EGGVP
European Group for Generic Veterinary Products

Position Paper

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Review of Legislation for Veterinary Medicinal Products

Directive 2004/28 entered into force on 1st May 2004, introducing many improvements for the transparent and harmonized authorization of veterinary medicines in the EU. However, a few years after implementation of these rules, the need to revise and address additional issues has been confirmed. EGGVP is aware of the enormous opportunities of improvement given by the ongoing process of the review of legislation and therefore welcomes this initiative. EGGVP is also very pleased with the statements made by the Commissioner John Dalli during his speech on 16th June 2011 at the IFAH-Europe Conference, where commitment and support towards a totally renewed and pragmatic legislation were corroborated.

According to EGGVP's position, the new legislation should reach **two fundamental objectives:**

1- Make the system more efficient:

The main focus of the review should be aimed at reducing the administrative burden both for the industry and regulators. Over the past years, regulators have taken the general approach to align requirements for both human and veterinary medicines. Even if this might be a logical approach, reality shows that the human and the veterinary markets are completely different, and this should be taken into consideration. Not doing so results in an enormous/disproportionate administrative burden for the veterinary industry, which results in expenses estimated at about 13% of total industry turnover; this is inadmissible in any context, but even more under the current economic scenario. In order to reduce any unnecessary burden - which is also very often not bringing any added value in terms of safety, quality and efficacy - the new veterinary medicines' legislation should be customized to the specific characteristics of this segment of the industry, thus uncoupled from human medicines' legislation.

2- Make veterinary medicines more available:

Data protection is essential to stimulate investment in new veterinary medicinal products and bring them into the market. The establishment of periods of exclusivity should balance the dual objectives of providing continued incentives for investment in the development of new products, while allowing the generic veterinary medicines' industry to enter the market at a point in time where investment from innovators has been recovered.

This balance is essential and incentives for the industry bringing generic veterinary medicines into the EU market should also be encouraged. Generic veterinary medicines create an appropriate competitive price environment, while increase the range of choices available for

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the consumer, offering more affordable options without compromising the quality, safety and efficacy. This higher availability, which is consequence of the presence of generics on the market, is also fundamental to provide quality safe food to a growing population in many geographic regions where the cost of non-generic medicines might not be affordable. Due to the price competition, safe and tested formulations are available to wider markets that previously may not have been able to afford them.

In order to achieve these two objectives, EGGVP would like to table the following proposals:

AUTHORIZATION PROCEDURES

- For new marketing authorizations, either submitted according to article 12 or article 13 of Directive 2004/28/EC, EGGVP supports the adoption of the 1-1-1 concept tabled by IFAH-Europe. This way, harmonized SPCs could be obtained throughout the EU and the system would also bring major advantages for products that are not eligible for the centralized procedure today.

- Alongside the 1-1-1 process for new marketing authorizations, and on a temporary basis (transition scenario), the existing procedures could still be an option.

  The reason for this is that with the 1-1-1 process, especially the small and medium sized companies, with only interests in one or a few individual markets, would be forced to go through a complex European assessment system. To give these companies a fair chance in the future, the now existing national procedures (if applicable to be followed with a relative small MRP procedure) should be kept in place as they are right now. Applications in individual Member States on basis of a national application should still be possible during a transition period for six years after coming into force of the new legislation.

  Furthermore, the European generic veterinary industry, which is mainly composed of small and medium sized companies, is very much concerned about the potential fee increases that applications under the 1-1-1 system could lead. EGGVP is afraid that the fees for the expert evaluation will head towards the costs (and work load) for a central registration, with the consequent difficulties to be handled by small and medium sized companies. It should be noted that some products are of interest to a few Member States only, and that the current authorization regimes allow an investment which is proportionate to the number of markets that companies have chosen. In case that fees associated to the 1-1-1 system were not proportionate, companies may not be able to support extra fees if they have no investment return in countries where there is no market for their products. Thus, an increase of fees under the 1-1-1 system would reduce or even prevent marketing possibilities. There should be guarantees that assessment fees linked to the 1-1-1 system will be proportionate. It is also essential that dossier requirements under this system remain balanced and fair; a further increase in requirements would harm the availability of veterinary medicines because it would no longer be possible for industry to sustain the profound investments in new products.

- For existing authorizations, the 1-1-1 approach would only be reasonable if veterinary medicinal products were authorized under the same conditions and evaluated under the same criteria. As this is not the case, such a system would imply a huge workload to reach harmonisation and would therefore not be suitable for existing medicines. Applying such an approach for existing veterinary medicines, where target species and indications may have been lost in one Member State whilst the product literature may have remained the same in other Member States, would result in triggering referrals over and over.

- With regard to the non-harmonised SPC's for existing products, EGGVP wishes to repeat its position. Harmonisation of SPC's is supported by EGGVP on the strict precondition that such a harmonisation would NOT be based on a re-assessment of old or new material. Such a process should entail a pragmatic approach, taking into account existing pharmacovigilance data.

PHARMACOVIGILANCE

Pharmacovigilance represents the highest percentage of administrative burden for veterinary medicines' companies, with a significant impact on small and medium sized enterprises' daily activities and resources. EGGVP believes that a drastic simplification of pharmacovigilance requirements is not only necessary but possible, as it has been proved that there is room for reducing this burden without compromising neither safety of medicines nor transparency of procedures. Some suggestions to reduce this burden are:

- Keep PSUR obligations to a minimum, in particular for veterinary medicines which have been in the market for many years and have no reported adverse effects. There is no need to report the same again and again for products that have never reported an adverse reaction. Periodicity could therefore be reduced. EGGVP's proposal is the following:
    - PSUR submission at 3 years after approval
    - PSUR submission at 5 years renewal
    - No more PSUR submission for this product unless any serious ADR has occurred; in this case, a 3 year periodicity would be recovered.
    - For veterinary medicines considered "risky products": periodicity to be agreed at the time of approval.

- Extend the deadline for reporting known serious ADRs (the current deadline of 15 days is hard to accomplish; extending the deadline to 30 days would result in higher quality reports).

- Keep the company's pharmacovigilance system description out of the authorization dossier(s), in order to allow modifications of the system without compromising the validity of the authorization dossier(s). Pharmacovigilance system should be linked to the marketing authorization holder rather than to applications.

- Promote and implement e-submission procedures: The possibility to submit electronic dossiers is not yet a reality in all Member States; EGGVP supports all efforts in order to fully eliminate submission of paper copies altogether.

- Create a centralized procedure for notification in a central database of friendly use. Abolish national reporting as much as possible.

- Harmonise the classification of "Serious Adverse Reactions" between EU and non-EU countries; the same criteria should apply.

DATA PROTECTION

EGGVP is favourable to an extended data protection for specific reasons (such as new indications, new species or new withdrawal periods), as long as the periods of extension are **proportionate** to the investment and **linked to the extent of innovation**. This means that any prolongation should solely be possible for the specific extension of a marketing authorization and not for the product in general. Thus, after the first protection period, generics should be possible but without the new species or indications of the related extension.

- Any extension in data protection should also be equally applied to innovation performed to generic veterinary medicines, and not only to originators.

- EGGVP proposes an extended data-protection period of a **maximum of 15 years** (except for products for minor species, where the period should be higher) to be foreseen in the new veterinary medicines legislation:
  - Initial data protection period: 10 (8 + 2) years
  - Additional data protection periods: maximum 5 years (in addition to the initial 10 years):
    - 1st addition for food producing species: +3 years
    - Further extra additions for food producing species: +1 year
    - Any addition for non-food producing species: +1 year
    - Additional indications: +1 year
    - Additional pharmaceutical forms: +1 year
    - New withdrawal period: +1 year

- There should be no restrictions with respect to time-point of submission, and no link to the MRLs regulations.

- Competent authorities should inform generic companies in the cases where additional protection periods for certain claims are given to the reference product. Additionally, full SPCs from all Member States should be and is only used by certain Member States.

PACKAGING AND LABELING

In general terms, EGGVP supports the proposals tabled by IFAH-Europe on this issue.

EGGVP believes that labelling requirements should be simplified, *i.e*. pictograms and abbreviations should be accepted in internal and external labeling/packaging, and no local languages should be required. Furthermore, the text in the product insert could be shortened in order to better attire the attention of the end-user.