

PGEU consultation response to EMA advice on criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans.

The Pharmaceutical Group of the European Union (PGEU) is fully supportive of the EMA advice on criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans. We consider this an important document proposing criteria which are balanced, acceptable and needed, suggesting many elements of evaluation of the problem and indications on how the solutions can be found.

Upon implementation, attention needs to be raised to article 112 (1. (b)) of the Regulation (EU) 2019/6 on veterinary medicinal products. This article foresees that where there is no authorised veterinary medicinal product in a Member State for an indication concerning a non-food-producing animal species, the veterinarian responsible may, under his or her direct personal responsibility and in particular to avoid causing unacceptable suffering, exceptionally treat the animals concerned with a medicinal product for human use authorised in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. When the use of an antimicrobial would be reserved for the treatment of certain infections in humans only, there should consequently be a restriction introduced for the possibility of prescribing this antimicrobial via a veterinary prescription. Moreover, since the Regulation also foresees the cross-border recognition of such veterinary prescriptions of human medicines issued for veterinary purposes, attention needs to be drawn to equally restrict the possibility of cross-border recognition of such prescriptions containing an antimicrobial reserved for the treatment of certain infections in humans only. Please also kindly refer to the [2015 PGEU Position Paper on Proposal for a Regulation on Veterinary Medicinal Products](#) where we have highlighted some additional concerns related to the cross-border recognition of veterinarian prescription of human medicines issued for veterinary purposes.

Complementary to this important work, we would like to stress that in order to tackle antimicrobial resistance it is necessary to focus as well on additional measures promoting the prudent use of antimicrobials in human and veterinary medicine. Community pharmacists are very committed to this cause and do this through taking preventative actions such as educating patients as to when antibiotics are convenient to treat infections and how to safely self-treat common illnesses and non-bacterial infections at home. They provide as well advice on and administration¹ of flu vaccines, and in many countries pharmacies are offering disposal and collection schemes for left-over and expired medicines. And of course they provide evidence-based information and advice on the prudent use of antibiotics when dispensing them. Please find [here](#) an overview of several of such community pharmacy best practices in tackling antimicrobial resistance and encouraging the prudent use of antimicrobials across Europe.

¹ Allowed in Denmark, France, Ireland, Norway, Portugal and the United Kingdom