

## Summary of the discussion dinner to provide input to the Government's 'accelerated access review', 13 July 2015

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### Summary

On Monday 13 July, the Academy hosted a Fellows' discussion dinner as part of its contribution to the Government's accelerated access review, which aims to speed up access to innovative drugs, devices and diagnostics for NHS patients.

This event, co-chaired by Professor Sir John Tooke PMedSci, President of the Academy of Medical Sciences, and Professor Sir John Bell FRS HonFREng FMedSci, Chair of the review's external advisory group (EAG), gave Fellows and other invited guests the opportunity to identify key priority areas for consideration by the review and suggest practical improvements and solutions. Attendees included Fellows drawn from regulatory agencies, the life sciences industry, academia and the third sector, as well as two members of the review's EAG and a representative from the Office for Life Sciences.

Key topics of discussion included:

- The crucial role played by both **patient and physician "pull"** in driving uptake of new products, and the need for innovation to more closely reflect society's wants and areas of **unmet clinical need**.
- The **importance of evaluation** and the huge opportunity **for real world data** to act as a tool for the early and continuous assessment of new products, enabling us to benefit quickly from those innovations that deliver value and reject those that do not.
- The need for a **more sophisticated approach to pricing and reimbursement**, and the potential for real world data to provide the basis for more flexible models that more effectively reward valuable products.
- The **long return on investment** often required for innovative products and the need to create "**headroom**" within the NHS's limited budget if such products are to be supported; for example by **de-listing** ineffective interventions, improving **patient adherence** to treatment, and making better use **of digital technologies** to deliver efficiencies.
- The need for the review's recommendations to acknowledge the **global context** in which the life sciences industry operates and build upon the **progress that has already been made** in recent years to streamline and modernise European regulatory processes.

This report summarises the key points of discussion.<sup>1</sup>

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<sup>1</sup> This report is a summary of a discussion and does not necessarily reflect the views of all attendees or of the Academy of Medical Sciences.

## Background

In November 2014, George Freeman MP, Minister for Life Sciences, announced the launch of the 'innovative medicines and medtech review', later renamed the 'accelerated access review'. Its aim is to "speed up access to innovative drugs, devices and diagnostics for NHS patients".<sup>2</sup>

The independent review, led by Sir Hugh Taylor, Chair of Guy's and St. Thomas' NHS Foundation Trust, will make recommendations on reforms to the pathways for the development, assessment and adoption of innovative medicines and medical products within the NHS. It is focussing on three types of product – medicines, medical technologies and digital health – and will address these pathways via four workstreams, each of which has been assigned an "external champion"<sup>3</sup>:

- Workstream 1 aims to develop a transparent framework **for early dialogue and collaboration**, which drives transformative innovation and supports partnerships from end to end. Champion: Dr Stuart Dollow, Founder of Vermillion Life Sciences.
- Workstream 2 aims to **streamline regulatory processes** and articulate a **clear accelerated process for innovative products**; or to build a best practice pathway where this does not exist. Champion: Professor Richard Barker, Director of CASMI.
- Workstream 3 will propose solutions to **integrate or accelerate national reimbursement processes** and fund clinically and **cost-effective innovation** across the pathway. Champion: Richard Murray, Director of Policy at the King's Fund.
- Workstream 4 aims to accelerate the speed at which **clinically and cost effective innovative products are commissioned and get to NHS patients**. Champion: Rob Webster, Chief Executive, NHS Confederation.

These four workstreams are underpinned by a programme **of patient and user engagement**, championed by Hilary Newiss, Chair of National Voices.

Sir Hugh is being supported in his work by an External Advisory Group (EAG), chaired by Professor Sir John Bell GBE FRS HonFREng FMedSci. In spring 2015, the Academy was asked by Sir John to host a Fellows' discussion dinner to explore some of the areas being tackled by the review and to provide further input. This took place on 13 July and was co-hosted by Sir John Bell and the Academy's President, Professor Sir John Tooke PMedSci. A list of attendees is included as Annex I.

Sir John Bell opened proceedings by reminding participants of the review's aims and the issues that it has been set up to tackle. Over the course of dinner, attendees then considered questions pertinent to each of the four workstreams.

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<sup>2</sup> <https://www.gov.uk/government/organisations/accelerated-access-review>

<sup>3</sup> <https://www.gov.uk/government/news/themes-and-big-questions-for-accelerated-access-review>

## Discussion overview

### Introductory comments

Sir John Bell noted that despite the UK's strong record of health technology appraisal (HTA), the NHS has a poor track record of adoption and diffusion of new medical products and can often be resistant to innovation. He highlighted that the NHS was extremely sensitive to budget impact and therefore distinguished between two categories of innovation:

1. Innovations which could lead to significant cost savings for the NHS; for example, digital tools for monitoring and tracking patient outcomes, which could help to reduce hospital admissions.
2. Innovations which could increase the cost to the NHS; for example, innovative products, such as immune-oncology drugs and drugs for rare diseases, which carry a high financial cost but have been shown to be extremely efficacious.

The challenge that the accelerated access review has been set up to face is to establish how the healthcare system can better embrace and deliver cost-effective innovations, while addressing affordability issues at a time when the NHS is operating under significant financial constraints.

### Workstreams 1 and 2

*Developing a transparent framework for early dialogue and collaboration which drives transformative innovation and supports partnerships from end to end; streamlining regulatory processes and articulating a clear accelerated process for innovative products.*

### **Encouraging early dialogue with regulators and HTA agencies**

- Workstream 1 focuses on developing a framework for early dialogue between industry, patients and regulators; however, participants highlighted that several such opportunities already exist. The Medicines and Healthcare products Regulatory Agency (MHRA), for example, currently offers around 300 scientific advice meetings every year and its new Innovation Office aims to be a single point of contact for those developing innovative products.<sup>4</sup> It was felt that efforts should be made by the MHRA to capitalise further on this resource. In addition, joint meetings are offered with both the MHRA and the National Institute for Clinical Excellence (NICE), although only three have actually taken place. Participants hypothesised that this may be because of concerns that such meetings may lead to "cross-contamination" of the roles of the two organisations, particularly as they often use the same data in their decision-making.
- The need for dialogue notwithstanding, it was considered vital that approval and reimbursement decisions remain mutually exclusive. This is in part because while approval is increasingly becoming a European or even global activity, reimbursement decisions are often made at the national level. Different countries may quite legitimately want to spend different amounts on healthcare, so while multiple countries might agree that a product is safe, they may reach different conclusions about whether or not it is cost-effective. Nevertheless, the need for continued close dialogue between the MHRA and NICE was recognised and valued.

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<sup>4</sup> This office offers scientific advice free-of-charge and answers queries from companies, small and medium-sized enterprises (SMEs), academics and individuals who have developed a novel medicine or device. <https://www.gov.uk/government/groups/mhra-innovation-office>

### ***Streamlining regulatory processes***

- It was noted that seeking opportunities to further streamline the regulatory system is very much a “well-ploughed ground”, with most of the obvious “tweaks” already having been tested. Participants also highlighted that, at the European level, several significant advances have been made in the last 12 months and schemes such as conditional licensing are now present within the legislation, ready to be taken up. It was considered important that the report acknowledges this and does not overlook what is already in place.
- The global regulatory context in which the life sciences industry operates was acknowledged. Attendees highlighted that while incremental changes – such as the UK Government’s ‘early access to medicines’ scheme – can be implemented at a national level, truly disruptive changes – such as the European Medicines Agency’s (EMA) ‘adaptive pathways’ programme – can only be achieved through international collaboration. It was felt that while the EMA has been very active in trying to drive transformative change and is already “sold” on the need to significantly accelerate access to medical innovations, the European Commission (EC) is much more conservative. There was seen to be a need for the review to be sensitive to these political factors when framing its recommendations.

### ***Aligning innovation with unmet need***

- Participants stressed the importance of “patient pull” as a driver of diffusion and adoption; the early and enthusiastic uptake of HIV drugs was offered as an example. It was noted that research and drug development are too often focussed on what industry professionals believe are the desired outcomes, rather than what patients actually want. Patient participation early in the R&D process offers pharmaceutical companies a better understanding of patients’ needs, in order to develop medicines tailored towards maximising outcomes and confronting unmet need. It was also considered crucial for patients to be involved in discussions with regulators and HTA agencies about the costs and benefits of particular innovations.
- Participants also highlighted the importance of “physician pull”; the slow uptake of biologics by rheumatologists was used to demonstrate the challenge of driving adoption in the absence of such pull. However, it was felt that this could be difficult to achieve given the “inherently conservative” nature of many physicians (with the notable exception of oncologists, who in recent years have embraced a broad array of innovative approaches and treatments).

### ***Using real world data to support innovation***

- It was noted that industry is generally in favour of accelerating access to its products – even if this is initially at a low price – because this provides it with time to build a market and collect data. However, accurately evaluating the value of products this early in the pathway is difficult and low prices, once set, have traditionally not been increased, acting as a powerful disincentive for early appraisal. Improving our use of real world data was seen to be key to resolving this issue and the UK was considered to be extremely well-placed to use such data as the basis for more sophisticated reimbursement models. However, up to now, industry has been wary of using real world data in regulatory submissions and questions remain about how this data can best be used to generate robust evidence.<sup>5</sup>

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<sup>5</sup> As part of its FORUM programme, the Academy of Medical Sciences is hosting a workshop on ‘Real World Evidence’ on 17 September 2015, to explore the acceptability of real world evidence on the safety, efficacy and value of drugs.

- It was noted that real world data does not have to be purely observational, and that 'real world trials' could still be randomised and placebo controlled.<sup>6</sup> It was felt that Academic Health Science Networks could play an important role in coordinating and facilitating such trials.

### **Workstream 3**

*Solutions to integrate or accelerate national reimbursement processes and fund clinically and cost-effective innovation*

#### ***Developing a more sophisticated approach to pricing and reimbursement***

- Some attendees considered current NHS drug pricing mechanisms to be rigid and non-transparent and felt that a more sophisticated approach was needed – for example, more flexible pricing models more closely linked to the collection of real world data. It was also suggested that a wider array of factors should be considered when calculating the value of a drug; for example, the employment impact on both the patient and their carer(s). However, it was noted that such an approach would require shared budgets across Government departments, as “the Department of Health cannot be expected to subsidise the Department for Work and Pensions”, and may therefore be difficult to achieve.
- It was proposed that while NICE’s assessments should continue to inform reimbursement, a broader “pricing board” might be convened to “make a deal” based on other factors such as volume and patent life. It was noted that these discussions have never previously taken place, except in the case of vaccines, where the Joint Committee on Vaccines and Immunisations plays an equivalent role. It was felt that companies may accept a lower price if the NHS was willing to bulk purchase, and that a central pricing board would potentially facilitate this.
- Some participants highlighted the attractiveness of ‘cost-sharing’ models, in which healthcare providers only pay for a product if it is shown to be effective. The Risk Sharing Scheme for Disease Modifying Therapies (DMT) in multiple sclerosis (MS) was offered as an example. This aims to ensure that DMTs can be provided to all eligible MS patients while measuring the cost-effectiveness of these treatments in clinical practice. Clinical outcomes from treated patients are entered into a health economic model, which allows the cost-effectiveness of each of the drugs in the scheme to be monitored. These data are assessed at two year intervals over ten years, at which point the price that the NHS pays may be adjusted.<sup>7</sup> There was some debate about the effectiveness of such schemes; however, participants agreed that cost-sharing was more likely to work once the necessary infrastructure to gather data from the NHS is in place.
- There was a sense that, whatever the mechanism for reimbursement, uptake of innovation would remain limited if clinicians and commissioners ignore NICE recommendations and that this was already a major driver of unfair “CCG prescribing” (a new form of “postcode prescribing”). It was felt that this also limits the amount of discount that a company can offer to the NHS, as low uptake leads to reduced volume and lower return on investment. However, it was also argued that the average cost per quality-adjusted life year (QALY) for products in the NHS is much lower than the £30,000 threshold currently used by NICE, meaning that there is an opportunity cost for commissioners who follow NICE recommendations.

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<sup>6</sup> The Academy has recently launched a working group project to explore how evidence that originates from different sources (e.g. randomised clinical trials and observational data) is used to make decisions about the risks and benefits of medicines.

<sup>7</sup> For more information see: <http://www.mstrust.org.uk/downloads/rss.pdf>

## **Workstream 4**

*Accelerating the speed at which clinically and cost effective innovative products are commissioned and get to NHS patients*

### ***Creating headroom for innovative products within limited budgets***

- Participants highlighted that innovation is often expensive and that return on investment takes time. While businesses tend to look at the long-term, the NHS is often focused on the short-term political cycle, making it difficult for it to support innovation. It was argued that we therefore have to create “headroom” to enable the NHS to either pay higher prices for innovative products or provide investment during the expensive development phase. It was proposed that the creation of a long-term capitalised fund – a so-called ‘implementation fund’ – dedicated to supporting medical innovation, might be created to bridge this gap.
- In order to create headroom, participants noted a need for the health system to become better at “de-listing” interventions that have been showed to be ineffective. One attendee observed that the government’s ‘Committee on the Review of Medicines’ used to do this, before it was disbanded several decades ago. The overuse of generics, especially in the elderly, was seen by some to be a clear example of such “over-medicalisation”. It was suggested that the review should also look into the low levels of patient adherence to treatment, as wasted medicines are thought to cost the NHS in England around £300 million per year as well as contributing to poor patient outcomes. It was noted that this was particularly important for high-cost, potentially high-value drugs which require a high level of compliance if they are to be effective; for example, those developed to treat hepatitis C. Compliance monitoring strategies are increasingly being developed to ensure that patients are taking such drugs correctly.
- The potential for digital technologies to create headroom for the NHS was also noted. For example, advances in IT infrastructure will soon make it possible to “bar-code track” drugs all the way to the patient, making it easier to collect effectiveness data and potentially facilitate de-listing. Technology-based methods for early detection of disease, such as screening tests for colorectal cancer, can also lead to cost-savings, creating headroom within the system but with potentially significant repercussions: for example, necessitating a reallocation of resources from radiotherapy departments to screening programmes. Participants noted that in the future, an increasingly “tech-savvy” elderly population would be able to measure and collect health data using digital devices, so it is important that the NHS is prepared to use such technologies alongside more conventional medicines. The ability of the current NHS workforce to cope with these types of developments was questioned.

### ***Ensuring that the ‘lit runway’ is an evaluative one***

- In describing the reasons for launching the accelerated access review, the George Freeman MP has spoken repeatedly of the need to ensure that there is a “lit runway” for innovators hoping to develop products for use in the NHS. Attendees emphasised the need for this lit runway to also be an evaluative one; that is, for the NHS to not only welcome the use of innovative products, but also their continued evaluation through data collection and analysis. This was seen to be fundamental both to facilitating novel approaches to drug assessment – such as adaptive licensing – and to engaging with health professionals to pave the way for uptake. Involving more clinicians in research was considered to be key, and several attendees suggested that better incentives were needed to encourage this and to reduce the opportunity cost for those who are open to participating.

## Concluding comments

At the end of the evening, each attendee was asked to identify a priority that they would like to see reflected in the review's final report. These can be summarised as follows:

- The report should take care to focus on **new opportunities** and not “go over the same ground as previous reviews” – the obvious solutions are, for the most part, already in hand.
- The importance of **patient buy-in** cannot be underestimated. This is likely to be a key driver of diffusion and adoption of innovation going forward.
- The NHS should work in partnership with industry to set up mechanisms to identify **priorities for drug discovery**; that is, interventions offering genuine therapeutic advances. It must then make it easy to conduct trials to meet these needs and to monitor outcomes. This would help industry decide where the priorities lie and speed up access to innovative products.
- Action needs to be taken to ensure that the ‘lit runway’ is an evaluative one; that is, that data collection and evaluation are part of the day-to-day business of the NHS. When we see innovation that is effective, we should ensure that it is adopted quickly, its impact is measured and its creators and early users rewarded. Over time, this will contribute to a more **innovative culture** across the NHS.
- Efforts should be made to **capitalise on existing investment** in Academic Health Science Centres (AHSCs) and Biomedical Research Centres (BRCs), which should form an important part of this ‘lit runway’. AHSCs and BRCs have the capacity to work in partnership with industry and provide access to NHS patients and data; in exchange, it may be possible to negotiate on price to ensure NHS access to emerging products.
- **Information Technology** (IT) should be made a far greater priority within the NHS. More should be done to routinely collect and analyse electronic health data, outcomes data and other relevant information to improve the evidence base and provide opportunities for future innovation; information should be captured for use in research, as well as administrative purposes. In order to achieve this, the IT infrastructure of the health service needs to be overhauled and IT needs to be reframed as a clinical resource. This will likely require a new cadre of expert NHS Chief Information Officers, amongst other things.
- Actions with a potentially **catalytic effect** should be prioritised. For example, within the NHS there would be value in identifying and focusing on the worst performing 10% in order to both improve poor performance and catalyse change elsewhere in the system.
- The report might usefully highlight that **return on investment in the NHS takes time** – often more than the five-year political cycle.
- The **European Commission** (EC) must be “brought on-side” with the UK innovation agenda. While the European Medicines Agency is conducting some good work in this area, the EC remains conservative and has the potential to act as a brake on progress.
- Consideration should be given to **how we drive behaviour change** – of practitioners, NHS management and patients. We also need a more sophisticated understanding of the kind of incentives and rewards that work in driving these behaviours; for example, in encouraging clinicians to participate in clinical trials. More research may well be needed.

- The report might usefully propose that HTA bodies focus more on **take up of their guidance and recommendations**. There is a need to think more carefully about the impact that these evaluations will have 'on the ground' and to provide more support for implementation.
- The field of **regulatory science** needs to be further developed in the UK in order to evaluate and predict some of the uncertainties linked with the drug development process, in addition to exploring the bioethics issues arising from drug development.

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### **The Academy of Medical Sciences**

The Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are converted into healthcare benefits for society. Our Fellows are the UK's leading medical scientists from hospitals and general practice, academia, industry and the public service.

The Academy seeks to play a pivotal role in determining the future of medical science in the UK, and the benefits that society will enjoy in years to come. We champion the UK's strengths in medical science, promote careers and capacity building, encourage the implementation of new ideas and solutions – often through novel partnerships – and help to remove barriers to progress.

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## Annex I: Attendees at the Accelerated Access Review discussion dinner

Name	Position and institution
Professor Sir John Bell GBE FRS HonFREng FMedSci	Regius Professor of Medicine, University of Oxford; Head of the Review's External Advisory Group
Sir Alasdair Breckenridge CBE FRSE FMedSci	Former Chairman, Medicines and Healthcare products Regulatory Agency (MHRA)
Dr Stephen Caddick	Director of Innovations, Wellcome Trust
Ms Victoria Charlton	Head of Policy, Academy of Medical Sciences
Dr Mehwaesh Islam	Policy Officer, Academy of Medical Sciences
Professor David Lomas FMedSci	Chair of Medicine and Dean of Faculty of Medical Sciences, UCL; Member of the Review's Advisory Group
Professor Sir Alex Markham FMedSci	Director of the Molecular Medicine Institute at St James's University Hospital; Non-executive director at MHRA; Member of the Review's Advisory Group
Dr Nicole Mather	Director, Office for Life Sciences
Dr Mene Pangalos FMedSci	Executive Vice President of Innovative Medicines & Early Development Biotech Unit, AstraZeneca
Professor Sir Michael Rawlins FMedSci	Chairman, MHRA
Professor Caroline Savage FMedSci	Vice President and Head of Experimental Medicine Unit, GSK
Professor Trevor Sheldon FMedSci	Professor of Health Services Research & Policy, University of York; Dean of the Hull York Medical School
Professor Sir John Tooke PMedSci	President, Academy of Medical Sciences
Professor Peter Weissberg FMedSci	Medical Director, British Heart Foundation
Dr John Williams	Interim Executive Director, Academy of Medical Sciences
Professor Sir Kent Woods FMedSci	Chair of the Management Board at the European Medicines Agency