Question for written answer P-007342/2017
to the Commission
Rule 130
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Subject: European Medicines Agency

The association 'Mieloma España' has expressed interest in the marketing authorisation for the medicine Aplidin (plitidespin), under evaluation by the European Medicines Agency (EMA), because it has high expectations for this medicine.

After 15 months of exchanges with the EMA, the applicant received the 'Rapporteurs' Day 180 Joint Response Assessment Report', and the 'Day 180 2nd List of Outstanding Issues (LoOI)', dated 26 October 2017, which constitute a framework for the final evaluation. Neither document raised any objections regarding the selection of the statistical method that tested the crossover effect on the secondary objective, namely overall survival.

The Oral Explanation was held on 7 November 2017, contradicting the framework established by the report and LoOI of 26 October 2017: it challenged the statistical methodology referred to above and elevated it to the category of a major objection. A negative vote ensued ('non-approvable').

Apparently conflicting with its own established procedures, on 16 November 2017 the EMA issued a redacted LoOI, nullifying the original support for the methodology and positive assessment.

Considering the Commission's supervisory responsibility over the EU agencies as per the Interinstitutional Agreements:

Does the Commission know about the details of this procedure?

Does the Commission consider that the procedure followed by the EMA is correct?