

**Question for written answer E-015427/2015**  
**to the Commission**  
Rule 130  
**Francesc Gambús (PPE)**

Subject: Stricter data protection rules for veterinary medicinal products and their negative impact on farmers and food producers

In its proposal for a regulation on veterinary medicinal products (COM(2014)0558), the Commission seeks to extend the current 10-year protection periods provided for in Directive 2001/82/EC up to a maximum of 18 years. During this period, applicants for a generic product are prevented from referring to the documentation submitted for the reference product and data provided to extend the generic product to another animal species is protected according to the same principle.

As a result, generic companies will in most cases be obliged to wait up to 18 years before being able to access the market after the protection period expires.

How does the Commission justify its proposal in terms of the impact on generic veterinary medicines, in terms of medicines availability, affordable prices and the potential risk for European farmers and food producers being put in a weaker competitive position compared to non-EU producers?