The Academy of Medical Sciences

41 Portland Place
London W1B 1QH
+44 (0)20 3176 2150
www.acmedsci.ac.uk

Professor Robert Souhami CBE FMedSci
Foreign Secretary

21 December 2012

Sandor Beukers
Medicines and Healthcare Products Regulatory Agency (MHRA)
5th Floor
151 Buckingham Palace Road
London SW1W 9SZ

Dear Mr Beukers,

The Academy of Medical Sciences welcomes the opportunity to respond to the Medicines and Healthcare Products Regulatory Agency (MHRA) consultation on the European Commission's proposals for a Clinical Trials Regulation (CTR). The proposals are an improvement on the current Clinical Trials Directive (CTD). We are particularly pleased that the CTR takes a more proportionate approach and that it formally introduces co-sponsorship for clinical trials. The ambitious assessment times described in the proposals would do much to speed the translation of research into benefits for patients. We also welcome the MHRA's efforts to engage stakeholders around the CTR and the increasingly facilitative approach the MHRA is taking in the implementation of the CTD.

Our outstanding concerns about the proposals for the CTR focus particularly on its impact on multi-state trials and include:

- We welcome the introduction of a single application portal with a single application dossier but would like European institutions to outline their plans for creating and implementing the requisite IT systems to take these plans forward.
- The Academy welcomes efforts to make clinical trials more transparent but care needs to be taken to ensure such measures are taken forward in a thoughtful manner that does not inadvertently impede medical research and thus patient benefit.
- Challenges remain around the perception of and terminology used in both the CTR and CTD. Greater efforts are needed to communicate with academics, NHS Trusts, higher education institutions and other stakeholders to avoid confusion and a highly risk adverse approach to clinical research.
- Allowing sponsors to choose the National Competent Authority (NCA) to which they apply may mean stronger NCAs, such as the MHRA, receive more applications than others NCAs. We would like reassurance that this would not have a negative impact on the processing of applications for both national and multi-national trials from the home country of stronger NCAs
- The need to ensure insurance arrangements in the CTR for multi-state trials are not too cumbersome.

The Academy has endorsed a recent joint statement about the CTR led by Cancer Research UK, a copy of which is enclosed. We are looking to continue to work closely with the MHRA with this issue over the coming months. If you have any queries please contact Laurie Smith who is leading for the Academy on this matter (tel.: +44 (0)20 3176 2167, e-mail: laurie.smith@acmedsci.ac.uk).

Yours sincerely,

The Academy of Medical Sciences is a company limited by guarantee. Registered in England Charity No: 1070618 Company No: 3520281