

**Voluntary Report** – Voluntary - Public Distribution

**Date:** April 07, 2021

**Report Number:** BE2021-0004

**Report Name:** European Commission Launches Publishes Consultation on Criteria for the Designation of Antimicrobials to be Reserved for Human Use

**Country:** Belgium

**Post:** Brussels USEU

**Report Category:** Livestock and Products, Dairy and Products, Poultry and Products, Agriculture in the News, Sanitary/Phytosanitary/Food Safety

**Prepared By:** Lisa Allen

**Approved By:** Anthony Gilbert

**Report Highlights:**

The European Commission launched a public consultation on the delegated act establishing the draft criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans. The European Commission will use these criteria to establish a list of antimicrobials to be reserved for use in humans as part of its legislation on veterinary medicinal products. Interested stakeholders have until April 23, 2021 to respond to the consultation.

**General Information:**

In January 2019, The European Commission published [Regulation 2019/6](#) on veterinary medicinal products. This regulation lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, control and use of veterinary medicinal products in the European Union. It also will apply certain aspects of the regulation to third countries exporting animals or products of animal origin to the EU.

One of the key elements of this regulation that will apply to third countries is Article 37(5) which establishes a list of antimicrobials reserved for human use. If on this list, the antimicrobial will not be able to be used in the treatment of animals. In order to establish such a list, the Commission first needs to come up with the criteria to be used to identify these antimicrobials.

The draft delegated act establishing the criteria states that the designation of antimicrobials to be reserved for human use must meet all three of the criteria set out in parts A, B, and C of the annex in order to be designated as reserved for treatment of certain infections in humans.

- Part A: Criterion of high importance to human health;
- Part B: Criterion of risk of transmission of resistance; and
- Part C: Criterion of non-essential need for animal health.

The Annex outlining the full draft criteria can be downloaded from [here](#).

U.S. Stakeholders who would like to comment on the draft criteria can do so on the following page:  
<https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11570-Establishment-of-Criteria-for-the-designation-of-antimicrobials-reserved-for-human-use>.

The deadline for input is 12:00 a.m. Brussels (Universal Time Coordinated + 01:00) on April 23, 2021. All comments provided through this consultation process may be released as public information.

**Attachments:**

No Attachments.