

**ENGLISH TRANSLATION BY CANIS ETHICA  
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Ref. Ares(2018)4166082 - 08/08/2018

**EUROPEAN COMMISSION  
HEALTH AND FOOD SAFETY DEPARTMENT**

Resource Management and Better Regulation  
Legal Questions

Brussels,  
On,

Sante A.2/IK/apc(2018) 4078641

Mrs. Thilo Hane  
8 rue de la Roche  
35400 Saint Malo France  
E-mail: thane@canisethica.org

**Subject: Complaint registered under the reference CHAP (2017) 2823 against France concerning the alleged violation of the rules concerning vaccination of pets**

Madam,

We refer to your complaint of 17 October 2017, registered under the reference CHAP (2017) 2823, and to the information communicated on 13 September 2017, on behalf of the organization "Canis Ethica", regarding the duration of the immunity related to rabies vaccination for pets.

**1. Your complaint**

In the complaint, it is stated that some pet vaccines in France related to rabies vaccines have a one-year immunity period whereas in the other EU Member States the same vaccines provide immunity of three years.

In addition, the complaint states that national legislation allows vaccine manufacturers to determine the duration of immunity. In particular, Article 3 of the "Decree of 10 October 2008 on the terms and conditions of rabies vaccination of domestic animals" allows manufacturers to decide on the duration of immunity conferred by vaccination. You also refer to the adverse effects that frequent vaccination would have on animals.

In your opinion, this type of circumstance discriminates against pet owners in France in relation to pet owners in other Member States, and national legislation does not comply with the Directive 2004/28 / EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82 / EC establishing a Community code relating to veterinary medicinal products

## **2. Our analysis**

With regard to the subject of the complaint, it should be noted that Directive 2001/82 / EC, as amended by Directive 2004/28 / EC, does not provide for rules on the duration of immunization of rabies vaccines. This directive governs, inter alia, the general procedure and the requirements for the authorization of veterinary medicinal products. The products mentioned in your complaint do not appear to be authorized under centralized management or the decentralized authorization procedure. Consequently, in so far as the infringement of Directive 2001/82 is relied upon in respect of those authorization procedures, that error is unfounded.

It should be recalled that Member States are entitled to authorize veterinary medicinal products, including immunological medicinal products, in accordance with their applicable national legislation and to provide for the effectiveness and duration of the immunization which depends on the composition of the vaccine and strains used. Similarly, the arrangements for vaccination recommendations fall within the competence of the Member States.

It should be noted that Article 168 (7) (point) of the Treaty on the Functioning of the European Union states that 'Union action shall be conducted in accordance with the responsibilities of the Member States in concerning the definition of their health policy [...]. "

Therefore, since the facts giving rise to your complaint fall within national jurisdiction, the Commission can not intervene and take corrective action. I therefore invite you to continue to follow the dossier with the competent national authorities, in accordance with the applicable national legislation and practices.

In this context, we refer to the European e-Justice Portal for more information on how to obtain legal protection at national level.

## **3. Conclusion**

We would like to inform you of our intention to close this file. If you have new information that could prove the existence of an infringement of EU law that the European Commission could pursue in accordance with the Commission Communication "EU law: Better application for better results , you can contact us within four weeks of the date of this letter, after which the case will be closed. You can send any additional information by e-mail to the following address: SANTE-CHAP @, ec.europa.eu.

Please accept, Madam, the assurance of my highest consideration.

Rossella Delfino

Head of Unit