Question for written answer E-014408/2015
to the Commission
Rule 130
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Subject: Orphacol: back again

We thought that the Orphacol saga was over after the Court of Justice, in its latest judgment, cancelled the marketing authorisation for the rival product for reasons related to infringement of the market exclusivity right.

The truth is apparently quite the reverse: the European Medicines Agency (EMA) delivered another favourable opinion on that rival product (Kolbam) on 24 September, in other words 17 days after the Commission had asked it to reconsider its position.

Can the Commission say why such a step was taken within such a short time, bearing in mind that the Commission itself stated in court that if the references to efficacy in the Orphacol indications were removed from the information relating to Kolbam, this would result in a decision which it, the Commission, would not have adopted?

Should not the Commission have asked the EMA to review every aspect of the case? Given that it has not done so, how can we imagine that the European public assessment report (EPAR) will amount to exactly the same as an entirely new approach?

In view of the background to this case, and in particular the favouritism shown to the rival company by DG SANCO, how can the Commission guarantee the necessary transparency?