Question for written answer E-010279/2014
to the Commission
Rule 130
Philippe Juvin (PPE)

Subject: Potential barriers to the development of academic research in Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

The rules for the labelling of investigational medicinal products and auxiliary medicinal products, specified in Annex VI to the regulation on clinical trials, could result in additional costs, thereby deterring non-commercial sponsors from conducting clinical trials and slowing down the development of academic research in Europe.

First, the obligation to state the period of use of the product on the primary packaging seems unnecessary (as this information appears on the secondary packaging) as well as dangerous, since it would mean investigational medicinal products would have to be handled repeatedly, to the detriment of the quality of the product and the safety of participants who use them.

Second, mandatory additional labelling for investigational medicinal products that have a marketing authorisation appears to be contrary to Recital 57, which states that, as a general rule, no additional labelling should be required for such authorised products, and to Article 67, according to which the labelling of authorised investigational medicinal products relates to the treatment, unless the products are blinded.

Is the Commission aware of these potential problems for institutional sponsors and does it intend to deal with them in the implementing acts and delegated acts that will implement the regulation on clinical trials?