ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Meeting date: 20 March 2024

Paper Title: VPAG Section 3 commitment implementation

Agenda item: 7

Report author(s): Fiona Bride, Director, Medicines Value & Access, NHS England

Paper type: For discussion

AAC Priority Area:

Research	☐	Building innovation capacity	☐
Demand signalling and horizon scanning	☒	Innovator support	☐
Uptake of proven innovation	☒	Cross-cutting (Health Inequalities, Net Zero, Life Sciences Vision)	☐
Other (statutory, governance)	☐		

Ask of the AAC Board:

- To note the paper.
- To commit to support the delivery of the access, adoption and outcomes commitments in the 2024 Voluntary Scheme for Branded Medicines Pricing, Access, and Growth (VPAG) and the development of a joint programme of work to ensure the successful delivery of specific VPAG commitments.

Executive summary:

The 2024 VPAG included several commitments relating to access, adoption and outcomes of medicines covering horizon scanning and system preparedness, value assessment, commercial arrangements, and equitable adoption of medicines. The successful delivery of these commitments will require continued cross-team and multi-agency working over the course of the five-year agreement and we ask AAC Board members to support these endeavors.

This paper is for noting only. A follow-up paper will be presented to a future meeting of the AAC Board which will provide prioritised recommendations for areas of joint working with the AAC, with a specific focus on horizon scanning and equitable adoption commitments.

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Background

1. The 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) came into effect on the 1st of January 2024, following successful negotiations with the pharmaceutical industry. The overarching objectives of this agreement are to:

    a. Promote better patient outcomes and a healthier population.
    b. Support UK economic growth.
    c. Contribute to a financially sustainable NHS.

2. In exchange for agreeing to a dynamic growth mechanism for newer medicines, protecting the NHS from significant fluctuations in the growth of newer medicines spend, HMG has made certain commitments to enhance the access environment for, and equitable adoption of clinically and cost-effective medicines. This paper summarises key commitments for the board's awareness and provides some initial next steps. Commitments were made across four themes: horizon scanning and system preparedness, NICE value assessment, commercial arrangements and equitable adoption. Each of these is now considered in turn.

Horizon scanning and system preparedness

3. This section recognises the shared ambition for all organisations involved in the provision of medicines across the UK to have complete and accurate information about the products coming through the pipeline and their implications on the system; and to progress towards a shared approach for horizon scanning.

4. Key commitments including:
    a. NHS England (NHSE) to support the development of UK PharmaScan on a new technological platform to better support the Medicines and Healthcare Products Regulatory Agency (MHRA), UK Health Technology Assessment (HTA) agencies and the NHS in their horizon scanning efforts.
    b. As part of its existing horizon scanning processes, NHSE to undertake more primary research and therapeutic deep dives of new medicines coming to market to support their introduction into the UK and understand the potential implementation challenges they may face.
    c. DHSC to publish an end-to-end pathway guide by the end of the first year of VPAG, outlining the routes to market, how regulatory, HTA and commercial pathways algin, and what the mechanisms are for company engagement.
    d. The MHRA to refresh and formalise the Medicines and Medical Devices Access Group (MMD-AG) terms of reference to include industry trade body representation (in a nondecision making capacity) and to better coordinate activities across organisational boundaries within the first year of the 2024 Voluntary Scheme.

5. While these commitments are specific, they demonstrate the need for an integrated approach to horizon scanning and information sharing under the

MMD-AG. MHRA, NICE, NHSE and other relevant system partners are already working on the implementation of these commitments.

NICE value assessment

6. The Government, NHSE and industry agreed that the 2024 VPAG would not include substantial changes to NICE's methods and processes as, following the NICE Methods Review, modular updates are the most appropriate mechanism for any future changes to HTA policy.

7. A key point of negotiation was industry interest in reducing the discount rate (the economic method NICE use to assess benefits and costs in different time periods) from 3.5% to 1.5%. HMG analysis concluded that changing the discount rate to 1.5% in isolation would lead to an exponential increase in medicines prices that would outlive the duration of the successor scheme. Negotiators therefore retained the discount rate at 3.5% for the course of the five-year VPAG.

8. Key commitments that were agreed to include:
    a. Industry funding to boost investment into further developing HTA methods and processes used by the UK's respective HTA bodies.
        i. In England, NICE's HTA Innovation Lab will test innovative value assessment methodologies for application on new medicines which may require a different evaluation approach.
        ii. The Scottish Medicines Consortium (SMC), the All Wales Therapeutics and Toxicology Centre (AWTTC) and the Northern Ireland Department of Health will also initiate projects to improve their assessment processes, support speedier adoption of recommendations and to help prepare the system for the number of new medicines coming to market.

9. By the end of April 2024, a programme of work for the HTA commitments under the VPAG Investment Programme will be developed and then agreed by the VPAG Investment Board. DHSC, the Office for Life Sciences (OLS) and NHSE are working closely with the ABPI and the UK's HTA bodies to develop these work programmes.

Commercial arrangement – *applicable to England only*

10. NHSE continues to favour a simple Patient Access Scheme (PAS) discount as the preferred means of providing a cost-effective price to the NHS. The Commercial Framework for New Medicines sets out NHSE's position on the commercial flexibilities which are offered to companies and the circumstances in which these apply.

11. Key commitments under the new voluntary agreement include:
    a. NHSE to launch a consultation on an update to the Commercial Framework within the first six months of VPAG, making more explicit when existing commercial flexibilities may apply.
    b. A further consultation on the Framework to be launched within the first 18 months of VPAG to align with updated regulatory and access

pathways, ensuring good connectivity with value assessment and commercial processes. These consultations have been split out to allow new regulatory pathways to bed in so their impact on NHSE commercial processes can be assessed.

c. NHSE and NICE to launch a consultation on the Budget Impact Test (BIT) threshold within the first six months of the 2024 VPAG coming into effect, exploring a possible increase to £40 million from £20 million for the life of VPAG.
d. The delivery of two innovative payment model pilots to explore the practicalities of outcomes-based agreements for Advanced Therapy Medicines Products (ATMPs).

12. Prior to the formal launch of the Commercial Framework and BIT consultations, NHSE and NICE will hold events with key industry trade bodies and patient organisations to set out the proposed scope and key areas for change for policies and gather initial feedback to inform the consultation documents. Roundtables with key stakeholders from across the health landscape will also be held during the 12-week consultation period to present and discuss the consultation documents. It is then NHSE's ambition to publish an updated Commercial Framework by December 2024.

Equitable adoption

13. Throughout VPAG negotiations, NHSE's Medicines Value & Access (MVA) and Innovation, Research and Life Sciences Strategy (IRLSS) teams have worked in partnership to develop negotiation positions on equitable adoption and built upon the findings of the IRLSS' Medicines Pathway Evaluation Programme.

14. The commitments made reflect a shared ambition across NHSE, industry and system partners, to ensure rapid and equitable adoption of NICE approved, clinically and cost-effective medicines throughout the NHS. Key commitments include:

a. NICE to increase its efforts for timely updates of clinical guidelines to incorporate technology appraisal guidance recommendations within the care pathway, in line with the appraisal guidance wording. Industry Funding will be allocated to support this and to address the backlog of recommendations awaiting incorporation.
b. Industry funding to be allocated to enhance NHSE and NICE's adoption and support materials to better support planning and implementation of NICE recommendations in local NHS systems.
c. NHSE to amend the national and regional clinical leadership job descriptions to embed their role in championing and advocating the use of NICE guidance and guidelines in relevant clinical communities.
d. Clinical communication cascade at national and regional levels will be improved and integrated into formal processes for disseminating information about new medicines to prescribing systems, to support rapid and equitable adoption of NICE guidance, guidelines, and best practice care pathways.

e. Continued development of uptake measurement tools, including the Innovation Scorecard and Estimates Reports, to track variation in uptake of NICE recommended medicines between Integrated Care Boards. The Innovation Scorecard and Estimates Report will be updated and published bi-annually.
f. NHSE to develop a local formulary national minimum dataset within the first half of the 2024 Voluntary Scheme to increase visibility of local variation in the implementation of NICE guidance.
g. The terms of reference for the Strategic Metrics Group, which has responsibility for the Innovation Scorecard and Estimates Report, to be reviewed as early as possible in 2024 to ensure it can provide adequate ownership and delivery for measurement tools.

15. Having secured the VPAG, work is now underway on a number of these commitments including review from the Patient Access to Medicines Partnership (PAMP) for NHSE's plans for the future of the Strategic Metrics Group, of which AAC members will play a crucial role.

Next steps

16. A cross government/NHSE programme of work is being stood up to ensure the delivery of the commitments made relating to access, adoption and outcomes. It is anticipated that that some of the specific actions on horizon scanning and equitable adoption of medicines will require continued joint work between IRLSS and MVA.

17. As a next step, Jenny Turton, Deputy Director, Medicines Innovation; Jack Turner, Deputy Director, Medicines Access; and Johanna Hulme, Deputy Director Medicines Optimisation are developing a high-level NHSE programme plan outlining projects and activities across NHSE to enable delivery of the agreed VPAG commitments. This will be presented to a future AAC board meeting and will additionally be put forward at the next PAMP meeting in September 2024, demonstrating how NHSE teams are working to support the uptake of clinically and cost-effective medicines, and specific delivery of the VPAG uptake commitments.

Board members are asked to:

18. Note the contents of this paper.

19. Commit to support the implementation of the access, adoption and outcomes commitments in the 2024 VPAG and the development of a joint programme of work to ensure the successful delivery of specific VPAG commitments.