Briefing

Initial Appraisal of a European Commission Impact Assessment

European Parliament

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Veterinary medicinal products

Impact Assessment (SWD (2014) 273, SWD (2014) 274 (summary)) of a Commission proposal for a Directive of the European Parliament and of the Council on veterinary medicinal products (COM (2014) 558).

Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's Impact Assessment (IA) accompanying the above proposal, submitted on 10 September 2014 and referred to the European Parliament's Committee on Environment, Public Health and Food Safety.

Veterinary medicines are regulated from manufacture to sale and use in order to monitor their quality and safety, whilst safeguarding animal and public health and ensuring the functioning of the internal market. The legal framework for this is provided by Directive 2001/82/EC on the Community code relating to veterinary medicinal products[1] and Regulation (EC) 726/2004[2] laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. A proposal to amend the latter Regulation in the light of the proposal on veterinary medicinal products is also currently going through Parliament.

The proposal on veterinary medicines, together with the parallel proposal on medicated feed, is part of an overarching goal of the Commission to address the problem of rising threats from antimicrobial resistance in the EU. Both the European Parliament, in its Resolutions of 27 October 2011 and 11 December 2012 on public health and microbial challenges, and the Council in 2012, have called for a European response to this issue.

The underlying idea behind the proposal is to tackle the lack of availability of authorised veterinary medicines in the EU, the use of veterinary medicinal products in species for which they are not authorised, and disproportionate regulatory burden hampering innovation. The veterinary pharmaceutical industry makes an estimated 4.6 billion euros in sales across Europe, with around 14 600 people directly employed in the veterinary medicinal products sector. It is made up of businesses involved in research and development of new veterinary medicines, manufacturers of veterinary medicinal medicines (including generics), importers, wholesalers and retailers (IA, p. 8). There are approximately 200 000 veterinary surgeons in Europe, and an estimated 60 000 pet specialist stores. The estimated annual value of pet related services, including those offered by breeders, groomers, dog trainers, and veterinary surgeons and related to sales of pet accessories, insurance, medication and vaccination is around 10.5 billion euros (IA, p. 66). The consensus of the pharmaceutical industry is that there are strong growth opportunities for

[1] Directive 2001/82/EC.
[2] Regulation (EC) 726/2004.

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development of veterinary medicines for food-producing species outside Europe as the growth is driven by global demands for milk, meat and eggs (IA, p. 67).

Problem definition

The main problem identified by the IA as needing to be addressed is the lack of availability of veterinary medicines. Member States and stakeholders have reported a lack of authorised medicines for rare or emerging diseases in minor species, such as bees, some fish species and turkeys, and for some diseases in major species (IA, p. 8). The reasons behind this are varied but it is in part due to the complex requirements for obtaining a marketing authorisation for a new veterinary medicine which involve large and costly administrative burdens for the pharmaceutical industry (IA, p. 10). According to the IA, the lack of access to such medicines is a cause for concern as there are increased risks to human health, animal health and welfare, and an economic disadvantage for EU farming (IA, p. 8).

The problem drivers are identified as:

i. a multi species market;
ii. costs of a pluri-national market;
iii. complex authorisation requirements[3];
iv. complex requirements for keeping a product on the market;
v. legislation not suited to innovation and a lack of clarity in the current framework.

Other issues related to veterinary medicinal products legislation include authorisation questions, internet retailing and antimicrobial resistance, which are explained in Annex VI. Even though the problem of antimicrobial resistance is not directly linked to the availability of veterinary medicines, the IA explains that the Commission has adopted an action plan which 'includes actions related to the authorisation and use of veterinary medicines' and that 'therefore, it is proposed to address the issue of antimicrobial resistance in the context of the regulatory framework for veterinary medicines, focusing on the authorisation and use of antimicrobials in this area' (IA, p. 20). It does not, however, explain in what way such measures will contribute to solving the broader problem of antimicrobial resistance.

Objectives of the legislative proposal

The general objective of the Commission proposal 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'[4]. In order to improve the regulatory environment in this area, the Commission identifies the following specific objectives:

1. Simplify and reduce administrative burdens whilst maintaining safeguards to ensure public and animal health, as well as safety to environment.
2. Foster the development of new medicines, including for minor species and minor use.
3. Facilitate the circulation of veterinary medicines across the EU, including new forms of retail, such as the internet. (IA, p. 19-20)

[3] There are currently four different routes of application: the centralised procedure (CP), the decentralised procedure (DCP), the mutual recognition procedure (MRP) and national procedures. (Annex VI, p. 84).
[4] Executive Summary, p. 2

A certain confusion is created in the IA by the way in which the specific objectives are then further described as being to:

i. expand the market beyond the top four animal species;
ii. simplify procedures for obtaining a marketing authorisation in multiple national markets;
iii. review data requirements in marketing authorisation procedures;
iv. simplify post authorisation requirements;
v. review incentives for breakthrough medicines;
vi. improve clarity in the legislation (e.g., internet retailing, inspections, authorisations of new treatments and medicines for emerging diseases) (IA, p. 20).

The specific objectives are broken down into a clear structure of operational objectives, although many of these could perhaps be better described as specific actions.

The IA includes a helpful framework, which links the problem drivers to the specific objectives, and these to operational objectives. The stated objectives match the problem definition.

Range of options considered

The IA presents an unusually high number of policy options - 31 in all - which are grouped according to the sub categories of specific objectives listed above. Annex X of the IA provides a description of other options discarded at the outset (p. 155).

Options 1, 6, 12, 15, 21, 23, 27: Baseline scenario. According to the IA, this would mean that public and animal health would stay at risk, with continued lack of availability of authorised veterinary medicines (IA, p. 21).
Options 2 to 5: Policy options to expand the market beyond the top four animal species.
Options 7 to 11: Policy options to simplify procedures for obtaining a marketing authorisation in multiple national markets.
Options 13 and 14: Policy options to review data requirements in marketing authorisation procedures.
Options 16 to 20: Policy options to simplify post authorisation requirements.
Option 22: Policy option for breakthrough medicines.
Options 24 to 26 and Option 4: Policy options to clarify rules on internet retailing, on the authorisation of new treatments, on inspections and on authorisation of medicines for emerging diseases.
Options 28 to 31: Additional policy options to strengthen veterinary medicines legislation with regard to the authorisation and use of antimicrobials.

It is not clear how the groups of options are combined together; for example, internet retailing of veterinary medicinal products (Option 24) is part of one group, while retailing of veterinary antimicrobials by veterinarians (Option 30) is analysed in another.

The *preferred choice* of options is compiled into a single package which the IA claims is designed to best address the problem of availability of medicines whilst still maintaining standards of public and animal health and environmental safety. Almost *all* of the policy options, with the exception of the baseline scenario ones, as well as options 7, 8, 20 and 30, actually constitute part of the preferred choice. This would seem to suggest that not all of them, at least, were conceived as genuinely distinct and alternative possible courses of action.

Options *not included* in the preferred package, other than the baseline options, are:
Option 7: allow for a marketing authorisation issued by one Member State to be made automatically valid throughout the Union. (The IA explains that this could lead to reduction in the quality of assessment standards and an increased number of referrals to the Committee for Medicinal Products for Veterinary Use (CVMP) (IA, p. 32));
Option 8: allow for a single dossier for an authorisation to be submitted to the assessment team for scientific contents;
Option 20: exempt homeopathic veterinary medicines from pharmacovigilance requirements;
Option 30: allow veterinary surgeons to prescribe antimicrobials to the animals under his/her care, but introduce a prohibition on the supply of these medicines.

Scope of the Impact Assessment

The IA presents what it considers to be the costs and benefits of each of the proposed groups of options. This is based solely on the information given by the stakeholders during the consultation exercises, and almost entirely in economic terms. The presentation is very general, and there is little quantitative analysis. Where figures are provided, the focus is mainly on potential savings for the pharmaceutical industry, without looking further at how those might be passed on to the end-users. For example, industry complains that high packaging and labelling expenses, especially for translation, currently make it difficult to make veterinary medicinal products available in smaller Member States. However, the IA does not consider the potential savings which a reduction in such costs might mean for end-users, such as farmers and pet owners, or to what extent it might lead to improved competitiveness for farmers. A considerable part of the IA is devoted to the discussion of costs, such as packaging and labelling, but innovation costs are not really explored.

Most of the qualitative analysis is very limited in nature, only claiming generally to reduce administrative burden or to be beneficial for the industry, with such assumptions not being fully explained in the IA.

Quantified data is provided mostly in relation to savings for the industry resulting from reduced administrative burden (for example, this would amount to EUR 67.9 million per year under Options 7 and 8; EUR 47.2 million per year under Option 16; EUR 10.9 million per year under Option 17 and EUR 67.5 million under Option 19). The quantified benefits provided in relation to the preferred package of options are similar to those estimated in relation to the small number of non-baseline options which are not included in the final selection. It is expected that costs would increase for the European Medicines Agency (EMA), as it may receive an increased workload due to a shift to the centralised procedure, and that these might amount to around EUR 1-1.5 million per year. The IA considers that this 'could be covered by a new structure and efficiency measures' (IA, p. 32). It does not explain, however, what those measures would be.

In the analysis of costs and benefits the IA only briefly touches upon public and animal health and welfare, as well as environmental safety, but no specific analysis dedicated to these impacts is given. Nor is there any analysis of social impacts, such as employment and job creation. Despite the IA's claim that one of the objectives of the proposal is better functioning of the internal market, this is only referred to in very general terms, if at all. In six of the options, it is actually mentioned that there will be no impact on the internal market.

Subsidiarity / proportionality

The proposal is based on Articles 114 and 168(4)(b) of the TFEU — functioning of the internal market and measures in the veterinary field directly aimed at protecting public health, which are areas of shared competence between the EU and Member States. The IA suggests that EU action is necessary because 'the existing provisions do not completely deliver the ambition of a functioning internal market and do not match the current needs of the veterinary sector' (IA, p. 19).

No Member State national parliament has issued a Reasoned Opinion raising problems with respect to subsidiarity or proportionality.

Budgetary or public finance implications

According to the Explanatory Memorandum of the proposal, the 'costs for the Medicines Agency for implementing and applying the new rules would be entirely covered by fees charged to industry. Therefore, the proposal is not expected to have any financial impact on the budget of the EU'. (Expl. Mem., p. 9)

SME test / Competitiveness

The IA provides a general description in Annex VIII of the situation of SMEs, based on the outcome of targeted consultations (p. 109). In the analysis of impacts, general attention is paid to the implications for SMEs, with several options (Options 9, 14, 16, 18, 24) explicitly providing that SMEs would also benefit from simplified rules on authorisations. In particular, the IA claims that the following actions will be beneficial for SMEs: harmonisation of clinical trials across the Union, the removal of the sunset clause[5] and the introduction of a legal obligation for national authorities to introduce supportive measures for veterinary SMEs (e.g., a help desk) (IA, p. 46).

Simplification and other regulatory implications

The proposal constitutes part of a more general initiative to reduce the risk of antimicrobial resistance, which includes revision of legislation in several areas. Annex III provides a list of legislation related to veterinary medicines (IA, pp. 63-64). The IA claims to correspond to the Commission's strategy 'in simplifying the regulatory environment and reducing administrative burdens in the Union' (IA, p. 44). Although a list of existing legislative measures is provided (pp. 63-64), there is no explicit explanation in the IA itself of exactly how this simplification strategy relates to the basic Directive 2001/82/EC. Only in the Explanatory Memorandum of the proposal itself is it explained that the centralised marketing authorisation for veterinary medicinal products is being decoupled from the medicines for humans, with the resulting amendments to the original act being presented in a separate proposal.

[5] Obligation to market a product within 3 years of approval.

Relations with third countries

No mention is made in the IA of any implications for third countries, although the proposal itself does refer to the need for minimum requirements to be applied to veterinary medicinal products manufactured in or imported from third countries (Recital 52).

Quality of data, research and analysis

In addition to the stakeholder consultations referred to below, preparation of the IA included consultations carried out by the European Policy Evaluation Consortium (EPEC) (between February and April 2011), with the aim of collecting qualitative and quantitative data (IA, p. 59). There is, however, no reference to any studies, other than an evaluation of the European Medicines Agency (EMEA), published in January 2010. How stakeholders and Member States have expressed the need for improved availability of veterinary medicines is not clear from the IA, especially given that data regarding national authorization applications was received from only one country, the UK (IA, Annex V, p. 73).

A positive aspect of the IA is that explicit attention is paid to the impacts on SMEs; however the analysis in this respect is mostly qualitative. Most of the analysis of other aspects is also qualitative and very general. Where quantitative analysis is provided, it relates mostly to savings for industry. Data is provided also about national regulators and individual Member States, but it merely serves as background information without being integrated into the analysis of the actual impacts themselves. In the context of lack of appropriate veterinary medicinal products, more attention could have been paid to the competitiveness of farmers across the EU, as end-users of such products.

The description of the problem definition is not very well structured, compared to the description of the options, which has a clear structure. Significant amounts of background information and problem descriptions are provided in the Annexes. Some of this, at least, might usefully have been included in the body of the text of the IA to improve readability and understanding (for example, one page of the IA contains references to five different Annexes (IA, p. 8)).

Finally, a clear distinction between veterinary medicinal products for farm animals, the products of which are used in human consumption, and for pets, would have been more coherent with the approach of the impact assessment on the parallel proposal on medicated feed.

Stakeholder consultation

A solid base of information has been collected in several consultations, such as the on-line survey, targeted consultations and expert meetings. A public on-line stakeholder survey was carried out between 13 April and 15 July 2010. Most replies to this were given by business organisations – 51.74 per cent (IA, p. 122).

The IA does not give a clear description of the implications for all stakeholder groups. Annex 9 provides a list of answers from the main stakeholders: industry, regulators, and end-users. It is, however, unclear which groups are represented in the end-user category: farmers, veterinarians, pet-owners or consumers. No distinction is made between the needs of farmers and pet-owners among the options proposed. It is not clear if any consumer organisations or NGOs have been consulted.

Monitoring and evaluation

The IA suggests that monitoring and evaluation will consider the extent of achievement of the stated objectives, and that the benchmark will be the current situation. An EU database on marketing authorisation will provide the legal basis for collecting data on the use of antimicrobials in all Member States. The IA provides a list of monitoring and evaluation criteria (p. 49), including an indication of who is responsible for collecting the data (Member States, EMA, etc.). The IA also mentions that the final legal instrument is to contain a review clause concerning the evaluation of the Regulation and the submission of a report to the European Parliament and the Council. However, such a clause seems to be absent from the Proposal.

Commission Impact Assessment Board

The Commission's Impact Assessment Board (IAB) delivered its first opinion on a draft version of the IA, dated 26 November 2012, indicating several serious shortcomings which needed improvement. The IAB's second opinion[6], published on 30 September 2013, required further work to be done on a number of significant aspects:

- A further strengthened problem definition.
- Better demonstration of the need for harmonisation at EU level, e.g., how national authorities are currently prevented from prohibiting or restricting the use of antimicrobials (IAB 2nd opinion, p. 1).
- Further detail on the options and their impact.
- Better presentation of the overall impacts, e.g., how 'the preferred set of options can realistically improve the availability of veterinary medicines across species and Member States' (IAB 2nd opinion, p. 1).

In addition, the IAB also asks to clearly present the views of all relevant stakeholder groups, including farmers and consumer organisations.

In response to the IAB opinion, the revised IA is claimed to include a strengthened problem definition, better illustration of the need for harmonisation at EU level (however, this is provided only in footnotes and Annex 6, but not in the main body of the IA), better explained options and standards of public and animal health, as well as better presentation of stakeholders' views (IA, pp. 7-8).

More could have been done on some points. The problem definition would have benefited from clearer illustration, especially regarding the needs of farmers and pet-owners. The options are explained, but no real choice between alternative options is offered. Regarding stakeholders' views, merely the results of the consultation are included in Annex IX, without any analysis, either in the Annex itself, or among the impacts addressed. The IAB asked for some of the information to be moved to the Annexes, but this has been done in such a way that some valuable information, for example with regard to the problem definition, is now lacking in the main body of the IA.

[6] 2nd IAB opinion July 2013

Coherence between the Commission's legislative proposal and IA

The proposal and the IA appear to correspond in that the proposal reflects the preferred options package. However, it should be noted that there are a number of provisions in the Proposal concerning delegated acts and implementing acts to which no reference is made in the IA. As mentioned earlier, there does not appear to be any review clause.

Conclusions

The defined problem is not convincingly illustrated in the IA. For example, the significance of the necessity for more veterinary medicinal products, and simplified authorisation procedures, could have been better explained from the point of view of other stakeholders, such as farmers, consumers and pet owners, and not only from that of the industry and veterinarians.

The assessments made are largely qualitative. Where figures are provided, these relate mainly to savings for industry, for which they are certainly informative, but no attempt is made to extrapolate them further. While the number of options identified is impressive, closer examination reveals that the majority of them are complementary and that there is little attempt to identify or assess alternative courses of action.

Finally, although the initiative is said to be part of the overarching goal to combat rising threats from antimicrobial resistance in the EU, the IA does not make clear how the measures envisaged – i.e. improving availability of veterinary medicinal products – will contribute to solving that broader problem.

This note, prepared by the Ex-Ante Impact Assessment Unit for the Committee on Environment, Public Health and Food Safety (ENVI) of the European Parliament, analyses whether the principal criteria laid down in the Commission's own Impact Assessment Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work.

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