EUROPEAN
COMMISSION

Brussels, 10.9.2014
SWD(2014) 272 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC

{COM(2014) 556 final}
{SWD(2014) 271 final}

1. INTRODUCTION

The purpose of this impact assessment (IA) is to support the changes proposed to the Directive 90/167/EEC setting out the conditions under which medicated animal feeds may be manufactured, placed on the market and used within the EU. Medicated feed is a mixture of feed materials and a specifically authorised veterinary medicinal product (VMP). It may be supplied to the holders of animals only on presentation of a prescription from a veterinarian.

Giving VMPs to sick animals via feed is one of several options for the animal holder. Depending on the specific situation on the farm, the treatment via medicated feed can be the first best route of administering the VMP to the animal.

2. PROBLEM DESCRIPTION: BASELINE AND PROBLEMS

The Directive dates back to 1990, has never been revised and, due to the diverging national implementations, the significance of medicated feed for farmed animals varies extremely between the Member States (MS).

Problem 1 (residues of VMPs in feed): In several MS with lax national requirements generous tolerance levels for the carry over of antibiotics from medicated feed into compound feed exist. If the microbes in the animal are exposed to a certain dosage of antimicrobials, a significant number of pathogens survive the treatment and their presence will stimulate the selection of resistant strains of microbes. In other MS there is no value for the carry over set which means legal uncertainty for the operators.

The consequences of the residues of the medicines are

- increased risk for the development of antimicrobial resistance (AMR) due to the generous tolerance levels of antimicrobials in feed in some MS and
- burdensome case by case evaluation in MS where no carry over limits exist combined with legal uncertainty for operators.

Problem 2 (imprecise dosage of VMP): The precise dosage of oral VMPs is crucial for an effective group treatment i.e. to ensure that each individual animal gets the correct therapeutic dose. Incorrect dosage may cause toxicity in the animal (too high dosage) or increase the risk that animals are not cured (too low dosage). Precise dosage is at risk on the one hand if the medicated feed manufacturing does not guarantee a homogeneous incorporation of the medicine into the feed e.g. in MS with lax rules or if the medicated feed intake of animals is lower than expected. Other MS have combined a rigid "zero tolerance" for VMPs in compound feed with burdensome rules for the production of medicated feed which leads to a de facto unavailability of medicated feed. As the overall quantities of VMPs administered to the animals are independent from the availability of the different routes of administration, the less precise and controllable administration routes of VMPs, e.g. top dressing of oral VMP powders, are dominant.

The consequences of the imprecise dosage are

- ineffective treatment of sick animals as they do not get the therapeutic level of the VMP (failure of therapy for under-dosed) and residues of the medicines in the animal products (over-dosed animals) both in MS where medicated feed is displaced by less precise oral powders and in those where homogeneity of medicated feed is not sufficiently ensured and

- increased AMR because of sub-therapeutic levels antimicrobials on farms in MS with a strict application of the zero tolerance due to increased use of less controllable alternatives to medicated feed.

Problem 3 (barriers to expand the production and intra EU trade of medicated feed): Each MS has created its own national system for medicated feed. This means in reality an extremely complicated but also costly situation, mainly for the concerned industries. One reason for this is that the EU-Directive contains vague provisions re manufacturing which are differently interpreted by the MS. Secondly, the EU-Directive offers several options for MS to design their national regimes such as allowing distributors for medicated feed or the anticipated production of medicated feed in advance of receiving the veterinary prescription.

Consequences of the existence of differing national schemes:

- Barriers to intra EU trade of medicated feed (walling-off), restricted competition and obstacles to the dissemination of innovations,
- high regulatory burden to the industry if they do not limit their business to the local market,
- unsatisfactory manufacturing quality in MS with lax rules and
- excessive costs for medicated feed in MS that "gold plated" their regime.

Problem 4 (impossible market access of medicated feed for pets): Generally medicated feed is used for the treatment of larger animal groups in livestock farming. However, for certain VMPs the treatment of pets via a medicated feed could be an excellent route allowing owners to provide for their pets medication in the form of prepared feed. However, several MS are unsure if the medicated feed legislation can even apply to pets as it is based on Article 43 (Common Agricultural Policy), thus considered to be applicable only for farmed animals.

The national implementations of the Directive are another driver: The requirement for a prescription to be available in advance of production (as distinct to delivery) goes against central production and distribution. Several MS do not allow anticipated manufacturing of medicated feed. Or others do not agree on distributors acting as intermediaries between manufacturer and user, insisting instead on distribution direct from the feed mill to the holder of the animal. Pet food marketing cannot comply with this requirement.

Consequences of the restrictions for medicated pet food are

- big barriers for innovative companies that want to expand their business in medicated pet food and
- the prevention of owners of pets with chronic diseases from treating them in this comfortable and efficient way.

3. NEED FOR EU ACTION - SUBSIDIARITY

The current legislation on medicated feed is a Directive that has been established before the creation of the internal market and that had never been adapted in substance. It can be considered an extreme example of subsidiarity: The national transposition of this legal instrument has given freedom to MS regarding interpretation and implementation of the legal provisions, but the flexibility does not deliver the ambition of a functioning internal market and cause public and animal health concerns. With respect to the development of the national systems, the trend over the decades shows that those problems have rather

deteriorated instead of improved even though many MS tried to tackle the problems with national action plans. Concrete harmonised measures at EU level were strongly desired according to the external study, targeted consultations and the online consultation of stakeholders and MS (88% of the respondents). Thus, there is clear evidence that an EU value added can be created in case the right legal instrument with proportionate measures is chosen.

Compared with scattered action at national level, action at EU level would produce clear benefits in the areas of economic viability, animal and public health. Therefore, the proposal aims to achieve harmonisation of the crucial parameters while simultaneously allowing the actors at the local level to choose the means to comply with them.

4. OBJECTIVES OF THE EU INITIATIVE

General policy objectives:

(1) The smooth functioning of a competitive and innovative internal market for medicated feed whilst

(2) ensuring a high level of protection of animal and public health.

Specific objectives:

- Overcome the zero-tolerance for unavoidable carry-over of VMPs
- Make medicated feed available to farmers and pet owners at a competitive price
- Curb AMR-risk from residual and sub-therapeutic administration of antimicrobials
- Improve animal health by precise dosage of oral VMPs
- Remove barriers for innovative, "novel" medicated feed.

5. POLICY OPTIONS

Option 1 - Maintain status quo - no policy change

No EU action is undertaken in the area of medicated feed. The existing Directive will keep its general character and still be subject to varying national interpretation and implementation. Specific rules will apply from one MS to another. MS will continue to have different residues levels for VMPs in compound feed.

Option 2 - Amend Directive 90/167 combined with soft law

The scope of the Directive would be clarified and also extended to cover medicated feed for pets. This option does not foresee any changes to the current Directive in terms of technical provisions. Guidelines for the national authorities and the operators are elaborated for the areas where problems were identified, such as control mechanisms, manufacturing standards or residues of VMPs in feed.

Option 3 - New EU Regulation with detailed rules

In this option the clarifications concerning the scope in option 2 are undertaken but in the legally directly binding form of a Regulation. Distributors will be allowed in the whole EU to intermediate between the manufacturers and the users of medicated feed which is critically important for medicated pet food. Precise EU criteria for medicated feed in terms of mixing technology and homogeneity will be established in the Regulation. Anticipated medicated feed production, mobile and on farm mixing will be authorised in

the EU, while simultaneously tightening the standards for these schemes. The issuance of precise veterinary prescriptions and their strict adherence by both the manufacturers and users of medicated feed has to be severely policed by the authorities of the MS.

EU wide tolerance levels will be set for the carry-over of VMPs in feed, based on an assessment of the risk for the animals and the humans with regard to the different types of active substances.

The competent authorities in the MS would be released the task of trying to interpret the general Directive and could focus their efforts to ensure that medicated feed is only delivered upon prescription, homogeneity criteria and carry-over limits are met by all manufacturers and misuse of medicated feed is avoided.

6. IMPACT ASSESSMENT OF THE POLICY OPTIONS AND COMPARISON

The policy options were tested against the objectives of the review of the legislation and evaluated for their impacts on economics, health and others:

In option 1, national implementation of the general EU-rules still leads to tremendously different economic and safety related parameters in manufacturing and use of medicated feed. The trend that fewer animals are treated via medicated feed will continue even if medicated feed would be the first best route of treatment. For innovative, new applications of medicated feed the marketing environment remains very scattered and exclusive. Manufacturers that want to expand outside their "home" MS have to cope with a different national scheme for medicated feed creates considerable compliance costs. Manufacturers who want to expand in medicated pet food would be blocked and many pet owners with chronically diseased pets would be deprived from this comfortable and efficient way of treatment. In MS with very demanding manufacturing standards for medicated feed, the farmers apply instead of medicated feed less controllable routes of medication. This has negative impacts with respect to correct dosage (=> efficient treatment) and to the problem of sub-therapeutic use of antimicrobials in non-medicated feed or water. The risk for AMR development would remain in MS with generous tolerance levels the residues of antimicrobials in feed.

In option 2, the economic parameters for the manufacturers of medicated feed still differ significantly because of the dominant role of the national regimes on the costs of medicated feed thus no significant change to the baseline can be expected. The explicit inclusion of pets into the scope opens a window of opportunities for medicated pet food. The potentially additional gross margin from medicated pet food could be in the order of € 6 mio in the short term. Also the industries administrative and compliance costs might be slightly smaller because they could rely more on the, then revised, EU guide for good manufacturing practice.

In one scenario of option 3, the additional costs due to the implicit upgrade of the manufacturing standards for 50% of the current production would be € 19 mio. For 25% of the current production no change would result from the new EU standard. The remaining 25% could realise cost reductions of app € 31 mio because the producers can (1) choose the most cost efficient production technology considering the regional situation and (2) profit from economies of scale because the demand for medicated feed will increase. For the EU as a whole, the manufacturing costs could be reduced by € 12 mio. A second scenario has been calculated as a sensitivity analysis (65% of the medicated feed production would be faced with cost increases - only 10% with reductions): The cost increase in the first group would exceed the savings in the second by € 12 mio.

With the new, harmonised EU standard for medicated feed production, the full potential for innovation could be activated which means only in the area of medicated pet food an additional gross margin in the order of € 15 mio in the short term and considerably more beyond. The setting of product criteria at EU-level implies very limited administrative costs for the national authorities and the Commission. In a longer term, the enforcement of the criteria will reduce the burden for the authorities: on the one hand, the control of the concrete criteria is simpler than the interpretation of general principles. On the other hand, the MS can save resources formerly used for the establishment of the national standards, if applicable. The compliance costs for the industry are significantly reduced because they are no longer obliged to follow the different national rules.

Animal health is significantly improved because medicated feed, produced at optimised standards, can be used as 'first best route' to administer medicines to a much higher percentage of animals. With respect to antimicrobials, fewer animals are exposed to sub-therapeutic levels in those countries where the homogeneity requirements for medicated feed are currently poor. This positive impact can be also expected in those regions where, due to preventive requirements for medicated feed manufacturing, the less precise routes of administration are currently dominant. Furthermore, public health will be significantly improved because the carry-over limits are set, EU-wide, at levels that marginalise the risk for the development of AMR both in the MS with generous tolerance levels or those with an unclear situation on this issue.

The Regulatory competence of the individual MS is reduced. Option 3 has a slightly positive impact on occupational health as fewer users are in direct contact with the VMP. Also on animal welfare a positive effect can be expected because fewer animals have to suffer from under-dosage and more animals (pets) are treated with their "normal" feed thus in a more comfortable manner.

7. CONCLUSIONS

In the light of the assessment above, it is considered that option 3 would have the most positive impacts and provides the best way forward to achieve the objectives for the EU as a whole. It should have a significant positive impact on cost efficiency and economic growth of the medicated feed manufacturing, also considering innovative applications of VMPs. Trade-offs in upstream and downstream activities are very limited. Animal and public health can be expected to be improved both in MS with currently lax standards for medicated feed and those with prohibitive standards. Safe maximum residue levels for the carry-over of VMPs in feed leads to a pragmatic and solid level playing field for the industry and the control authorities.

The monitoring of the manufacturing and use of medicated feed would be eased because of the EU-wide establishment of product criteria. These could be also the base for the evaluation to which extent the objectives of the legislation have been met. In case these are deemed not to be sufficient, additional indicators such as price difference between medicated feed and compound feed or share of VMPs sold as premixes could be sourced from representatives of the industry. Thus, sufficient data for the evaluation should be available to examine whether or not the policies implemented achieve the objectives with respect to the internal market for medicated feed, the competitiveness of medicated feed production, animal and public health.