

## Press release – June 21<sup>st</sup> 2018

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### **Agreement on the EU Regulation for veterinary medicines: EGGVP preliminary views**

Brussels, 21 June 2018 - Following the Coreper approval last week of the provisional text on the new Regulation on Veterinary Medicines, the text has now been voted upon at the European Parliament (ENVI Committee) during its 20-21 June session. The procedure is now expected to be completed in autumn 2018, with the vote in Plenary Session, and subsequent adoption by the Council.

EGGVP is pleased to see that this long-awaited agreement has finally been reached, and appreciates the tireless work of all parties involved throughout interinstitutional discussions. While many technical and fundamental issues remain unresolved and will have to be adopted by means of delegated and implementing acts, EGGVP remains hopeful that the objectives and opportunities brought by the modernisation of this piece of legislation will be met.

In particular, EGGVP welcomes the provisions for a more efficient and EU-wide harmonised system for the authorisation of veterinary medicines, sustained by science-based and stringent safety parameters. This approach shall ultimately have a positive effect for the animals and human welfare, as well as for the environment and the whole EU agri-food sector.

EGGVP also welcomes the new and positive rules aiming to fight antimicrobial resistance in animals and people under the principles of responsible use. Regarding the complete ban of certain antimicrobials for animal use, EGGVP remains vigilant for those cases where no suitable alternative is available, as that could lead to serious animal health and welfare issues. EGGVP will continue to be an active participant in the upcoming discussions with legislators, agencies and other stakeholders on this subject, aiming for a Regulation that takes due account of science evidence and risk-benefit based approaches.

However, EGGVP is discouraged and concerned by the agreed rules on exclusivity periods for new veterinary medicines. Whereas EGGVP was in favour of changing the current status quo by providing

more proportionate incentives to innovation for all players, the new requirements go far beyond and remain largely unbalanced. Furthermore, the new measures are imprecise and non-transparent, leading to legal uncertainty for the generic players. These provisions undermine the importance of the timely availability of generics veterinary medicines at the expense of veterinarians, farmers and pet owners' access to therapies. Generic medicines are pivotal in increasing access to medicines. Amongst their benefits to society, generics help addressing challenges such as lack of availability, in particular for small and limited markets, and ensure a competitive environment which nurtures innovation to the advantage of all stakeholders. As such, it is considered that the proposed regulations are a missed chance in this regard.

EGGVP will continue to engage with the legislators and stakeholder community at large in the coming years to actively participate in the development of secondary legislation and to support its members during the implementation of the new measures.

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