

# The review of the veterinary medicines legislation: An update

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## Abstract

The review of the legislation governing veterinary medicinal products (VMPs) formally began in 2010 and now has reached an important juncture. The critical issues have been identified. A public consultation has been conducted on the issues and policy options, and the results published. The impact assessment work has been completed and an Impact Assessment Report is being drafted (to be finalised and published later in 2012), and the European Commission (EC) has already begun drafting its proposals for revised legislation for internal consultation. This is a good moment to review the outcome of these activities and take stock of where we are in the debate about how the VMP legislation should be amended and improved.

## Why the review in 2010?

First, a quick reminder about why the legislation is being reviewed now. It was last renewed and updated in 2004.<sup>1</sup> The standard clause within the legislation is for the next review to be in ten years or earlier. In this case, pressure for an early review came from both the industry and regulators after important deficiencies in the 2004 legislation came to light. In particular, industry was concerned about ineffective data protection clauses and the failure of the legislation to deliver a true single market in the EU for VMPs. The insufficient and uneven availability of VMPs across the EU is also a key driver common to all stakeholders.

However, the final trigger for the review came in 2008 following discussions between the EC and the European Parliament during the co-decision procedure for the adoption of the revised legislation governing the establishment of residue limits in foodstuffs of animal origin (Regulation (EC) No 470/2009). The outcome of these negotiations was a commitment made by the EC in January 2009 in a Communication from the Commission to the European Parliament<sup>2</sup> to review the VMP legislation in 2010 (ie, four years earlier than the default deadline).

## Milestones to the present day

Over the past four years the issues to be resolved have been well characterised, and some proposed solutions presented, in a series of milestone events and milestone documents. The process of identifying and describing the issues began in 2007 at the IFAH-Europe annual conference, and was continued biennially at IFAH-Europe's annual conferences in 2009 and 2011. In the intervening years, a public conference was organised by the presidencies of the

Heads of Medicines Agencies (HMA) (Paris, September 2008 and Madrid, May 2010).

Of equal importance are the accompanying series of milestone documents produced by the key stakeholders. IFAH-Europe published its first detailed proposals for regulatory reform in July 2008. In January 2009, the European Commission published a declaration of its commitment to review the veterinary pharmaceutical legislation in 2010.<sup>2</sup> The first key document from the regulatory authorities came from the HMA in June 2009 in the form of a draft "Reflection Paper on opportunities for improvement of the veterinary pharmaceutical legislation",<sup>3</sup> which was finalised in a letter to DG SANCO in July 2011.<sup>4</sup>

This was followed by the publication in September 2011 of a summary report on the EC's (DG SANCO) Public Consultation on Better Regulation of VMPs (April–July 2010).<sup>5</sup> Also published the same month was a report from the consultancy GHK (part of the European Policy Evaluation Consortium (EPEC)) which had been contracted by the EC to collect data for the obligatory impact assessment.<sup>6</sup> These milestones and their chronology are shown in Table 1.

This paper will now focus on the contents of these last two documents.

## Impact assessment and policy options

These days, any major legislative proposal from the EC must follow its principles of "Better Regulation"<sup>7</sup> and must be preceded by an impact assessment and a public consultation on the issues and potential solutions. Therefore, the "2010 Review" began with the appointment by DG SANCO of a consultancy, EPEC/GHK, to collect the necessary data for the impact assessment during 2010. This consultancy was required to collect data to address 12 areas where information would be needed for the impact assessment. In parallel, IFAH-Europe undertook its own impact assessment exercise in order to collect and present data to give the industry's perspective on the 12 data sets and the impact of the current legislation on the business environment in the European animal health sector.<sup>8</sup>

The first phase of the GHK impact assessment work focused on "defining the problems" through both desk research and field work; an analysis of this phase 1 data and the outcome of the DG SANCO public consultation (see below) were used by DG SANCO to elaborate a set of 49 policy options to address the eight main issues (see below). This set of policy options was released in February 2011 and can be found in chapter 3 of the GHK/EPEC report: "Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation" (see Table 2).<sup>6</sup>

The objective of the second phase of the GHK impact assessment work was to collect feedback on the potential impact of these policy options. To achieve this objective, a questionnaire on the policy options was sent to the main stakeholders, and six representative countries were selected for in-depth interviews of their local stakeholders. In addition, an industry workshop was organised by GHK/DG SANCO in March 2011 to confirm the main findings of phase 1 and to discuss the policy options. These were also discussed with the regulatory authorities during an HMAV stakeholder workshop later in March 2011.<sup>9</sup> The final GHK report, dated July 2011, was published by DG SANCO in September 2011.

**Table 1: Timeline summary of milestone activities from three main stakeholders**

Year	IFAH-Europe	HMA-veterinary	European Commission
2004	April: New Directive published in the Official Journal		
2005	November: New Directive comes into operation		
2006	<ul style="list-style-type: none"> <li>Surveys of implementation and functioning of new procedures</li> <li>Global benchmarking survey</li> </ul>		
2007	<ul style="list-style-type: none"> <li>June: Annual conference – issues and solutions first voiced</li> </ul>		
2008	<ul style="list-style-type: none"> <li>Detailed proposals released, including “1-1-1 Concept”</li> </ul>	<ul style="list-style-type: none"> <li>January: HMAv Task Force set up</li> <li>April: HMAv Task Force first meets</li> <li>September: HMAv Conference, Paris</li> </ul>	
2009	<ul style="list-style-type: none"> <li>June: Annual conference – issues and solutions discussed</li> </ul>	<ul style="list-style-type: none"> <li>June: Reflection Paper released, draft position and ideas to consider</li> </ul>	<ul style="list-style-type: none"> <li>January: Declaration – commitment to review the legislation in 2010</li> <li>June: Stakeholder information meeting</li> <li>November: GHK consultancy appointed</li> </ul>
2010		<ul style="list-style-type: none"> <li>May: HMAv conference, Madrid</li> </ul>	<ul style="list-style-type: none"> <li>January: GHK impact assessment work phase 1 begins</li> <li>April–July: EC public consultation</li> </ul>
2011	<ul style="list-style-type: none"> <li>June: Annual Conference – “The Big Debate”</li> </ul>	<ul style="list-style-type: none"> <li>March: HMAv Stakeholder workshop</li> <li>July: HMAv letter to EC, final position</li> </ul>	<ul style="list-style-type: none"> <li>January: GHK impact assessment work phase 2 begins</li> <li>February: EC Policy Options released</li> <li>March: GHK/DG SANCO workshop for industry</li> <li>July: GHK final report to DG SANCO</li> <li>September: EC publishes report on the public consultation</li> <li>September: EC publishes GHK final report</li> </ul>
2012			<ul style="list-style-type: none"> <li>Expected: EC impact assessment report and Commission to the European Parliament (COM) legislative proposals</li> </ul>
2013–2014			<ul style="list-style-type: none"> <li>Expected: Co-decision procedure</li> </ul>

### DG SANCO public consultation

In parallel to the impact assessment work, DG SANCO also organised a public consultation, via a web-based discussion document and questionnaire. This document provided a detailed problem description for the eight main issues that DG SANCO wanted to address during the review of the legislation. These were:

- 1 Innovation and data protection
- 2 The authorisation procedures
- 3 Packaging and labelling
- 4 Pharmacovigilance and monitoring
- 5 The distribution channel
- 6 Off-label use
- 7 Harmonisation of already authorised veterinary products
- 8 New needs and new challenges.

The online document then requested answers to a series of questions addressing various approaches to resolving those issues. The questions were a mixture of scoring questions using fixed scales and free text replies.

DG SANCO received 172 responses (15% citizens, 16% non-business, 17% public authority, 23% veterinarians, 20%

pharmaceutical industry, 4% farmers, 2% manufacturers, and 6% “others”). The summary report of the outcome of this public consultation,<sup>5</sup> and all of the individual replies from stakeholders,<sup>10</sup> were published on the DG SANCO website in September 2011 (see [http://ec.europa.eu/health/veterinary-use/rev\\_frame\\_index\\_en.htm](http://ec.europa.eu/health/veterinary-use/rev_frame_index_en.htm)). At the same time, the EC also published the final report from the GHK consultants on an “Assessment of the impact of the revision of VMP legislation” (dated July 2011).<sup>6</sup> This was followed by a DG SANCO Stakeholder workshop in September 2011 to discuss the outcome of the public consultation and proposals for resolving the issues.

### What happens next?

DG SANCO will use the GHK consultancy report to prepare an internal EC impact assessment report on the issues affecting the sector and the possible policy options for improving the legislation. This report should by now have been drafted and begun its journey of internal consultation within the EC, including a review by an Impact Assessment Steering Committee comprising other interested DGs, and a formal critique by the EC’s Impact Assessment Board, before being finalised sometime in 2012.

Policy area	Policy option
Authorisation procedure for new products	Making a single marketing authorisation valid throughout the EU/EEA. The quality of the work of the competent authorities would be ensured by an independent EU body.
Data requirements for authorisation	Data requirements for product authorisations are reduced. Under certain circumstances products are granted authorisations without the submission of full dossiers.
Existing authorisations	Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment. Systematically harmonise summaries of product characteristics (SPCs) for authorised products.
Pharmacovigilance	Simplify pharmacovigilance requirements.
Marketing authorisation renewals	Restrict the requirement to renew an MA to specific cases based on the risk profile of the product.
Data recording and reporting	The amount of data that must be recorded and reported is reduced.
Packaging and labelling	Prior approval of packaging and labelling by the authorities is abolished. The amount of text required on packaging and labelling is reduced. The authorities may authorise the use of non-official languages.
Variations	Simplifying variations requirements.
Data protection	Rewards for new product developments are decoupled from the initial authorisation. The data protection period for environmental risks is changed to match that for safety and efficacy data. The period of data protection for fish, bees and other specific species/indications is extended to 20 years.
New treatments	Clarifying the scope of the legislation with regard to new types of treatment.
Control and monitoring	National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems. Harmonised EU sanctions are introduced for non-compliance. Enforcing a European database of authorised products.

In parallel, DG SANCO will be drafting and consulting internally on its proposals for amended legislation. It is expected that these will also be released in late 2012 (possibly delayed until early 2013), thus triggering the start of a co-decision procedure with the European Parliament and the Council.<sup>11</sup>

### Key findings

Some key findings from the GHK final report were presented by DG SANCO at the IFAH-Europe annual conference in June 2011, which was organised to provide the opportunity for public debate on the three priority topics, namely: (a) data protection; (b) how to deliver a true single market by simplification of the marketing authorisation procedures; and (c) how to bring existing nationally registered VMPs into a true EU single market.

Perhaps the first key finding is that all stakeholders, whether regulators, industry, veterinarians or farmers, agree there is need for a significant change in the legislation. This spirit was captured by John Dalli (Member of the European Commission, responsible for Health and Consumer Policy) in his speech at the IFAH-Europe conference, when he said that “the current review provides a massive opportunity – an opportunity for all to engage in a fundamental rethink of the whole system of veterinary medicines... It is an opportunity to remould the model; to modernise and to improve it.”<sup>12</sup>

The key drivers behind this sentiment are the poor availability of VMPs across Europe, a significant increase in the cost and time of product development over recent decades, the specific nature of the animal health sector (fragmented small markets/return on investment difficult) and a noticeable slow-down in innovation.

Other key findings from the EC public consultation confirmed the other key drivers; for example, the number of authorised VMPs varies widely between member states (non-functioning single market), there is a lack of medicines for “minor species”, and there is a disproportionately high administrative burden for both industry and regulators. The administrative burden had been analysed according to each of the main regulatory procedures, which revealed that the legislative requirements concerning packaging and labelling were responsible for the largest slice of the administrative burden pie.

### What is industry proposing?

The key proposals from IFAH-Europe are:

- 1 Improved data protection: to change the current data protection provisions from the current (8+2)+1+1+1 years, giving a maximum of 13 years if three additional food-producing species are added to the first product, to (8+2)+3+3+3+3 years, giving a maximum of 22 years if four additional major innovations are added to the first product.

- 2 Simplification of procedures: the current system utilising several regulatory procedures (ie, centralised, mutual recognition, decentralised and national) should be replaced by a single regulatory procedure using the best aspects of the centralised and decentralised procedures. This procedure would be based on a single data dossier (in English) and a single scientific assessment, and would result in a single decision for marketing authorisation in Europe.
- 3 Existing products should be brought into the single market using the same principles of a single scientific assessment leading to a single marketing authorisation for the EU. As all existing products have already had a scientific assessment, this should be valid for the entire EU. Therefore there should be a simple administrative procedure to harmonise the summaries of product characteristics (SPCs) of existing products and issue a single EU marketing authorisation. No new data and no re-assessment would be required. A transition period will be necessary before all products must be harmonised.
- 4 The pharmacovigilance system should be simplified to reduce the administrative burden while not reducing animal and public health. This can be achieved by focusing the limited resources on where the most impact can be achieved (ie, a risk-based approach) and eliminating unnecessary duplication and administration.
- 5 Packaging and labelling requirements should be simplified to reduce the administrative burden while not reducing animal and public health. This will include the facilitation of multilingual labelling by the use of some pictograms and abbreviations for defined pieces of information on the labelling, while maintaining all the necessary information in the pack leaflet.

### So where are we now?

There is considerable alignment among all stakeholders, including industry and regulators, that there is a need for significant changes, what the main issues are and what the solutions should be. However, there are differences of opinion on the details of the solutions. For example, while industry, veterinarians and farming organisations all support the “single procedure” approach to the simplification of procedures, as conceptualised by the “1-1-1” approach [1 dossier, 1 scientific assessment and 1 marketing authorisation for the EU], this view is only partially shared by the regulatory authorities, several of which support maintaining at least two procedures (eg, one for innovative products and one for generic products). Similarly, mixed views are found concerning the degree to which the SPCs of existing products can be harmonised via a simple administrative procedure, or the degree to which information can be transferred from the immediate pack label to the pack leaflet.

The positions of the various stakeholders can be determined from an analysis of the responses to the EC public consultation, both from individuals and also from specific groups such as the Committee for Veterinary Medicinal Products (CVMP), Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv), Federation of Veterinarians of Europe (FVE) and European Farmers and Agri-Cooperatives (COPA-COGECA) (see DG SANCO website).<sup>10</sup>

### Conclusions

As stated above, there is considerable alignment among all stakeholders that there is a need for significant changes. The need to capitalise on this strong motivation for change was captured by Commissioner Dalli, who stressed this is “a massive opportunity... to engage in a fundamental rethink” and “to remould the model”.

An external viewpoint on the way forward may be found in the GHK final report (“An assessment of the impact of the revision of veterinary pharmaceutical legislation”, dated 11 July 2011).<sup>6</sup> The conclusions of the report were:

- The analysis supports the case for legislative reform
- The VMP sector faces a number of problems
- There is considerable appetite for change within the sector
- There is common ground to provide a foundation for negotiated reforms
- A package of proposals could make a significant difference.

The consultants then made a recommended synthesis package of policy options from the 49 policy options it had been asked to assess in the impact assessment work. The package was constructed to provide a balanced approach to the three main objectives of the review.

The conclusion of the GHK report is that this package of policy options would: (1) reduce the administrative burden in the animal health sector by approximately one third of current levels (reduction of €193.5 million per annum); (2) deliver improvements to the availability of VMPs; and (3) improve the functioning of the single market for these products. A streamlining of the system would deliver considerable benefits to all stakeholders (regulatory authorities, manufacturers and end-users), and improve animal health without compromising public health.

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