



MINISTRY FOR AGRICULTURE, FISHERIES,
FOOD AND ANIMAL RIGHTS

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Summary and explanation on provisions related with antimicrobials in LN179/2021 of the 23.04.2021 that amends S.L 437.47 on Veterinary Medicinal Products

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The amended SL.437.47 will provide increased control and better use of all VMPs, including those containing antimicrobials. In addition, there are a few requirements in some of the Regulations that are specific to antimicrobials. These Regulations are being listed below and explanations are given for each Regulation.

The Regulations mentioned below are about the use of VMP containing antimicrobials . The Regulations are intended to increase the prudent use of antimicrobials. These put obligations on prescribers, dispensers and, where relevant, farmers.

It is important to clarify a point on 'Preventive use'. Such use is banned. Preventive use is distinct from the other terms (prophylactic and metaphylactic use). The word 'preventive' in these Regulations has more meaning than in its purely language sense.

Reg No	Legal Text	Explanation
2	"preventive use of an antimicrobial agents" means the administration of antimicrobial agents to healthy animals to prevent infections to compensate for inadequate good farming practice;"	<p>Insertion of a new definition on preventive use. Although prophylactic use (which is an acceptable practice) is also a form pf prevention it was felt necessary to define the word 'preventive' and reserve it when associated it with mal practices that increase AMR prevalence. This will distinguish the 3 practices.</p> <p>When read together with the definitions of Metaphylaxis and Prophylaxis this definition intends to convey the meaning that 'preventive use' should not be used on the pretext of either prophylactic or metaphylactic use.</p>



2	"prophylactic administration of antimicrobials" means the administration of a veterinary medicinal product or a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection:	<p>Insertion on a new definition of prophylactic. Regulation (EU) 2019/6 which comes into force in 22-01-22, contains such a definition so it was included in the text to align the LN with the new EU Regulation. Moreover, there are several new provisions in the text which are specifically on prophylactic use.</p> <p>Bacterial infections in large flocks or herds often appear at identifiable and predictable stages during the lifetime of the animal, e.g. respiratory problems after regrouping, colibacillosis during the post-weaning period, shipping fever following transport, etc. Treating in situations like this is referred to as prophylactic treatment. The farmer and the veterinarian are familiar with imminent disease hazards on their farms, and early action, carefully and selectively carried out, is a necessary part of disease management. This action is like that practiced in human medicine in cases such as bacterial meningitis outbreaks in schools or colleges where the group of students potentially exposed will be treated in such a manner.</p>
2	"Metaphylactic" means the administration of a veterinary medicinal product or a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick and controlling the spread of the disease to animals in close contact and at risk and which may already be sub clinically infected;"	<p>Insertion on a new definition of Metaphylaxis. Regulation (EU) 2019/6, which comes into force in 22-01-22, contains such a definition so it was included in the text to align it with the new EU Regulation. Moreover, there are several new provisions in the text which are specifically on prophylactic use.</p> <p>Frequently, animals are kept in groups and whilst this is beneficial from practical husbandry and animal welfare aspects, it means that the group may be at risk when a disease strikes. As a result, it is sometimes necessary to treat the group. This would be the case where it is known that an infectious disease is present and where experience shows that the disease will infect most, or even all the animals in the group once one animal shows symptoms of infection. Such use is sometimes termed 'metaphylaxis'.</p>
4D	before a decision on antimicrobial veterinary medicinal products and products that have a hormonal activity is	When deciding about the procurement of VMPs containing antimicrobials by private individuals the Veterinary Services must base its opinion on scientific grounds while placing EU/national legislation into context. For example, although an antimicrobial may



	taken, a risk assessment shall be prepared by the Veterinary Services in a timely manner;	be present for the treatment of a particular condition it may not be the first line of treatment. It might be the case that a VMP procured in this way will be a first line of treatment that will pose less risks on AMR. Such procurement of VMP is not excluded from a veterinary prescription. Moreover, the Veterinary Services keeps a register of such procurements which it uses for its risk assessment. Very frequent procurement of the same VMP by the same individual may prompt the Veterinary Services to ask the private individual to procure the VMP by other legal means, e.g. through article 10 or 11 of S.L 437.47
59	When dispensing an antimicrobial agent the dispenser must be satisfied that all necessary precautions have been taken to minimise the risks of antimicrobial resistance and that the prudent use of the antimicrobial agent have been taken in consideration, in particular to the use of critically important antimicrobials.	An obligation was inserted on the dispenser to ascertain that antimicrobials are used prudently, particularly those antimicrobials that are also important and used in human health (known as critical antimicrobials). Dispensers of VMPs are not just regular salesman handling an item. They should be knowledgeable in the subject, provide information to the user and in a way 'double check' what is written on the veterinary prescription. It is the professional duty of the dispenser to communicate with the prescriber in case of any doubts to ascertain that all precautions are taken to minimise AMR development.
59A	<p>(d) all necessary precautions have been taken to minimise the risks of antimicrobial resistance and that the prudent use of the antimicrobial agent have been taken in consideration, in particular to the use of critically important antimicrobials.</p> <p>(10) When prescribing antimicrobial agents veterinary surgeons shall consider the latest guidelines issued by the Veterinary Services, and other relevant national, European and International organisations with regard to critically important antimicrobials.</p>	<p>A number of obligations for prescriber were inserted to ascertain that antimicrobials are used prudently to minimise risk on AMR .</p> <p>These all take in consideration the knowledge that prescribers should have on this subject. It is important that when prescribing the prescribers also consider aspect of AMR and not only the short-term treatment of the animals.</p> <p>It is not enough for the veterinarian to consider only the well-being of the patient. The veterinarian should look at the bigger picture and consider other aspects (in this case AMR) that might not be evident at the moment. The Veterinary Services will be helping the prescribers to make the informed decision by issuing information about that from time to time. This may be in the form of guidelines, leaflets, and circulars. Veterinarians</p>



		should refer to information that can be obtained from well-established organisations related with animal Health such as OIE and EMA to keep themselves updated . Where possible the Veterinary Services will also disseminate such information.
62	scientific justification as to why antimicrobial veterinary medicinal products or medicinal products were prescribed by the veterinary surgeon in the case of metaphylactic and/or prophylactic use."	<p>The vet must provide justification when recommending antimicrobials for metaphylactic and/or prophylactic use. As explained preventive use (as defined) cannot be used on the pretext of metaphylactic and/or prophylactic use. If a farm has bad feeding practices, is unhygienic and maintains poor biohazard measures the risk for disease outbreak is high. 'Prevention is better than cure', thus the veterinarian must first guide the farmer to remedy these problems before treating or continuing treating (as the case may be) with antimicrobials.</p> <p>The said justification should be included on the veterinary prescription. When veterinary prescriptions are collected, collated, and studied by the Veterinary Services trends in disease development can also be investigated with this information. It will also observe trends in prescribing.</p>
79(A)	<p>(5) Metaphylactic or prophylactic antimicrobial treatment may be allowed with conditions. Preventive use of antimicrobials veterinary medicinal products or medicinal products is not allowed.</p> <p>(8) Stockpiling of antimicrobial veterinary medicinal products or medicinal products in a farm to be administered at a later stage is not permitted.</p>	<p>The 'conditions' mentioned in the text (5) are those specified in the definition of each terms and as may be issued by the Veterinary Services in the form of guidelines.</p> <p>Packs of antimicrobials are supposed to be manufactured and packed in the quantities necessary for treatment. All quantity should be used. On the other hand, antimicrobials should be prescribed by the veterinarian and obtained from the farmer only when needed. In principle this means that none should be present when the animals are not being treated or no disease are present. This is the reason why 'stockpiling' mentioned in (8) is not permitted. Stockpiling of antimicrobials may increase the tendency for</p>



	<p>(9) Use of combination of antimicrobials should be scientifically supported."</p> <p>(6) Except in emergency situations, before prescribing a veterinary medicinal product or a medicinal product that contains an antimicrobial agent classified as critically important to human health or that is reserved for treating infections in animals for which no effective alternative treatments exist, the prescribing veterinary surgeon shall take into account the results of the diagnostic laboratory information (pathogen isolation, identification and antibiogram).</p>	<p>farmers to use them due to ease of availability and what is incorrectly though as convenience.</p> <p>The 'combination of antimicrobials' mentioned in the text (9) does not refer to those already present in the finished VMP containing antimicrobials. This should already have been studied and decided at Marketing Authorisation stage. Rather this refers to the decision by the veterinarian to treat the animal with different VMPs containing different antimicrobials.</p> <p>Although sensitivity testing is not a requirement for the majority of antimicrobial use an obligation to conduct these tests was inserted for those occasions when a critical antimicrobial will be prescribed. The list of critical antimicrobials shall be decided by the EU Commission and the Veterinary Services will inform veterinarians on them.</p>
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