

**From the President
Professor Sir John Tooke PMedSci**

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Mr Ian Bishop
Medicines and Healthcare products Regulatory Agency
5th Floor
151 Buckingham Palace Road
London
SW1W 9SZ

Dear Mr Bishop,

Academy of Medical Sciences response to the Medicines and Healthcare products Regulatory Agency's consultation on a proposal to introduce an early access to medicines scheme in the UK.

We welcome the opportunity to respond to the Medicines and Healthcare products Regulatory Agency's consultation on a proposal to introduce an early access to medicines scheme in the UK.

The Academy's mission is to promote medical science and its translation into benefits for society. This requires that approaches to evaluate new innovations continue to evolve to accelerate the speed of appraisals and bring efficacious medicines to the NHS, and therefore society, in a cost-effective manner.¹

We warmly welcome this signal of political will for changing pharmaceutical regulation to improve patient access to innovative medicines and stimulate their development. Nonetheless, it will be important to ascertain whether this scheme, as proposed or with modification, would stimulate innovation and improve patient access beyond existing MHRA schemes, as intended by the Life Sciences Strategy. The Academy would hope that more than 1 or 2 products per year would be eligible (as estimated in the consultation document). However, only industry can meaningfully project the uptake and therefore impact of the proposed scheme, and make suggestions for its optimisation. We understand that such projections and suggestions will be included in submissions to this consultation from the UK BioIndustry Association (BIA) and the Association of the British Pharmaceutical Industry (ABPI).

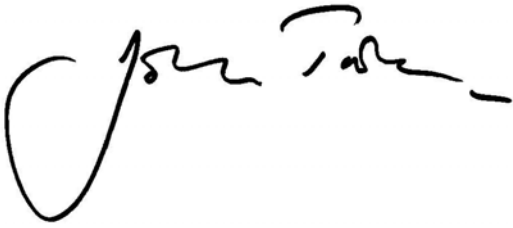
The consultation correctly clarifies that this is a separate and independent initiative to the development of adaptive approaches to licensing, which have a significant regulatory dimension. Whereas this scheme would exist within the current regulatory framework, adaptive approaches will require a new regulatory framework: a prospectively planned approach involving multiple phases of evidence gathering, evaluation and licensing adaptation.² This should incorporate clarity around unmet need, and an earlier and fuller appreciation of the potential value of a new development as a precursor to the limited licensing of drugs after Phase II of clinical trials. As detailed in our response earlier this year to the House of Commons Science and Technology Committee inquiry 'Bridging the "valley of death": improving the commercialisation of research', the Academy strongly supports the development of adaptive approaches to licensing, which would provide new drugs for patients more quickly to address unmet need, and in the process help Small and Medium sized Enterprises generate much

¹ Academy of Medical Sciences (2010). *Academia, industry and the NHS: collaboration and innovation*. <http://www.acmedsci.ac.uk/p48prid75.html>

² Eichler H-G, *et al.* (2012). *Adaptive licensing: taking the next step in the evolution of drug approval*. *Nature Clinical Pharmacology and Therapeutics* **91(3)**, 426-37.

needed revenue earlier, critical for late stage trials.³ The experience gained could inform the development of a stratified medicine approach to a wider population, targeting new therapy at those most likely to benefit. Consequently, we hope that the early access scheme will be a welcome first step in the evolution toward a more fundamental reconsideration of drugs regulation, i.e. the ongoing development and proper consideration of adaptive approaches to licensing. The Academy would be happy to contribute to the ongoing development of such approaches.

Yours faithfully,

A handwritten signature in black ink, appearing to read 'John Tooke', with a large, stylized initial 'J'.

Professor Sir John Tooke PMedSci

cc: Rt Hon David Willetts MP, Minister of State for Universities and Science

³ Academy of Medical Sciences (2012). *Academy of Medical Sciences response to the House of Commons Science and Technology Committee inquiry into bridging the 'valley of death' and improving the commercialisation of research.* <http://www.acmedsci.ac.uk/p100puid245.html>