TERMS OF REFERENCE: INNOVATIVE MEDICINES AND MEDTECH REVIEW

The review will:

- Make recommendations to Government on reforms to accelerate access for NHS patients to innovative medicines and medical technologies (including devices and diagnostics), making our country the best place in the world to design, develop and deploy these products.
    - These recommendations could include the role of statutory bodies including NICE and MHRA.
- Look specifically at three key areas of potential reform:
    - Regulation – how we could more quickly assess the safety and efficacy of innovations by adapting systems and better exploiting our unique advantages as an integrated healthcare system with world-renowned research medicine ethics and infrastructure;
    - Reimbursement – how we might adapt our systems of health economic assessment to: reflect technological advances in genomics, precision medicine and informatics; take time and risk out of the traditional Research and Development model; and better exploit the potential of our integrated healthcare system to pioneer new models of reimbursement for innovative products, including payment by results and Evaluation through Commissioning; and,
    - Uptake – how the NHS can better support and drive medical innovation (including through specialist commissioning).
- Build on lessons learnt from previous reviews to:
    - Better align existing assets and initiatives in a faster and more navigable ‘lit runway’ along the development pathway for innovative medicines, devices and diagnostics, from proof of concept through regulation, cost-effectiveness assessment and adoption and diffusion in the NHS;
    - Identify key priorities for action – both strategic and operational – and suggest practical improvements;
    - Develop an ambitious framework to support and drive medical innovation, and identify opportunities to increase the impact or reduce the cost of delivering healthcare to NHS patients; and,
    - Consider the long term landscape for innovation adoption and how schemes like the CDF, PPRS and Value Based Pricing may fit into an integrated specialist commissioning system over the longer term.
- Map the current landscape for the adoption of innovative medicines, devices and diagnostics from proof of concept through to patients, identifying where there are currently barriers to and opportunities for innovation and proposing solutions for faster adoption:
    - Consider the role of NIHR in the evaluation and assessment of innovative medical technologies in a clinical setting;

- Considering how we might strengthen the Early Access to Medicines Scheme, taking into account how this fits with the Adaptive Pathways Pilot, NICE Technology Appraisal, the NICE Implementation Collaborative and other schemes such as Evaluation through Commissioning;
- Identify requirements for real-time data and monitoring when innovations are applied in the NHS, so that the whole system, including the sponsors of innovative products, can develop evidence to optimise adoption and diffusion driven by real-time data which is subject to normal data governance and privacy requirements;
- Analyse international best practice in innovation adoption, such as the FDA 'breakthrough designation', and identify competitive pressures and opportunities for the UK: where the UK has the strongest levers, any parts of the pathway outside UK Government control, opportunities for the UK to be the best gateway in to the EU market and any reforms to the EU Framework needed; and,
- Consider how the NHS can collaborate to provide real life evidence of utility and cost effectiveness, which can be used internationally to promote innovative drugs, devices and diagnostics.

- Consider both cost-effectiveness and affordability, reflecting the resource environment facing the NHS/public services and the requirement that public spending delivers value for money, and explore how the NHS could both accelerate access for patients and healthcare providers to innovation whilst considering cost pressures on the system.
- Address medicines, devices and diagnostics equally ensuring no one interest dominates, and consider new emerging technologies and the way in which technological convergence is breaking down traditional barriers between regulator categories.
    - In particular it should consider advances in digital technology, stratified medicines and their partner diagnostics, digital devices, apps and new therapeutic technologies; this includes whether current funding structures and ways of working best support innovation.
- Explore how to best accelerate the use of data and measurement to drive evidence-based development and commissioning of effective innovative medicines, devices and diagnostics:
    - Including the de-commissioning of less-effective approaches, ensuring that we get better value out of what the NHS currently spends on medicines and medical products.
- Consider how to ensure patient trust in the regulation and assessment of medicines and medical technology, and recognise the importance of the patient voice and role of medical research charities as both sponsors and beneficiaries of innovation.
- Consider how our system could generate long-term incentives for development in currently under-incentivised therapeutic areas.
- Make both short and medium/long-term recommendations for action, up to a 10 year horizon.

- Set out clear steps for implementation and accountable monitoring of measureable success metrics so that third parties can have confidence in implementation.
- Respect the existing statutory responsibilities of NHS bodies and the European legislative frameworks for regulation and procurement of medicines and medical technologies.

The review will not:

- Change the existing PPRS agreement for branded medicines, negotiated with industry, which lasts for 5 years. The work could however consider issues relating to reimbursement prior to regulatory approval, the extent to which existing flexibilities and incentives for innovative medicines could be better used to overcome barriers, and any potential longer-term pricing and reimbursement issues.

Notes

1. Whilst noting that some elements of the pathway are devolved, the review's ambition is to develop a joined-up, globally competitive landscape across the whole of the UK. The DH will work with the Devolved Administrations where appropriate in order to do this. Issues related to regulation will be addressed on a UK-wide basis, whilst cost effectiveness and adoption will focus on England.
2. The review will take a holistic not piecemeal approach. It may identify packages of measures, including tariffs, incentives, guidance, regulatory changes and clinical support to promote faster uptake and adoption; or areas where multiple regulatory pathways and multiple barriers are hindering progress.