ROYAL PHARMACEUTICAL SOCIETY

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Dear Sir/Madam,

RE. REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC – CONCEPT PAPER

We write on behalf of the Royal Pharmaceutical Society and its partner group, the National Pharmacy Clinical Trials Advisory Group (NPCTAG), to respond to the above public consultation document.

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

The National Pharmacy Clinical Trials Advisory Group, originally a subgroup of the National Pharmaceutical Quality Assurance, was established in its current form in 2010. Membership includes representatives from a range of hospital pharmacy disciplines and other relevant specialist groups, MHRA and the National Institute of Health Research. The group's objectives are to provide advice to NHS pharmacy services, to the National Institute of Health Research Clinical Research Networks Coordinating Centre, to support education & training of pharmacy staff, and to provide a forum for communication with MHRA about clinical trial issues.

Herewith our comments on the concept paper:

Consultation item 1: Agreed, a single submission will help resolve the current workload for sponsors.

Consultation item 2: Agreed, we will not resolve the current issues by having Member states undertaking their own independent assessments.

Consultation item 3: Agreed, a central assessment would also prove very difficult and maybe delay proceedings even further.

Consultation item 4: No comment.

Consultation item 5: Agreed in principle but noting that in a), "normal clinical practice" will vary from member state to member state. b+c should be dealt with by each member state.

Consultation item 6: First approach preferable – allow member states to opt out where appropriate.

Consultation item 7: Second approach preferable – CAP mandatory for all multinational trials.

Consultation item 8: Agreed. This would be especially helpful to non-commercially sponsored studies.

Consultation item 9: Agreed, need to harmonise the definition of and requirements for all clinical trials in all member states

Consultation item 10: Agreed, commercial and non-commercial trials should be regulated in the same way.

Consultation item 11: Agreed.

Consultation item 12: No comment.

Consultation item 13: Agreed. 'Auxiliary medicinal products' should be exempt from labelling and storage requirements. There is a large number of studies in, for example, haemato-oncology involving multiple drug regimens, where all except one or two drugs are standard care. There are also many studies where a licensed drug is used for a licensed indication or would have been prescribed even if the patient weren't in the trial. These drugs should not be defined as IMPs.

Consultation item 14: Opinion divided! The argument that liability should lie with Sponsors and not member states favours option 1. A counterargument is that even "low risk" trials may generate unforeseen challenges & liabilities and individual member states should be free to impose their own requirements for managing this risk. However, Option 1 (removing current requirements need not exclude Option 2 (Optional indemnification).

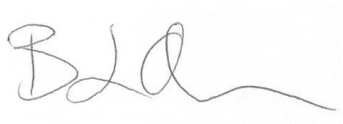
Consultation item 15: Agree with Option 1. Multiple-sponsorship could prove unworkable in practice.

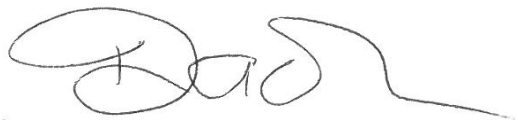
Consultation item 16: Agreed but two options should be discussed. 1) All standard treatments must be exhausted before treatment via clinical trial route or 2) Where trial drug is used further up the treatment pathway, use of trial drug should not exclude patients from other non-trial treatment options if the trial drug treatment fails.

Consultation item 17: Agreed. The legislation should apply in any non-EU country in which the trial is undertaken if the data is to be used in the EU. On a related issue, GCP training to ICH standards should be recognised in all ICH countries. E.g. training UK must be acceptable to US Sponsors and no repeat training should be required.

Consultation item 18: No comment.

Kind regards,





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