Question for written answer E-006256/2015
to the Commission
Rule 130
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Subject: European Medicines Agency (EMA) Transparency Policy/0070

In view of the European Medicines Agency (EMA) Transparency Policy/0070, which came into effect on 1 January 2015:

1. In the Q&A document accompanying the policy, the EMA states that 'The policy has been shaped in the absence of any specific legal provision mandating the Agency to publish documents submitted by third parties'. In the Commission's view, is it legitimate for the EMA to act without a legal basis?

2. Given that the definition contained in the EMA policy relating to whether or not data have already been published is relevant to whether they can be considered to be commercially confidential information (CCI), should a decision with such implications for the fundamental rights of the marketing authorisation holder (MAH) not be based on a decision taken by the legislator?

3. Against this backdrop and given that, according to the policy, the 'Agency accepts no responsibility for the user's compliance with the ToU' (terms of use), i.e. for competitors misusing data provided by the EMA, how does the Commission intend to ensure that the legitimate interests of the MAH who creates and owns the data are respected by the EMA in practice, especially when deciding on redaction requests by an MAH?