Dear Colleagues
The National Pharmacy Clinical Trials Advisory Group (NPCTAG), a partner group of the Royal Pharmaceutical Society, was established in 2010 and is a partnership group of the Royal Pharmaceutical Society (RPS) the professional body for pharmacists in Great Britain. NPCTAG's objectives are to provide advice to NHS pharmacy services, to the National Institute of Health Research (NIHR) Clinical Research Network, to support education and training of pharmacy staff, and to provide a forum for communication with MHRA about clinical trial issues. Membership is drawn from NHS Trusts Pharmacy Departments, NHS Production Committee, UK Radiopharmacy Group, NIHR Clinical Research Network Coordinating Centre, UK Clinical Pharmacy Association, Medicines and Healthcare products Regulatory Agency (MHRA) and Clinical Research Network, Community Pharmacy and Clinical Trial Units.

NPCTAG welcomes the opportunity to respond to the public consultation on the revision of the '**Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)**'and wishes to submit the following comments:

Section 3.3
The flexibility to allow Member States to decide the requirements of the application dossier for AMPs seems at variance with the aim of the Regulation to bring about a single application. It may be useful for the EC to provide some guidance on the use of AMP that is authorised in the EU but available in a number of country specific presentations within the EU. On occasions, the sponsor will purchase a country-specific presentation of an AMP and supply it to all sites. This leads to a less than ideal situation as the package leaflet will not be in the official language for every Member State in which the trial is taking place (e.g. German participants being supplied with an authorised AMP with only Spanish labelling and package leaflet).

I consent to publication of all information in this contribution in whole or in part including the name of my organisation, and I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication.

Kind regards

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