EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Quality, Research & Innovation, Outreach
The Director

Brussels,
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Dear Madam,

Thank you for your letter of 9 October 2019 (your reference: RF-052/2019) regarding organic production rules on veterinary medicinal products and the settings of withdrawal periods.

In your letter, you ask for more consistency and harmonisation in EU legislation on veterinary medicine; you asked also whether it can be confirmed that the use of vaccines is not affected by the double withdrawal period or the 48 hours rule; finally, you suggest that the Commission should consider not to apply the double withdrawal period or the 48 hours rule to parasiticides.

Regarding the definition of veterinary medicinal product, please note that under Article 3(43) of Regulation (EU) 2018/848 on organic production and labelling of organic products[1], a veterinary medicinal product means a veterinary medicinal product as defined in point (2) of Article 1 of Directive 2001/82/EC[2]. This Directive will be repealed as of 28 January 2022 by Regulation (EU) 2019/6 on veterinary medicinal products[3]. Article 149 of this Regulation states that references to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in Annex IV. The reference of Article 1 of Directive 2001/82/EC corresponds to Article 4 of Regulation (EU) 2019/6 where a "veterinary medicinal product" is defined as any substance or combination of substances which fulfils at least one of the following conditions:

1 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571666841552&uri=CELEX:32018R0848

2 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571666918979&uri=CELEX:32001L0082

3 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2019:004:FULL&from=EN

(a) it is presented as having properties for treating or preventing disease in animals;

(b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;

(c) its purpose is to be used in animals with a view to making a medical diagnosis;

(d) its purpose is to be used for euthanasia of animals.

Hence, there are no inconsistencies in the definition of a "veterinary medicinal product" between the provisions of Regulation (EU) 2018/848 on organic production and labelling of organic products and Directive 2001/82/EC and Regulation (EU) 2019/6 on veterinary medicinal products. However, for the purpose of the implementation of certain rules specific to organic production, Regulation (EU) 2018/848 refers to immunological veterinary medicinal products, chemically synthetised allopathic veterinary medicinal products, antibiotics, substances to promote growth or production, hormones and similar substances for the purpose of controlling production or for other purposes, phytotherapeutic products and homeopathic products. Please note that such types of references already exist under the current organic rules[4].

Concerning vaccines, you ask whether it can be confirmed that the use of vaccines is not affected by the double withdrawal period or the 48 hours rule as laid down in point 1.5.2.5 of Annex II part II of Regulation (EU) 2018/848. Indeed, both Regulation (EU) 2018/848 on organic production and labelling of organic products (point 1.5.1.2 of Annex II part II) and Directive 2001/82/EC (Article 1(7)) and Regulation (EU) 2019/6 on veterinary medicinal products (Article 4(5)), recognizes the specificities of immunological veterinary medicinal products. Further, the rules on the withdrawal period laid down in point 1.5.2.5 of Annex II part II of Regulation (EU) 2018/848 applies specifically to "a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic". We consider that "vaccines" when they correspond to the definition of an "immunological veterinary medicinal product" are not "a chemically synthetised allopathic veterinary medicinal product, including of an antibiotic" within the meaning of Regulation (EC) 2018/848 and hence the rules of point 1.5.2.5 of Annex II part II of Regulation (EU) 2018/848 on withdrawal period do not apply in that particular case.

Finally, you suggest in your letter that the Commission should consider not to apply the rules of point 1.5.2.5. of Annex II part II of Regulation (EU) 2018/848 to parasiticides. Please note that the Commission has no empowerment to change these rules under Regulation (EU) 2018/848.

Nevertheless, following requests from several stakeholders, the Commission intends to further analyse the legal changes introduced by Regulation (EU) 2018/848 regarding withdrawal periods in organic production.

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R0889-20181112&qid=1571668788457&from=EN

The present opinion is provided on the basis of the facts as set out in your letter of 9 October 2019 and expresses the view of the Commission services and does not commit the European Commission. In the event of a dispute involving Union law it is, under the Treaty on the Functioning of the European Union, ultimately for the European Court of Justice to provide a definitive interpretation of the applicable Union law.

Yours sincerely,