

Brussels, 11 March 2016

### **Veterinary medicines legislation: EGGVP statement on European Parliament's Plenary vote**

11 March 2016 – The European Parliament gathered yesterday in plenary session in Strasbourg and voted on the Commission proposal for regulation on veterinary medicines. The European Group for Generic Veterinary Products (EGGVP) welcomes this adoption, which recognises the important role of veterinary medicines for the health of animals and people, as well as for the environment.

After many years of careful preparation of the proposal by the European Commission, an important step took place with the Plenary adoption of about 300 important amendments, which are the result of intense work and long negotiations at the European Parliament. “At EGGVP, we would like to thank all MEPs for their work and involvement in this very complex and technical piece of legislation, in particular those MEPs who have contributed to address the concerns of the industry of generic veterinary medicines”, said EGGVP’s President Ma Dolores Cainzos.

Much work and resolutions have been focused in addressing the public health risks of antimicrobial resistance. EGGVP firmly supports the European Parliament in fighting antimicrobial resistance in animals and people under the principles of responsible use. However, serious concerns remain regarding the complete ban of certain antimicrobials for animal use when there is no evidence that the risk-benefit of a prohibition remains positive and no suitable replacement is available.

Intense debate has also taken place on the possible mechanisms to incentivise innovation. Even if a few EGGVP concerns have been addressed by the European Parliament (provisions to increase transparency for generics and also to protect the innovation of existing products), the exclusivity periods for new authorisations – without generics competition – are too lengthy and disproportionate. This will have negative consequences for the availability (supply control with no substitutes) and affordability (price control) of medicines for animals. EGGVP is firm on the views that more proportionate and balanced formulas exist to incentivize innovation without harming the viability of the generic industry. It is necessary to ensure a timely access to generic medicines for veterinarians, farmers and pet owners while creating a healthy competitive environment. Thus, EGGVP urges the relevant bodies involved in this co-decision procedure to further consider this matter.

EGGVP fully supports the adopted provisions aiming at reducing the administrative burden both for industry and authorities, which was one of the main objectives of the regulation due to its disproportionate dimension in veterinary medicines. However, some other provisions – in

particular in the area of pharmacovigilance – suppose a step back to the principles of “better regulation” previously set up in the Commission proposal, while they do not bring any added value to the protection of animal or public health or the environment.

Now the Council is working independently on the text and hopes to have a version adopted by the end of this year. Yesterday MEPs voted to open negotiations with the Council, with the aim of reaching a first reading agreement on the proposals.

### **About EGGVP – European Group for Generic Veterinary Products**

EGGVP is a high level group of 21 companies representing the pharmaceutical industry of generic veterinary medicinal products in Europe. It represents the interest of its members in order to achieve a transparent, harmonized, pragmatic and proportionate regulatory environment.

EGGVP membership is mainly composed of small and medium sized companies (SMEs), representing an industry that has more than 5000 direct employees in the EU and a sales turnover of over €1.3 billion per annum.

Headquarters of all EGGVP companies are located in EU Member States. 19 out of 21 EGGVP members are “veterinary only” companies.

EGGVP is a member of the European Platform for the Responsible use of Medicines in Animals (EPRUMA) and firmly sticks to its principles to promote the responsible use of medicines in animals in the EU.

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