EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

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

(resubmitted draft version of 23 July 2013)*

(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. This legislation 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: POSITIVE

While the report has been revised to some extent along the lines of the Board's recommendations, it should be further improved in a number of respects. In particular, it should better justify the need for harmonisation of issues such as national controls on the veterinary medicine distribution chain or internet retailing. As regards antimicrobial resistance, the report should better explain how the current regulatory set up prevents national authorities from prohibiting or restricting the use of antimicrobials and provide more details on divergent "decisions" of Member States in this context. On this basis, it should present the options in more concrete terms, for instance by explaining how the envisaged risk-based approach would work in practice or what exactly the introduction of more flexibility on the use of the Cascade means. The report should then make a greater effort to indicate the extent to which the preferred set of options can realistically improve the availability of veterinary medicines across species and Member States, namely by better indicating the relative importance of measures introducing additional costs on industry and/or decreasing the availability of antimicrobials. To substantiate the conclusion that the standards of public and animal health protection would be overall maintained, the report should better explain how the related concerns of stakeholders and national authorities in particular have been addressed.

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

(C) Main recommendations for improvements

(1) Strengthen the problem definition. While having provided a number of useful examples, the report should still clarify to what extent the variation in the number of authorisations across Member States can be used as an indicator of the availability of medicines (given, among others, the uneven geographical distribution of diseases). The analysis of the problem drivers should be further streamlined by merging the description of market characteristics with the corresponding regulatory failures, i.e. merging multi-species market (2.3.1) with legislation not suited to innovation (2.3.5), and pluri-national market (2.3.2) with complex marketing authorisation requirements and procedures (2.3.3). This should also include a better explanation on the problems related to the current use of the Cascade. In order to better demonstrate the extent to which some of the regulatory requirements may be considered as unnecessary (namely in relation to the risks involved), the report should more systematically complement the views of industry with the views of national authorities, as is for example the case for the PSUR (currently judged excessive by "both the industry and some regulators").

(2) Better demonstrate the need for harmonisation at the EU level. The report should revisit presenting the problems on internet retailing, new treatments and clinical trials as a lack of legal "clarity", since these issues may well be clearly regulated at national level. More convincing argumentation and concrete evidence should therefore be provided to demonstrate that these issues need to be harmonised at EU level. For example, it does not seem obvious that the non-harmonised controls by Member States are currently "detrimental" to the operation of the internal market. The report should also better explain what the potential for cross-border internet sales of veterinary medicines is, given national language and authorisation requirements. As regards antimicrobial resistance, it should: (i) better explain how the current rules prevent authorities from prohibiting or restricting the use of antimicrobials; (ii) provide more details on the "disharmonised decisions" (and views) of Member States in this context; and (iii) clarify if the concern that veterinary surgeons can be "pressurised" to prescribe unnecessary antimicrobials is only a hypothetical one. Against this background, the report should identify a set of specific and operational objectives for antimicrobial resistance, including the corresponding risks to public and animal health (this should be done also for the problem of the lack of availability of veterinary medicines).

(3) Further improve the presentation and description of the options. While having discarded a number of unrealistic options, the wide range of remaining options could be further reduced by focusing on the key choices. For example, database-related issues (i.e. options 4 and 31) or the removal of an inconsistency in the legislation (i.e. option 13) could be referred to as flanking measures and analysed only in an annex. Nonetheless, the report should still explain why, for the large majority of problem issues, no feasible alternatives have been considered. It should then provide a more detailed description of policy options, including their implementation and enforcement arrangements. For instance, the report should clarify: (i) what exactly the introduction of more flexibility on the use of the Cascade means (option 2); (ii) on what basis some data requirements for certain products could be reduced and how the corresponding risks would be managed (option 4); (iii) in which aspects would the national control systems as well as new treatments and clinical trials be concretely harmonised; (iv) how is the risk-based approach envisaged to work in practice (e.g. how would the higher safety risk of "legacy" medicines be defined); (v) how would the legal obligation to implement supportive SME measures be enforced; or (vi) on what basis would competent authorities decide as to whether a class of antimicrobials should be authorised and its use restricted. Finally, the

report should better explain the need to address specifically medicines for bees and homeopathic medicines.

(4) Better present the overall impacts. Given the wide range of impacts generated by measures aiming at the same time to simplify, modernise and harmonise the current legal framework and given the level of analysis which is mainly qualitative, the report should make further effort to better indicate the extent to which the preferred set of options can be realistically expected to improve the availability of veterinary medicines across species (i.e. farmed animals, pets, minor species) and/or Member States. In doing so, it should: (i) provide the order of magnitude of the currently non-quantified additional costs (related to, for example, packaging/labelling or variations); (ii) better explain the importance of measures that are likely to decrease the availability of medicines (namely antimicrobials); and (iii) indicate which operators (e.g. originators, generics producers, SMEs) and national authorities (to the extent possible), are going to benefit most. An indication of the total implementation costs for the EU budget and the European Medicines Agency (EMA) should also be provided, including a better explanation of the possibility to minimise some of these costs and/or to cover them by fees (e.g. as envisaged for fast-tracking by EMA some of the marketing authorisation applications of industry). With a view to corroborating the conclusion that the standards of public and animal health protection would be overall maintained, the report should better explain how the related concerns of national authorities have been addressed (including on the relaxation of labelling requirements). Finally, the report should better link the assessment of the options' effectiveness to the corresponding (specific) policy objectives and the assessment of efficiency to the implementation and enforcement costs.

(D) Procedure and presentation

The report should make a further effort to clearly present the views of all relevant stakeholder groups, including farmers and consumer organisations. The report should clarify against which benchmark the progress on the suggested monitoring indicators would be measured and should link them more closely to the revised specific objectives. Finally, it should ensure that the numbering of options in the main text and the annexes is aligned.

(E) IAB scrutiny process	
Reference number	2012/SANCO/002
External expertise used	No
Date of IAB meeting	Written procedure An earlier version of this report was submitted to the IAB in November 2012, for which the Board issued its opinion on 21 December 2012