



Report of the Federal Ministry of Food and Agriculture on the Evaluation of the Antimicrobials Minimisation Concept introduced by the 16th AMG Amendment

Executive Summary

Infections caused by bacterial pathogens are treated with antimicrobials in both humans and animals. Resistant bacteria have the ability to protect themselves from the action of antimicrobials and thus impair the efficacy of these medicinal products. The key to preventing antimicrobial resistance is the prudent and overall reduced use of antimicrobials in both human and veterinary medicine, particularly in the case of active substance classes that are deemed to have priority (“critical”) for public health.

With the entry into force of the **16th Act to Amend the Medicinal Products Act** (*Sechzehntes Gesetz zur Änderung des Arzneimittelgesetzes – 16. AMG-Novelle*) on 1 April 2014, a system was established in Germany for the first time for the nationwide minimisation of antimicrobial use in animal keeping for certain fattening animals (known as “types of production” – fattening piglets, fattening pigs, fattening calves, fattening cattle, fattening chickens and fattening turkeys).

The core elements of the **Antimicrobials Minimisation Concept** (sections 58a to 58d AMG) encompass: the duty of the keepers of the above-mentioned fattening animals to send notifications about their livestock and their use of antimicrobials; the half-yearly calculation by the competent authorities of a farm-specific indicator (“treatment frequency per farm”), and the duty of the animal keepers to take steps to reduce their use of antimicrobials when it is higher than the nationwide totality of treatment frequencies (above the nationwide indicators).

As part of the evaluation of the effectiveness of the Antimicrobials Minimisation Concept, the data collected by the authorities could be evaluated centrally for the first time. The attainment of the goals was assessed on the basis of the **three goals** set out in the legislation.

Goal 1: To reduce the use of antimicrobial veterinary medicinal products in the keeping of certain fattening animals

This goal was achieved for all six types of production.

- The quantities of antimicrobial substances (supplied quantities of antimicrobials) supplied to veterinarians fell by a total of 57% between 2011 and 2017. Between 2011 and 2014 this decrease amounted to 467 t or 27.4 % but was far more pronounced between 2014 and 2017 (505 t or 40.8%).
- The total consumed quantity of antimicrobial substances for the types of production considered fell by a total of 94 t (31.6%) from 298 tonnes to 204 t between the second half-yearly period 2014 (HYP 14/2) and HYP 17/2. The biggest reduction by far was achieved for pigs.
- All types of production and farms of all sizes experienced a significant reduction in treatment frequency per farm between HYP 14/2 and HYP 17/2. This development, too, was the most pronounced and most consistent in the case of pigs.

Goal 2: To promote prudent and responsible antimicrobial use in the treatment of diseased animals in order to limit the risk of the emergence and spread of antimicrobial resistance

The reduced use of antimicrobials that resulted from the 16th AMG Amendment has had positive effects on the development of the resistance situation.

- For all six types of production, a general trend towards a larger proportion of antimicrobial-sensitive isolates was observed.
- The spectrum of active substance classes used for the six types of production remained steady from HYP 14/2 to HYP 17/2. Consequently, there was no increase in the use of the critical active substance classes. The reduction achieved in the consumed quantities of antimicrobials was mainly due both to the reduced use of "non-critical" active substance classes that were administered in large quantities (penicillins, tetracyclines and sulfonamides) and to the reduced use of the "critical" active substance classes of macrolides and polypeptide antimicrobials.
- In the case of fattening piglets, fattening pigs, fattening calves and fattening cattle, the five critical active substance classes each accounted for less than 10% of the recorded consumed quantity for each type of production. In contrast, in the case of fattening chickens and fattening turkeys, the proportion of critical active substance classes made up approximately 40% of the consumed quantities determined in each case.

Goal 3: To facilitate effective task performance by monitoring authorities, particularly on livestock farms

The instruments in the 16th AMG Amendment created by the legislature enable the authorities, in principle, to perform their tasks pertaining to enforcement set out in that Act.

- For the involved stakeholders from authorities, veterinary practice and livestock farms, implementation means a high burden.
- The availability of quantifiable, Germany-wide comparable indicators and the raising of awareness amongst all stakeholders was seen as positive by these target groups.
- A holistic improvement in animal health has been mentioned by all stakeholders as a prerequisite for potential further reductions in the use of antimicrobials. Therefore, legal areas beyond the scope of the Medicinal Products Act should also be taken into account in reflections on conceptual changes.