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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on veterinary medicinal products

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1. PROBLEM DEFINITION

Directive 2001/82/EC and Regulation (EC) No 726/2004 provide the legal environment on the manufacture, authorisation, marketing, distribution and use of veterinary medicines. Over the years, this regulatory framework has been amended in response to scientific advances and the needs of the veterinary sector. However, stakeholders and Member States have expressed concerns that the current legislation is no longer fit for purpose and have reported an overall lack of authorised veterinary medicines for minor species (such as bees), for rare or emerging diseases and for some diseases in major species. This lack of veterinary medicines poses significant animal health and welfare problems, increased risks for human health, and economic and competitive disadvantage for EU farming.

Veterinary medicine is private medicine and therefore product development by the industry y is driven by successful returns to investments. The veterinary pharmaceutical market is a multi-species and a pluri-national market. Furthermore, the requirements and procedures for obtaining a marketing authorisation to a veterinary medicine and for keeping it on the market are complex and generate administrative burdens to the pharmaceutical industry (estimated to be of 13% of the total turnover of the sector). These factors, and a legislation which is not suited to innovation, interfere with returns to investments and are at the root-problem of the lack of available authorised veterinary medicines.

2. NEED FOR EU ACTION AND SUBSIDIARITY

Legislation in the area of internal market (Art 114 of the Treaty on the Functioning of the European Union - TFEU) and regarding standards of quality and safety for medicinal products (Art 168(4) (b) TFEU) is a shared competence between Union and Member States. Directive 2001/82/EC and Regulation (EC) No 726/2004 are based on Articles 95 and 152 (4)(b) of the Treaty establishing the European Community respectively. Incorrect transposition of the provisions of the Directive has led to different levels of public and animal health protection and created obstacles to the functioning of the internal market. Action at the EU level to draw up a harmonised and proportionate regulatory framework on veterinary medicines would create an improved, modern legal environment, thus improving the veterinary sector in general.

3. OBJECTIVES OF THE EU INITIATIVE

The objective is to improve the functioning of the internal market whilst maintaining the level of animal, public health and environmental protection and improving the availability of medicines across the Union. This would require improving the regulatory environment to:

1) simplify the regulatory environment and reduce administrative burden;
2) stimulate the development of new veterinary medicines;
3) facilitate the circulation of veterinary medicines across the EU.

4. POLICY OPTIONS

Policy options were grouped by specific objectives. “No new EU action” (options 1, 6, 12, 15, 21, 23, 27) was taken as the baseline scenario against which the other options were evaluated in this report.

Policy options to expand the market beyond the top four animal species

Option 2 - Improve the Cascade – to modify the Cascade to allow veterinary surgeons to choose the best available treatment to animals under their care.

Option 3 – Expand the database to cover all veterinary medicines – to create a single, comprehensive EU database.

Option 4 – Reduced data requirements for medicines for limited markets - to facilitate the authorisation of some types of veterinary medicines.

Option 5 – Reduced data requirements for medicines for bees.

Policy options to simplify procedures for obtaining a marketing authorisation in multiple national markets

Option 7 - Automatic recognition of a national marketing authorisation.

Option 8 - Single marketing authorisation procedure for all products – to ensure that following the assessment of an application a single decision would be adopted by the Commission or an authorisation issued by all Member States.

Option 9 – Wider scope for the centralised procedure – to extend the scope of the procedure to make it available, to all types of products.

Option 10 – Simpler packaging and labelling – to allow the use of standard pictograms and abbreviations.

Option 11 – Already nationally approved veterinary medicines allowed to freely circulate across the Union - to "roll out" across the EU of "legacy" veterinary medicines which already have a marketing authorisation in one Member State.

Policy options to review data requirements in marketing authorisation procedures

Option 13 – Generic applications may refer to environmental data.

Option 14 – Harmonisation of clinical trials procedures across the EU.

Policy options to simplify post authorisation requirements)

Option 16 – Risk-based pharmacovigilance

Option 17 – Review procedures to change a marketing authorisation (variations) – to further simplify variations to a marketing authorisation.

Option 18 – Delete the obligation to market a product within 3 years of approval.

Option 19 – Delete the automatic requirement for renewals.

Option 20 – Exempt homeopathic veterinary medicines from pharmacovigilance requirements.

Policy options for breakthrough medicines

Option 22 - Extend the data protection period for new veterinary medicines: to extend the overall data protection period to a maximum of be twenty years and create particular provisions for certain medicines.

Policy options to clarify rules on internet retailing, on the authorisation of new treatments, on inspections and on authorisation of medicines for emerging diseases

Option 24 – Authorisation to sell veterinary medicines through the internet in all Member States.

Option 25 – Establish a framework to authorise new treatments.

Option 26 – Establish a basis to harmonise the controls on the veterinary medicine distribution chain.
Option 4 – Reduced data requirements for veterinary medicines for limited markets.

Additional policy options to strengthen the veterinary medicines legislation regarding the authorisation and use of veterinary antimicrobials in veterinary medicine
Option 28 - Introduction of legislative measures to allow restrictions to be placed on the authorisation and use of veterinary antimicrobials
Option 29 - Measures regarding advertising of veterinary medicines, including antimicrobials
Option 30 - Measures regarding retailing of veterinary antimicrobials - Veterinary surgeons would not be allowed to supply antimicrobials for animals.
Option 31 - Introduction of a legal basis for the compulsory collection of data on the use of antimicrobials

5. ASSESSMENT OF POLICY OPTIONS AND COMPARISON OF OPTIONS

Main costs and benefits of the policy options

The baseline used was "no new EU action" (no changes to the current provisions)

Costs and benefits of options to expand market beyond the top four animal species
Option 2 - Improve the Cascade – benefits to animal health and welfare; food safety, public health and the protection of the environment will still remain assured.
Option 3 – Expand the database to cover all veterinary medicines – more transparency to the sector and benefits to animal and public health
Option 4 – Reduced data requirements for medicines for limited markets – more medicines for minor species and minor uses, and for use in an emergency.
Option 5 – Reduced data requirements for medicines for bees – more medicines for bees

Costs and benefits of options to simplify the authorisation procedures
Option 7 -Automatic recognition of a national marketing authorisation – reduced administrative burdens on companies (estimated savings of 67.9 million euros per year); benefits to the free movement of veterinary medicines in the Union. Differences in resources, expertise, policy context and geographical animal health might affect the focus of the dossier assessment rendering the opinion of a specific competent authority not acceptable to other countries.
Option 8 - Single marketing authorisation procedure for all products – reduced administrative burden to the industry by ca 67.9 million euros per year. Regulators concerned that the lack of a peer review stage might affect the quality of individual marketing authorisation assessments.
Option 9 – Wider scope for the centralised procedure – more flexibility and choice; savings in administrative burdens to the pharmaceutical industry of 5.6 million euros per year.
Option 10 – Simpler packaging and labelling – reduced administrative burden to the pharmaceutical industry.
Option 11 – Allow already nationally approved veterinary medicines to freely circulate across the Union – reduced administrative burdens to the industry by ca14.2 million euros per year.

Costs and benefits of options to review data requirements for marketing authorisation procedures

Option 13 – Generic applications may refer to environmental data – reduced administrative burden to the industry, leading to an increase in the number of generics, increasing competition and thus driving down the prices to end-users. No negative impact on the environment expected.

Option 14 – Harmonisation of clinical trials procedures across EU – reduced administrative burdens to the pharmaceutical industry and benefits to SMEs

Costs and benefits of options to simplify post authorisation requirements

Option 16 – Risk-based pharmacovigilance – reduced administrative burdens to the industry worth 47.2 million euros per year.

Option 17 – Review of procedures to change a marketing authorisation (variations) – reduced administrative burdens to the pharmaceutical industry by 10.9 million euros per year, reduced costs and resources to the competent authorities.

Option 18 – Delete the obligation to market a product within 3 years of approval –benefits in particular to SMEs; improved availability of medicines.

Option 19 – Delete requirements for renewals –reduced administrative burdens to the pharmaceutical industry of ca 67.5 million euros per year; efficiency measure to the competent authorities.

Option 20 – Exempt homeopathic veterinary medicines from pharmacovigilance requirements simplifies the requirements for homeopathic medicines; potential increased risk to animal health.

Costs and benefits of options to review incentives for breakthrough medicines

Option 22 - Extend the data protection period for new veterinary medicines –benefits to innovation and better availability of veterinary medicines.

Costs and benefits of options to clarify rules on internet retailing, on authorisation of new treatments, inspections, authorisation of medicines for emerging diseases

Option 24 – Authorisation to sell veterinary medicines through the internet in all Member States – better operation of the internal market; more business opportunities; increased competition and thus greater accessibility of veterinary medicines. Benefits animal and human health. Some increased costs to the national authorities to introduce procedures to regulate the sector.

Option 25 – Establish a framework to authorise new treatments – harmonisation on the area and improved animal health across the Union; improved internal market.

Option 26 – Establish a basis to harmonise the controls on the veterinary medicine distribution chain – an improved level playing field across the Union regarding control activities. Some increased costs to national authorities to improve their inspections programmes.

Costs and benefits of additional options to strengthen the veterinary legislation regarding authorisation and use of antimicrobials in veterinary medicines

Option 28 - Introduction of legislative measures to allow restrictions to be placed on the authorisation and use of veterinary antimicrobials – Benefits to human health. Some savings to the pharmaceutical industry and the national competent authorities due to reduced referrals.

Some loss of income regarding the sales of some types of antimicrobials. Some negative impact on the availability of medicines.
Option 29 - Measures regarding advertising of veterinary medicines including antimicrobials less pressure from farmers and pet owners on veterinary surgeons for the prescription of certain types of "convenient" antimicrobials so benefits to public health. Less information on veterinary medicines being transmitted to end users.
Option 30 - Measures regarding retailing of veterinary antimicrobials – Significant negative economic impact on veterinary practices; unclear if there is any significant positive effect on public health.
Option 31 - Introduction of a legal basis for the compulsory collection of data on the use of antimicrobials – some increased costs to the national authorities. Benefits to animal and public health.

Preferred choice of options:

The preferred options were compiled in a single package, designed to improve the availability of veterinary medicines without sacrificing standards to public and animal health and safety to the environment. This package would deliver a total reduction of administrative burdens to the industry of at least 145.4 million euros per year:
The preferred option regarding the authorisation of veterinary medicines extends the scope of the centralised procedure (option 9), making it optional, whilst still maintaining the possibility of national authorisations. It introduces flexibility to the system whilst still allowing the pharmaceutical industry to benefit more from the centralised procedure. The measures to simplify the packaging and labelling of veterinary medicines (option 10), renewals (option 19), variations procedures (option 17) and pharmacovigilance (option 16) should significantly reduce the administrative burdens to the industry and therefore free resources for the development of innovative medicines. The preferred package also introduces measures to extend the period of data protection for new developments including medicines for bees (options 22 and 5), which should improve the availability veterinary medicines.
The removal of an inconsistency within the legislation to allow the protection period for safety data to cover environmental data (option 13) could bring benefits to animal and public health by encouraging applications for generics and so improve price-competitiveness. It will also be possible for companies to join efforts to generate data on particular substances (option 11), to cover any deficiencies regarding information on safety to the environment that might be detected.
The "rolling out" of "legacy products" already authorised in the EU (option 11) could reduce administrative burdens in the long term and increase the range of veterinary medicines available across the Union. This could also reduce the price of medicines through improved competition. In addition, the introduction of a legislative basis for the regulation of internet retailing (option 24) could stimulate business growth, improve competition and accessibility of medicines to end-users.
The options to regulate the authorisation of new treatments (option 25), improve the Cascade (option 2), reduce data requirement for medicines for limited markets (option 4), and improve the database for products authorised in the Union (option 3) would benefit animal health.
An improved harmonisation of controls carried out on the distribution of veterinary medicines (option 26) would further benefit animal and public health.
The Union rules apply to all veterinary medicines, and any safety risks to the animals, users, consumers and the environment are the same irrespective of the size of the business.

Therefore no exemptions could be specifically created for SMEs. However, their concerns were taken on board and it is proposed to harmonise the authorisation procedures for clinical trials across the Union (option 14), to remove of the Sunset clause (option 18) and to introduce measures to assist SMEs at national level (option 9).
The package of preferred options tackles the issue of antimicrobial resistance and introduces provisions to minimise risks to public health arising from the authorisation and use of antimicrobials (option 28), to harmonise the collection of data (option 31), to incentivise the development of antimicrobials specific for veterinary medicine (option 22), and to clarify the rules regarding advertising of prescription medicines, including antimicrobials (option 29). These measures take on board the need to promote the continued availability of effective antimicrobials for use in veterinary medicine whilst at the same time support their responsible use, to contribute to the management of antimicrobial resistance in humans.

Regarding the choice of legal instrument, the analysis of the problems identified with the current legislation, the objectives of the proposal, and in light of the Articles 114 and 168 (b) TFEU, led to the conclusion that the proposal should take the form of a Regulation. This sets out clear and detailed rules which will become applicable in a uniform manner across the Union. The choice of a Regulation still allows Member States to retain their competence for granting of marketing authorisations, enforcement, authorisation of clinical trials, pharmacovigilance monitoring, and authorisation of wholesalers and retailers of veterinary medicines.

6. CONCLUSIONS, MONITORING AND EVALUATION

The key indicators to assess whether or not the review has achieved its objectives will be, for example, the volume of novel veterinary medicines authorised, applications submitted by SMEs, variations submitted, infringements, internet retailers authorised across the Union. These data will be evaluated 10 years after the implementation of the legislation.