Question for written answer E-002407/2014
to the Commission
Rule 117
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Subject: Development and use of advanced therapy medicinal products (ATMP) treatments by university hospitals

In its answer to Written Question E-012229/2013, the Commission recognises that only four advanced therapies have so far been granted a licence. Meanwhile, the Commission gives a positive evaluation of the active participation of university hospitals in the development of advanced therapies. New advanced therapies should be easily accessible and affordable for citizens in Europe.

The accessibility of well developed advanced therapies should be of major concern, especially with regard to deadly diseases for which advanced therapies can be life-saving and where they contribute significantly to public health. The largest and most innovative activities in the development and administration of advanced and personalised therapies are today almost exclusively performed by university hospitals. However, the framework for the current hospital exemption for ATMPs laid down in Regulation (EC) No 1395/2007 does not offer enough flexibility for university hospitals to use the clinical data from these activities for scientific research. No clinical trials can be performed and manufacturing is restricted to non-routine productions.

What concrete modifications to the hospital exemption clause could the Commission envisage to facilitate and stimulate the development and use of successful advanced, personalised and multimodal therapies for severely diseased patients by university hospitals through clinical trials, thereby respecting the highest standards of quality as well as affordability and accessibility for patients?