EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2017
EMA/144816/2017
Veterinary Medicines Division

# Questions and answers on veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs

Outcome of a referral procedure under Article 35 of Directive 2001/82/EC (EMEA/V/A/117)

On 10 November 2016, the European Medicines Agency (the Agency) completed a review of the consumer safety of the withdrawal periods for cattle (meat and milk) and pigs (meat and offal) for veterinary medicinal products containing gentamicin presented as solutions for injection. The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the overall benefit-risk balance for veterinary medicinal products containing gentamicin presented as solutions for injection is positive and recommended amendments to withdrawal periods for cattle and pigs to provide assurance for consumer safety.

## What is gentamicin?

Gentamicin is an aminoglycoside antibiotic indicated for the treatment of a variety of bacterial infections. It is normally used as the sulfate salt. In veterinary medicine gentamicin is used mainly as a solution for injection for cattle, pigs, horses, cats and dogs.

## Why were veterinary medicinal products containing gentamicin presented as solutions for injection reviewed?

Belgium noted that there are different approved withdrawal periods for cattle and pigs for veterinary medicinal products containing gentamicin presented as solutions for injection across the European Union, e.g. cattle meat and offal from 28 days to 210 days; cattle milk from 2 to 7 days, with some of the products stating 'do not use in cows whose milk is intended for human consumption'; and pig meat and offal from 28 days to 150 days.

On 8 January 2016, Belgium initiated a procedure under Article 35 of Directive 2001/82/EC for veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs, due to concerns related to the withdrawal periods set for the aforementioned products. The CVMP was requested to review all available residue depletion data and recommend withdrawal periods for cattle (meat and milk) and pigs (meat and offal).

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## Which data has the CVMP reviewed?

Proprietary data and scientific references on residue depletion were provided by the marketing authorisation holders.

## What are the conclusions of the CVMP?

Based on the evaluation of the currently available data, the CVMP concluded that the overall benefit-risk balance for veterinary medicinal products containing gentamicin presented as solutions for injection is positive and agreed that the withdrawal periods for cattle (meat and milk) and pigs (meat and offal) should be amended to provide assurance for consumer safety and also agreed that the subcutaneous route should no longer be recommended for cattle and pigs since the depletion kinetics from the injection site remain unknown. The CVMP recommended that the marketing authorisations for veterinary medicinal products containing gentamicin presented as solutions for injection should be varied in order to amend the product information accordingly.

The European Commission issued a decision on 27 February 2017.