EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title **DG SANCO – Impact Assessment on the revision of the framework on veterinary medicinal products**

(draft version of 26 November 2012)*

(A) Context

Directive 2001/82/EC and Regulation (EC) No 726/2004 provide the legal environment on authorisation, production, marketing, distribution and use of veterinary medicines. It is complex legislation that aims to ensure the quality, safety and efficacy of veterinary medicines and so safeguard public health, whilst at the same time ensuring the functioning of the single market for veterinary medicines. In response to the concerns raised by stakeholders, the Commission committed to conduct an assessment of the problems in the application of the veterinary medicinal products Directive, contributing to the lack of availability of veterinary medicines. In addition, there is also a wide-spread concern that antimicrobial resistance arising from the incorrect or excessive use of antibiotics in farmed animals affects human health. This impact assessment therefore examines how to make the existing legislation more effective and efficient and how to manage the risk of antimicrobial resistance.

(B) Overall assessment

The report requires significant further work on several important aspects. Firstly, it should further analyse the scope, scale and drivers behind the partial lack of availability of veterinary medicines, particularly in smaller markets and for minor species across the EU. For example, the report should clearly identify which elements of the current regulatory system are considered excessive in terms of health or environmental protection and substantiate these with evidence or via a comparison with other sectors/third countries. The problems related to antimicrobial resistance need to be better demonstrated before any action can be envisaged. Secondly, the report should assess how the lack of availability of medicines would develop in the absence of EU action and better justify the need for further harmonisation in a number of areas, such as in-market controls, retailing of veterinary medicines and new treatments. Thirdly, it should design and present alternative packages of options that are realistic and proportionate vis-à-vis the identified problem. Fourthly, it should improve the assessment of risk, costs and benefits of the retained (packages of) options and complement stakeholders' views with robust evidence. The report should provide a comprehensive comparison of options in terms of their effectiveness, efficiency and coherence. Finally, it should provide more detailed evaluation and monitoring arrangements.

Given the nature of these recommendations, the Board asks DG SANCO to submit a revised version of the report, on which it will issue a new opinion.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Better present the main problem, explain its drivers and support it with evidence. The report should better demonstrate the scope and scale of the main problem that this initiative aims to address, i.e. the lack of availability (and affordability) of veterinary medicines. In particular, it should explain and substantiate with concrete evidence in which markets and sectors (such as medicines for pets, farm animals or minor species, originator vs generic medicines) this lack of availability is most pronounced and what the characteristics of these markets are. The report should then better present and substantiate the relative importance of the identified problem drivers, primarily related to: (i) excessive or unnecessarily burdensome requirements; (ii) insufficient incentives for the development of new medicines (namely data protection period); and (iii) barriers to cross-border trade. In doing so, it should avoid confusing problem drivers with the actual problem and provide anecdotal evidence or comparison with other sectors/third countries, such as the U.S. or Japan. Finally, the report should clarify if this initiative aims to address the concerns related to antimicrobial resistance, and if so, provide a fully developed and substantiated analysis of this problem and its drivers.

(2) Improve the baseline scenario and better demonstrate the need to act. The report should develop the baseline scenario by assessing how the availability of medicines and antimicrobial resistance would develop if the current EU regulatory framework for veterinary medicinal products was not changed. For example, it should elaborate on the envisaged use of the 'Cascade' and the related health and safety risks and on the impacts of the market concentration on the availability of medicines. On that basis, the report should justify that further harmonisation at the EU level would add value over and above what could be done at national level, namely in relation to harmonisation of controls and sanctions, retailing of medicines or novel therapies and treatments.

(3) Improve the intervention logic and option design. On the basis of a revised problem definition, the report should better explain the correspondence between problems and their drivers, objectives and policy options. It should analyse in depth only those options that are realistic and that could be defined in sufficiently concrete terms. For example, options such as abolishing the entire system and making the centralised procedure mandatory should be discarded upfront; the feasibility of options such as a single market authorisation and SME support should be clarified. Instead, more attention should be paid to identifying the key choices, particularly related to decoupling the procedures for veterinary from human medicines (and the introduction of the risk-based approach) and the envisaged level of harmonisation (e.g. sanctions, advertising provisions, new therapies, antimicrobials). Finally, the report should rationalise the large number of options by presenting them upfront in comprehensive packages and clarifying the inherent complementarities or trade-offs.

(4) Better assess and compare options. The report should further improve the assessment of risks, costs and benefits for all realistic options and complement stakeholders' views with more substantive, factual evidence. Where further evidence cannot be provided and/or the analysis remains inconclusive, this should be clearly indicated. In particular, a conclusive, evidence based assessment of options needs to be provided where regulators raised concerns in terms of risks to public and animal health. The report should assess specific impacts on pets, farm animals and minor species, originator vs generic products and on the Member States that would be the most affected (positively as well as negatively) by the proposed options. All options should be systematically and transparently assessed in terms of public health and environmental

impacts. Finally, the report should present a comprehensive and substantiated comparison of options in terms of their effectiveness, efficiency and coherence against the developed baseline scenario. It should present the overall impact of the envisaged initiative, including total implementation costs to be borne by national authorities, the EU and the European Medicines Agency.

(5) Improve monitoring and evaluation arrangements. The report should provide more detailed evaluation arrangements based on well-defined monitoring indicators. To do so, it should define objectives in SMARTer terms and link them to the identified progress indicators. The report should also provide more information on the data collection strategy (e.g. data availability, source, collection costs).

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

An effort needs to be made to turn the report into a self-standing document, while keeping the length of the report at an accessible level. In particular, the essential elements of policy options should be described in the main text and details provided in an annex. The report should avoid early references to the legislative instrument likely to be proposed which should instead be the conclusive outcome of the intervention logic. The executive summary should be sufficiently informative on all the key elements of the report, particularly the assessment and comparison of policy options. Finally, the report should clearly present the views of all relevant stakeholder groups, including consumer organisations.

(E) IAB scrutiny process	
Reference number	2012/SANCO/002
External expertise used	No
Date of IAB meeting	18 December 2012