

WRITTEN QUESTION P-2044/09
by Thomas Ulmer (PPE-DE)
to the Commission

Subject: Legal certainty concerning the status of a new active substance (NAS)

When a medicinal compound is given status as a new active substance (NAS) it attracts data exclusivity for a period either of 6 or 10 years, depending on the Member State in question and the data of authorisation of the compound.

Are there any circumstances under which it would be legally possible for the compound's status as a NAS to be challenged during the period of data exclusivity?

If that status were to be challenged, for example, after it had been granted unanimously by the Member States, would it be deemed by the Commission to be reasonable for some of those same States then to support licence applications from generics manufacturers that challenged the NAS status within the period of data exclusivity?

Under such circumstances, how would the Commission adjudicate as to the validity of the applications, and would this be a suitable subject for the comitology process?