programme | Class Based Product Evaluations | UDI & Master Product Register | |
| Supply Resilience Plans | Innovation & Value Classification | Equipment & Inventory Tracking | |
| Perfect Customer (SMEs) | Single Clinical Voice Clinical Councils | Spend Data Cleanse | Part IX Tariff Consultation |
| Category Strategies & Contracts | End-to-End Innovation Pipeline | Expand Outcome Registries | National Diagnostics Programme |
|  Priority One Resilience and Continuity of Supply |  Priority Two Innovative and Dynamic Markets |  Priority Three Enabling Infrastructure |  Priority Four Specific Market Focusses |

Annex B: Single Medicine Fund v. Fragmented MedTech Funding Programmes

