



Recommendation 1

**Current scenario of critical veterinary products**

CONSIDERING THAT:

1. Veterinary products play a key role in the prevention and control of animal diseases;
2. Access to Veterinary products is essential for both animal health and welfare, influencing and having an impact on “One Health” results, including the fight against antimicrobial resistance;
3. According to Chapter 6.10 on *Responsible and prudent use of antimicrobial agents in veterinary medicine* of the *Terrestrial Animal Health Code*, Veterinary Authorities should promote the availability of authorised antimicrobial products on the market in collaboration with the veterinary pharmaceutical industry to follow-up any potential products shortages;
4. According to the same Chapter, the pharmaceutical industry should endeavour to ensure that authorised antimicrobial products are available and cooperate with the Competent Authority to forecast and avoid any shortages;
5. Ensuring that everybody has a role to play in the availability of critical veterinary products. This includes the national Competent Authorities, the veterinary pharmaceutical industry and their international associations, the wholesale and retail distributors, the veterinarians, and the breeders, owners and keepers of animals;
6. Veterinary product shortages may cause negative impacts on animal health and welfare, public health and even food production chains;
7. There is no harmonised definition of critical or essential veterinary products, besides specific initiatives such as the *WOAH List of antimicrobial agents of veterinary importance* and the *List of essential medicines for food producing animals* developed by Brooke and the World Veterinary Association (WVA);
8. It is important to identify the causes and impact of essential or critical veterinary product shortages to define effective measures to prevent and solve the lack of availability;
9. In most Members of the Regional Commission for the Americas, no plans or programmes were identified either to define and study the causes of shortages or to implement measures to avoid essential or critical veterinary product shortages.

THE REGIONAL COMMISSION FOR THE AMERICAS

RECOMMENDS THAT:

THE VETERINARY AUTHORITIES OF THE MEMBERS:

1. Draw up a list of essential or critical veterinary products taking into consideration existing lists defined by international organisations, including the *List of antimicrobial agents of veterinary importance* compiled by WOAHA and the WVA/Brooke *List of essential medicines for food producing animals*, as well as the epidemiological characteristics of the country itself, ensuring that such document is continually updated;
2. Design an action programme including measures to prevent, combat and mitigate shortages of essential or critical veterinary product shortages;
3. Involve all the relevant actors in the veterinary products manufacturing and distribution chain, as well as veterinary professionals and society in the development and implementation of such a programme;
4. Participate and promote in the existing initiatives aiming for the harmonisation of technical requirements for the registration of veterinary products including the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and the Americas Committee for Veterinary Products (CAMEVET). Collaborative actions should be directed to reduce regulatory barriers;
5. Create a task force or working group to identify and assess all aspects related to essential product shortages, including the characterisation of the shortages, the definition of the causes and their impact;
6. Establish communication mechanisms with information exchanges on critical products shortages between the regulatory authorities and private sector companies such as manufacturers, importers, distributors and marketers, so that a critical veterinary product stockout risk assessment system can be introduced;
7. Establish contingency measures for shortage crisis situations, evaluating the adoption of procedures such as import and use authorisations in emergency situations, the use of inputs whose manufacture may have been suspended because of failures in Good Manufacturing Practices (GMP) or the lengthening of product shelf lives, always as part of a risk-benefit approach;
8. Promote incentives through formal recognition of companies that operate highly efficient quality systems;
9. Foster improving quality systems to avoid the risk of product supply disruptions.
10. Advocate for the development of policies and regulatory frameworks that support access to innovative veterinary products.

WOAH:

1. Develop guidelines to assist Members in defining critical or essential veterinary products, adapted to the needs and specificities of each country, in particular some relevant criteria that countries should take into account when drawing up their own list of essential or critical veterinary products;
2. Promote cooperation and harmonisation of technical requirements between countries in cases of shortages of veterinary medicine in all situations, including crisis, through the National Focal Points for Veterinary Products;
3. Facilitate discussion platforms to enable solidarity-based cooperation with countries facing shortages of essential veterinary products and restrictions on their supply, particularly in crisis situations.