ACCELERATED
ACCESS
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ACCELERATED ACCESS COLLABORATIVE (AAC) BOARD

Paper Title: The UK's innovative access system – building a world leading approach

Agenda item: 4

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Paper type: For discussion and approval

AAC Priority Area:

Demand signalling / horizon scanning	☒	Adoption and spread	☒
Increasing research	☐	Working with partners	☒
Increasing uptake	☒	Other (statutory, governance)	☐

Ask of the AAC Board:

The Board are asked to:

- Note and support the ongoing work to improve the UK's access and uptake environment.

- Discuss and agree the priorities for future areas of collaboration and the approach of focusing attention in 2 or 3 key clinical areas aligned to the Long Term Plan and Life Sciences Vision. The initial focus would be within CVD, early cancer diagnosis, mental health, and neurodegeneration.

Executive summary:

1. The UK's response to the pandemic showed the effectiveness of the UK's access system when focused on agreed priorities and working in collaboration to rapidly trial, assess, and deploy new innovations.

2. This paper sets out the ongoing activities by MHRA, NICE and NHSE to accelerate the access environment through earlier engagement, parallel processes, greater flexibility, and clarifying implementation roles within the NHS.

3. It then seeks board agreement on the priorities for future activity:

    a. Delivering the existing programmes being delivered by MHRA, NICE and NHSE.

    b. Undertake work over next year to improve joint working focused on – shared horizon scanning and demand signaling, better information and

data sharing between partners, and increased early engagement from NHS as part of MHRA and NICE processes.

c. Clearly prioritising 2 or 3 areas of activity, based on Long Term Plan and Life Science Vision key areas: With proposals that, capacity permitting, these will be within early cancer diagnosis, cardiovascular disease (CVD), mental health (with a particular focus on digital products), and neurodegeneration (with particular focus on dementia).

Background

1. The Accelerated Access Collaborative (AAC) was established to create an accelerated route from research to adoption in the NHS, shortening the time it takes new innovations to reach the full patient population as soon as possible. The AAC board was tasked with creating a system which gives patients and NHS staff absolute confidence in the efficacy and cost effectiveness of treatments, is fast and efficient to enable patient access as soon as possible – and which balances certainty and clarity for industry whilst allowing for the necessary agility and flexibility to adapt to new technologies and approaches.

Learning from the pandemic

2. The response to the pandemic, and particularly the rapid development, identification, trialing, and rollout of treatments such as dexamethasone and the vaccines showed that UK's health innovation system , when aligned around a clear, shared, mission can deliver these outcomes in a world leading way.

3. For dexamethasone, the UK system:
   a. Created a collaborative structure to drive information sharing between partners through Rapid C-19, enabling parallel activity by NICE and MHRA.
   b. Rapidly identified potential products through ongoing active horizon scanning between NICE and the NIHR innovation observatory.
   c. Put in place flexible regulatory approaches including label extensions.
   d. Enabled rapid trial set up through RECOVERY and the NIHR Clinical Research Network with rapid approval by MHRA.
   e. Delivered clear, rapid, clinical policy development and commercial and procurement decision making from NHSE on back of clinical evidence.
   f. Change in standard of care as soon as positive appraisal complete.

4. We fully recognise the pandemic was a unique situation with the whole (global) health system focused on a singular clinical issue developing a well-defined set of solutions. We can adapt and build from this experience. The business of usual of our work is over longer time horizons, the balance of risk and benefit in the speed of creating patient access won't always be as clear cut, and there is far

more limited access to funding and resources to dedicate to develop and deploying new treatments.

5. But there are key lessons we can take for the access system moving forward:
   a. The system has been at its most transformative when focused on highest patient and NHS needs - and where there is top to bottom clarity that this was a priority.
   b. We should be focussed on looking at range interventions with potential to transform a pathway – not individual treatments in isolation.
   c. When products are trialed and designed to collect real world evidence in UK, we get better outcomes from ongoing benefit risk evaluation and they are more likely to be adopted within the NHS.
   d. If we can begin planning for Health Technology Assessment (HTA), commercial agreement and patient adoption as early as possible, we can deliver much faster uptake and access.
   e. The biggest opportunity for collaboration is in addressing population level interventions.
   f. Real time data on uptake allows us to adapt and support systems to tackle unwarranted variation in access.

6. Other countries are also making progress in this space (the FDA's breakthrough innovation regulations, Germany's DIGE for DHTs, France's approach to partnering with life sciences companies) and this is making it more competitive. Therefore, it is right we consider how best to ensure the UK remains a key destination for the life sciences industry.

The Current System

7. The good news is that the building blocks are in place. MHRA, NICE and NHSE have made significant interventions to improve our access process - delivering on individual organisational strategies which have focussed on innovation and delivery of government's life sciences vision. These programmes have focussed on:

   I. **Getting clearer signals to the research environment** –the Governments Life Sciences Vision set out a shared set of priority areas have set out areas of biggest preventable disease and death. Significant additional R&D funding is being allocated to these missions – and cross partner programmes of work are being established.

II. **Earlier engagement and co-ordination -** The “innovation passport” process established by the MHRA and embedded in the Innovative Licensing and Access Pathway (ILAP) is enabling (1) early engagement with the regulator to understand best trial design and use of real world data together with patient views (2) discussions with NICE around likely evidence needs for TA process, and (3) early consideration of implementation and commercial issues. New international partnerships through e.g. project ORBIS, is allowing earlier regulatory decisions. And the new commercial framework within NHSE puts in place a framework for early commercial and clinical surgeries so NHSE can better understand implications for the health service.

III. **Speeding up how we deliver regulatory, HTA, and commercial decisions** – NICE now undertakes assessments of all new active substances and delivers initial recommendations for all assessment to a 90 target. New methods and processes are allowing increasing use of Real-World Evidence (RWE) to be considered in assessments, supported by NICE’s RWE framework and new programmes of support through NHSE, the NIHR and the AHSN network. Increased commercial capacity within NHSE is allowing for much faster and more flexible commercial agreements, allowing for rollout of products within NHS as soon as NICE approves. New assessment and commercial arrangements are being developed for digital products, including early value assessment and conditional access schemes.

IV. **Increased support for innovators during a period of conditional access** – particularly around evidence collection or managing uncertainty. This included the launch of the innovative medicines fund, the publication of the real world evidence framework by NICE, direct support to MedTech and digital products through evidence support programmes like the AI award and SBRI programmes, and ongoing support to companies through NIHR translational research programmes and from the AHSN network.

V. **Faster NHS adoption –** Rapid uptake programmes supported by the IRLS team in NHSE and the AHSN network have increased patient access to a number of innovative products, and ongoing work with Integrated Care System (ICS) teams to identify priority health inequality interventions.

Is it working?

8. Despite the disruption of the pandemic, the UK continues to be internationally comparable to international peers on access:
   a. **On availability**: The availability of medicines in England is significantly higher than the European average: For every four treatments available in Europe, there is an additional medicine available in England with around one quarter more orphan medicines and close to a third more cancer drugs are available in England compared to the rest of Europe[1].

[1] *Figures from EFPIA Patients W.A.I.T Indicator 2021 Survey, published April 2022. IQVIA*

b. **Speed of availability of medicines**: Between 2015-19, UK was 3rd globally in the number of medicines commercialised within one year of their first approval in any jurisdiction[2].
c. **Speed of approval**: WAIT data[1] reports that England is 6th in Europe on time to availability of new active substances, with a mean of 340 days for access, compared to the EU average of 511 days[3]. Although this number is skewed by outliers with the median number lower. Analysis of NICE's internal performance data shows that the factors which prevent a fast appraisal and timely recommendation are significantly dependant on industry, including requests for delays and submissions of revised prices
d. **Earlier engagement and commercial agreement** – There have been a number of examples where NHSE has been world leading in agreeing early and quickly. For example, in early lung cancer treatments the NHS has worked with NICE to agree a number of 'early access' deals for lung cancer treatments approved through the Project Orbis route, including a first in Europe access deal for the drug Sotorasib.
e. **Uptake:** the UK's uptake ratio of new medicines relative to comparator countries was 0.58 1 year after launch, which was similar to medicines launched in 2015-2019. 5 years after launch this rose from 0.6 to 0.81 although based on a small cohort of medicines[4]

9. Despite some improvements, we aren't having the transformative effect we had during the height of the pandemic. From discussions with partners, there are a number of factors which, if met, would better enable rapid access and adoption:
   a. A clearer view from the NHS and government on priorities and areas of focus to allow best allocation of resource, a real commitment to pro-actively focus our innovation work in those areas, be willing to take action earlier, and with an element of risk.
   b. The acceleration programmes are promising but aren't fully joined up, still happening too sequentially rather than in parallel, and may need additional resource – 29% of NICE topics in 21/22 were delayed due to NICE capacity[5].
   c. Earlier provision of information and best value offers are needed from industry upfront – in 21/22, 48% of topics were notified to NICE late; 33% saw a request for delay from industry; and, 78% of draft recommendations based on the initial value offer were negative, in comparison to 15% for final guidance[6].
   d. A need for greater clarity on the NHS approach to preparing for and driving adoption of innovation in the new operating model, including the role of ICSs – and how NICE and MHRA will feed into that.

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[2] *Patented Medicine Prices Review Board, Canada. National Prescription Drug Utilization Information System (NPDUIS). Meds Entry Watch. 6th Edition. April 2022*
[3] 2021 EFPIA WAIT Indicator Survey, published April 2022
[4] Life science competitiveness indicators 2022, Office for Life Sciences, published July 22
[5] NICE July 22 board paper on "Access to new medicines: performance data"
[6] Ibid.

e. Greater inclusion, or additional, acceleration programmes for MedTech and digital products.

Where next?

10. To address these challenges, we propose driving forward an ambitious programme of work:

Step 1: continue to improve the programmes being delivered by AAC partners:

11. MHRA is reviewing the Innovative Licensing and Access Pathway (ILAP) to learn lessons from the first 20 months – making it a fully defined entry point into accelerated access in the UK, with clear roles and responsibilities of partners, with a more focussed scope and a greater focus on priority technologies. It is working with NICE and other partners to develop a similar access pathway for medical devices and MedTech. MHRA is making improvements to its systems for scientific advice to better support innovators, as they accumulate evidence of safety and efficacy and will be revising legislation and guidance on medical devices and clinical trials.

12. NICE is:
    a. Embedding improved, more flexible methods and processes following a full review in 2021. The first topics evaluated using the new methods and processes have reached committee, with recommendations due to be published soon.
    b. Taking a new, proportionate approach to the appraisal process, allowing NICE to apply light touch, faster evaluations to low risk treatments – increasing capacity for new evaluations by 20% by 23/24. This will be supported by new HTA Lab – a 'safe space' to design, test and co-create new methods and processes.
    c. Increasing the number of evaluations of medical technologies – and moving to the assessment of classes of technology rather than individual products.
    d. Delivering a new early value assessment (EVA) for medical devices, diagnostics, and digital products. NICE recently published the second piece of draft guidance under EVA, recommending digital technologies for use in the NHS while further evidence is generated.

13. NHSE is:
    a. Clarifying support for innovation in its new operating framework – with clearer roles and responsibility and oversight across NHSE and the broader NHS, including:
        i. IRLS focussed on horizon scanning and demand signalling, providing direction and support in NHS research, and co-ordinating implementation planning for new products.
        ii. Commercial and clinical teams will support early conversations on innovative technologies to develop clinical policy and discuss potential for commercial flexibility.

iii. The selection of specific technologies and delivering rapid spread will be led by ICSs, with oversight through regional directors and the directorate of the Chief Operating Officer.
iv. Additional monitoring support on product spread will be provided by the Data team.

b. Undertaking cross AAC review of approaches to adoption for 18 medicines archetypes, so there is a clear route to adoption for key drug types. We are working with AAC partners on this project with first outputs by March 23.
c. Developing a clear new commercial and adoption pathway for MedTech and digital health therapeutic products. This follows detailed engagement with AAC partners and industry during summer 22.
d. Reviewing its current award programmes (SBRI, AI Award etc.) to ensure they are aligned to product needs in the access pathway – to be completed by June 2023.
e. Developing a new commercial strategy across NHSE to better support innovative products (presented elsewhere for consideration on the AAC Board agenda).

Step 2: improve ways of working between NICE, MHRA and NHSE

14. Development of a new horizon scanning and demand signalling approach –with a focus on agreed NHSE time horizon for innovation of 2-3 years.

15. Data and information sharing between partners– focussed on 3 areas:
    - Better, earlier, sight of products in pipeline
    - How to improve collection of data at early stage, sufficiently enough to enable implementation and commercial decision making.
    - Sharing of information between partners at key points in the process to ensure smooth transition between decision-making steps.

16. Process to enable early engagement on implementation issues from the NHS– building on the paper endorsed by NHSE executive group which set out the NHSE approach; and committed to prioritised engagement from across NHSE structures at least 2-3 years ahead of launch and support ahead of, and to enable but not prejudice, NICE approval.

Step 3: Focus the above on clear priorities

17. We propose selecting 2 or 3 clinical areas and take prioritised, co-ordinated, collaborative approach to bring key technologies through research and access system faster. These will be based on LTP and LSV priority areas and endorsed by NHSE exec as areas where focusses attention should be placed from whole NHS.

18. The recent NHS England Board paper on the future of life sciences in the NHS[7] provided a commitment to tackle the biggest causes of disease, and the necessity of embracing innovation and transformation to meet the needs of all patients. The NHSE executive sub-committee met on 8th November and highlighted the clear alignment between area of greatest need for health equity (core20PLUs5), areas of opportunity for delivering the life sciences vision (emerging trends), and the biggest drivers of disease. Of these, the key areas of opportunity with greatest maturity, alignment and focus were suggested to be mental health, CVD, early cancer diagnosis, and neurodegeneration. We therefore propose focussing on these in the first instance. However, in order to have a transformative effect, we may need to prioritise further. We will bring an implementation plan to the next board with actions against each step of accelerated process for each agreed category area.

What we need from partners and industry to make this happen

19. The chief executives of the AAC, NICE and MHRA are committed to delivering on the above action plan. But this will only be possible with support from other partners.

20. It will need confirmation that the mission areas are clear priorities for the government, which, using its convening power will to bring together senior leaders and hold them to account and make resource available to support AAC partners to deliver in a globally competitive way.

21. From industry:
    a. An understanding that the process will require relevant kinds of evidence, including preclinical data, real world evidence, trials based on representative population level patient cohorts, and where possible from trials based in UK.
    b. A willingness for sharing and transparent publication of uptake and sales data to enable monitoring of unwarranted variation.
    c. Presenting best value pricing upfront to HTA and commercial discussions to enable rapid assessment and commercial discussion.
    d. Early and timely engagement in the process, including early signalling through relevant horizon scanning capability and information sharing across NICE, MHRA and NHSE.
    e. Ensure security of supply for products receiving accelerated support by UK, including where possible a UK manufacturing base.

Board members are asked to:

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- Discuss and agree the priorities for future areas of collaboration and the approach of focusing attention in 2 or 3 key clinical areas, aligned to the Long-Term Plan and Life Sciences Vision. The initial focus would be within CVD, early cancer diagnosis, mental health, and neurodegeneration.