wellcome trust

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Consultation on the MHRA's draft 2013-18 corporate plan

Thank you for the opportunity to comment on the Medicines and Healthcare products Regulatory Agency's draft 2013-18 corporate plan. The Wellcome Trust's support for research covers a wide range of areas aligned with the MHRA's activities, including proof-of-concept research and the development of new healthcare products; public health; and research using patient data.

We welcome the way in which the draft incorporates the diverse functions that will be housed in the MHRA. The draft is particularly clear around the integration of these functions and opportunities for synergies between them, for example ensuring that data from the Clinical Practice Research Datalink (CPRD) are used to provide information on products to support the MHRA's regulatory functions. We also support the draft's general comments on the importance of running an efficient organisation with sustainable funding.

We are pleased that the draft recognises the potential economic benefits of CPRD. In the future we hope to see a more focused plan from CPRD on how this vital research resource will be developed. Similarly, it will be important that the National Institute for Biological Standards and Control ensures that a plan is in place to maintain its strengths in research throughout the transition to MHRA.

We welcome the draft's focus on improving the regulatory environment, including promoting a consistent, proportionate approach. However, we recognise that a one-size-fits-all regulatory pathway is becoming increasingly outdated and a more flexible and responsive regulatory framework is now needed. We are therefore pleased to see that the MHRA is involved in discussions to introduce an adaptive licensing pilot, and we encourage you to give more attention to developing this area over the next five years.

Flow diagram one demonstrates the importance of clear roles and responsibilities and collaboration between stakeholders to build a better regulatory system. However, we consider that the accompanying text could better reflect the MHRA's role in the wider UK regulatory landscape. In particular, we would welcome information on the MHRA's relationship with the Health Research Authority, their shared goals and proposed framework for working together.

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We look forward to seeing the final version of the corporate plan later this year, and working with you as you deliver it.

Sir Mark Walport
Director, Wellcome Trust