AAC (009)

ACCELERATED ACCESS COLLABORATIVE

INNOVATIVE DEVICES ACCESS PATHWAY (IDAP)

Executive summary

- The IDAP is a joint project between NICE, the MHRA, Health Technology Wales (HTW) and the Scottish Health Technology Group (SHTG). The pathway will offer a supported research and access route for innovative medical technologies and digital devices that meet a critical need in the NHS.

- The aim is to develop a pathway that allows manufacturers to provide their innovative device to healthcare professionals and patients at the earliest, safe, opportunity. The proposed pathway will be piloted with digital health technologies and will need to dock into the reimbursement pathways being developed.

- This paper provides an update on this ongoing project.

Board members are asked to:

- Note the update on progress of this project

Background

1. Following the UK exit from the EU, it is important for the MHRA, NICE, HTW and SHTG (part of Healthcare Improvement Scotland) to work more closely together to ensure patients in Great Britain have early access to effective and innovative devices in a safe manner. The MHRA can now look beyond the confines of the Medical Devices Directive to consider new regulatory opportunities.

2. Innovative devices can be key in addressing unmet clinical need, allowing clinicians to offer hope for a better quality of life, and even better prognosis. MHRA, NICE, HTW and SHTG have an opportunity to be pivotal in offering support to innovators in getting their devices to patients at the earliest point in a safe and controlled manner.

3. The proposed Innovative Devices Access Pathway (IDAP) route builds on MHRA's current exceptional use route that is available to manufacturers who wish to supply their devices in emergency situations. These can be approved on a named patient basis or as a broader derogation, as was seen in response to the demands of the pandemic. This new pathway takes this further in two key ways: 1) it creates a regulatory 'sandbox' for innovators that crucially will have healthcare system buy-in, and 2) it involves NICE, HTW and SHTG as

core partners to ensure that support for health technology assessment (HTA) is built into the pathway from the start.

Proposed pathway

4. Our proposal for the IDAP is a staged approach that can accommodate strategic changes that may arise as part of the development of the new medical device legislation.

5. Stage 1 does not require legislative change for the MHRA. A brief overview of the steps proposed in stage 1 are outlined below:

- Entry into the pathway: Core partners will identify areas of critical need in the health and care system and then publish a call for applications that meet baseline criteria, including a requirement that technologies applying for entry onto the pathway are new and innovative, meet the defined unmet need within a priority area and meet relevant safety standards. Successful applications are granted an innovation passport.
- Target Development Profile (TDP): If entry into the pathway is granted, the applicant is invited to work with the core partners of the pathway (MHRA, NICE, HTW and SHTG) and other relevant stakeholder to agree a target development profile. This TDP would include review of the implementation and use of the device by MHRA to assess whether their exceptional powers could be applied and if so, to ensure safety standards would be met. The data collection programme would be agreed by all stakeholders to ensure the right outcomes are being collected for all decision-making purposes. If detailed advice on study design is needed, core partners can offer joint scientific advice. If MHRA cannot use their exceptional use powers to grant early access, the developer can still access support on their clinical study and access plans through the pathway.
- After completion of the agreed protocol, the MHRA will provide a position statement on the future of the device, such as a decision to proceed to conformity assessment via an approved body.
- Access support: At the point where MHRA reviews the dataset and publishes a position statement on the product, a decision will be made with core partners and the other system partners as to whether to offer the developer additional access support, such as market access advice (e.g. through NICE's Office for Market Access) and signposting.

6. Stage 2 would require legislative changes using the powers of the Medicines and Medical Device Bill. The pathway would remain as above, except MHRA would be able to offer an "innovative licencing" route which would mirror the "innovative licencing and access pathway" for medicines. NICE, HTW, and SHTG will work closely with the MHRA to understand the impact of this on our role as partners in this pathway.

7. The following are examples of the type of technologies that would benefit from IDAP:

    i.   A digital health technology that is aimed at treating adolescent people that have depression with electronic cognitive behaviour therapy. This is an area of significant need and with very few treatment options, as existing digital therapeutics are aimed at adults only. This pathway would recognise that the technology meets a critical unmet need and would offer the innovator a supported pathway to streamline the regulatory process, providing scientific advice and where safe to do so early market access to ensure patients have access to the much-needed innovation.

    ii. Technologies that improve early diagnosis of rare cancer types, such as gliomas. Rare cancers can be hard to diagnose and delays in diagnosis result in poorer prognosis. Additionally, evidence generation is challenging due to the rarity of the condition in the population. For this type of technology, the innovator would benefit from advice and early access to help them build a realistic diagnostic evidence base to support a conformity assessment submission. The innovator could also gain further support from the pathway's market access advice and signposting offer.

Progress on IDAP development

8. The original core team of NICE and MHRA has been expanded to include HTW and SHTG. This has broadened the reach of the pathway to the whole of Great Britain.

9. The scope of the project has been developed. Work packages have been produced and are in the process of being delivered, they include:

    i.   Selection criteria and identification of priority areas of unmet need

    ii.   Pathway application and assessment

    iii. Target development profile

    iv.   Outlining the pathway

    v.   Models for interim data collection

10. Stakeholder engagement has commenced and key system partners (AAC, NIHR, AHSN, NHSX, NHSE/I), as well as industry bodies, have all been introduced to the project. The stakeholder engagement strategy for this project is significant, as each work package will hold a workshop and invite key stakeholders to share feedback and considerations. Patient organisation engagement is planned to ensure the patient voice is incorporated into the pathway.

11. Good progress has been made with the work packages. A workshop to present the deliverables for work packages 1 and 2 was held on the 24th September 2021. The workshop consisted of representatives from all core partners and key system partners. Work package 1 and 2 deliverables are now being finalised based on workshop feedback, including the process for identifying priority areas of unmet need in the NHS and the application form for the pathway.

12. A dedicated workshop is being planned to update industry on the progress of the project.

13. Following the completion of work package 1 and 2, user research will commence to gain user insights and feedback on the application for entry into the pathway.

14. Work packages 3 and 4 have started. After their completion, the core team will pilot the application, selection, and target development profile aspects of the pathway.

Board members are asked to:
- Note the update on progress of this project

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