



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 December 2020  
EMA/649279/2020  
Veterinary Medicines Division

## Questions and answers on the review of veterinary medicines containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use given to pigs

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMA/V/A/137)

On 9 September 2020, the European Medicines Agency (the Agency) completed a review of the safety and effectiveness of veterinary medicines containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use given to pigs. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of these medicines continue to outweigh their risks but that their use should be restricted to prevent the development of resistance.

### What is tiamulin?

Tiamulin is an antibiotic belonging to the class of the pleuromutilins. It works by preventing certain bacteria from making proteins, thereby stopping their growth. Tiamulin has been shown to work against some microorganisms which infect pigs, chickens and rabbits.

Tiamulin is only used in veterinary medicine and is usually given to animals in their food or water. In pigs it is often used to treat a bacterial infection called swine dysentery, but it can also be used for the prevention or metaphylaxis of that infection. This means not for treating pigs which are already diseased, but to protect healthy animals when they are at risk of becoming infected.

The products included in this procedure were limited to veterinary medicines containing tiamulin which are given to pigs in their feed only for the prevention or metaphylaxis of swine dysentery. They are available in Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Malta, the Netherlands, Poland, Portugal, Romania, Slovak Republic, Spain and the United Kingdom.

### Why were tiamulin containing products for pigs reviewed?

The Belgian veterinary medicines authority noted new data which showed that *Brachyspira hyodysenteriae*, the bacterium which causes swine dysentery, is increasingly developing resistance against tiamulin, which will reduce its effectiveness.

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



Antibiotic resistance is the ability of bacteria to grow in the presence of an antibiotic that would normally kill them or limit their growth. This means that the antibiotic may no longer work on bacteria infecting either animals or humans.

When using tiamulin only for the prevention or metaphylaxis of swine dysentery (not at the same time as treating diseased pigs), usually very low doses for a prolonged period of time (mostly 4-6 weeks) were approved, to cover the period for which the animals were considered at risk. It is generally accepted that using such small amounts of antibiotics for a long duration contributes to the development of antibiotic resistance. The Belgian authority considered that the use of tiamulin only for the prevention or metaphylaxis of swine dysentery may no longer be appropriate.

Consequently, the Belgian authority asked the CVMP to carry out a full assessment of the benefit-risk balance of tiamulin when given to pigs in their feed for the prevention or metaphylaxis of swine dysentery and to issue an opinion on whether the marketing authorisations for the products should be maintained, varied, suspended or withdrawn across the European Union.

### **Which data has the CVMP reviewed?**

The CVMP reviewed studies on the fate of tiamulin in the bodies of healthy pigs, studies on the effectiveness of tiamulin in preventing swine dysentery, data on the susceptibility of *Brachyspira hyodysenteriae* to tiamulin and published literature.

### **What are the conclusions of the CVMP?**

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CVMP concluded that tiamulin given to pigs in their feed is an effective medicine against several diseases and it is very important in the treatment of swine dysentery. To limit the potential for development of antibiotic resistance and thus maintain its effectiveness, tiamulin should not be used unnecessarily. Tiamulin use at low doses for extended periods of time was not proven to be effective and was considered to increase the risk for development of resistance, therefore it is no longer justified.

The CVMP concluded that the benefits of veterinary medicines containing tiamulin hydrogen fumarate presented as premix for medicated feeding stuff and oral powder for in-feed use given to pigs continue to outweigh the risks. The Committee recommended that the approved separate doses for prevention or metaphylaxis should be removed and the use should be limited to the treatment and metaphylaxis (at the same time) of swine dysentery, when the products are given at a higher dose for a shorter period.

The full changes made to the product information are detailed in Annex III of the CVMP opinion under 'All documents'.

The European Commission issued a decision on 9 December 2020.