



*Committee on Agriculture and Rural Development
The Chair*

09.01.2024

Mr Pascal Canfin

Chair of the Committee on the Environment, Public Health and Food Safety
Brussels

IPOL-COM-AGRI D(2023) 43992

Subject: Opinion on the Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 (COM(2023)0193 – C9-0144 – 2023/0131(COD))

Dear Mr Canfin,

Under the procedure referred to above, the Committee on Agriculture and Rural Development (AGRI) has been asked to submit an opinion to your committee. At its meeting of 23 May 2023, the committee decided to issue an opinion in the form of a letter and adopted it on 24 January 2024.

The main reason the AGRI Committee send an opinion relates to its competence over veterinary matters as set out in paragraph 3(a) of Annex VI(XIII) of the Rules of Procedures.

- **Governance of the European Medicinal Agency**

AGRI Committee welcomes the simplification of functioning of the Agency which can bring benefits to its work, including in veterinary medicinal products; recalls that appropriate funding is important to ensure effective regulatory control, while enabling innovation and availability of medicinal products.

- **Antimicrobial resistance and prudent use of veterinary medicines**

AGRI Committee welcomes the incentives for developing ‘priority antimicrobials’; stresses that in order for all users to have continued recourse to a full range of effective antimicrobials, for both human and animal health, antibiotics should be developed, marketed, delivered and used responsibly and prudently in line with the “One Health” approach and Regulations (EU)

2019/5 and (EU) 2019/6; highlights the urgent need to bring new antibiotics onto the market, while maintaining high levels of health and safety; calls for better implementing existing approaches against antimicrobial resistance including prevention and surveillance, and innovating new ones;

- **Free Trade Agreements and reciprocity of norms.**

AGRI Committee strongly calls for equivalent measures to those laid down in this proposal, on veterinary products for Union trade partners, to be inserted when negotiating free trade agreements; considers that no veterinary products nor animal products should be imported without a strict reciprocity of norms.

I would be grateful if the ENVI committee could take into account the above considerations in view of the adoption of its report on the Commission proposal in question.

Yours sincerely,

Norbert Lins

**ANNEX: ENTITIES OR PERSONS
FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT**

The rapporteur declares under his exclusive responsibility that he did not receive input from any entity or person to be mentioned in this Annex pursuant to Article 8 of Annex I to the Rules of Procedure.