

Statement

On European Commission Implementing Regulation (EU) .../... of XXX on measures on good distribution practice for veterinary medicinal products

GIRP welcomes the opportunity to comment on the revised drafts of the "COMMISSION IMPLEMENTING REGULATION (EU) .../... of XXX on measures on good distribution practice for veterinary medicinal products".

GIRP member associations and companies undertake considerable efforts to fulfil their legal obligation to ensure the supply of the population with medicinal products for human use in compliance with the regulatory requirements of the EU-GDP Guidelines with medicinal products for human use. In addition, GIRP members supply pharmacies and veterinarians with veterinary medicines.

We warmly welcome the approach of the European Commission in their draft implementing regulation on measures on good distribution practice for veterinary medicinal products to avoid unnecessary administrative burdens and costs, as wholesale distributors store and deliver human and veterinary medicines. It is therefore not practicable to deviate from the GDP Guidelines on Good Distribution Practice for Medicinal Products for Human Use (2013/C 343/01) for veterinary medicinal products.

In order not to adversely affect the availability of veterinary medicinal products, no more stringent requirements should be imposed on GDP for veterinary medicinal products, other than those that already in place for medicinal products for human use.

In this respect, we kindly ask you to take into consideration the following comments:

Alignment with Good Distribution Practices of medicinal products for human use

Physical and/or electronic segregation of products

GIRP invites the Commission to reassess the relevance of the dual requirements of physical and electronic segregation of products as foreseen in the current articles 12(6), 12(7), 25(1), and 31(2) insofar as the possibility to recourse to sole electronic segregation ensures at least the same level of quality and security of the products according to Article 3(2) of the GDP of medicinal products for human use. GIRP invites the European Commission to align the measures on GDP for veterinary medicinal products with the GDP of medicinal products for human use and always provide for physical **or** electronic segregation.

GIRP invites the Commission to amend Articles 12(6), 12(7), 25(1) and 31(2) and for each of these provisions to replace 'physically and electronically' by 'physically **or** electronically'.

Returned veterinary medicinal products

GIRP invites the Commission to reassess the relevance of the requirement of the production of records of temperature readings during transport in the case of returned veterinary medicinal products as foreseen in Article 30(3)(f) insofar as such records are not available in the case of so-called passive deliveries and would potentially reduce access to veterinary medicines. In addition, such requirements are too stringent considering the use of veterinary medicines and are unnecessarily stricter than the requirements in the case of GDP of medicinal products for human use where no such conditions are stated.

GIRP invites the Commission to delete Article 30(3)(f).

Addition of technology

GIRP invites the Commission to reassess the relevance of the requirement for additional of technology in vehicles and equipment used to distribute veterinary medicinal products as foreseen in Article 37(4)(b), insofar

as such requirements are too burdensome in the case of veterinary medicinal products and would potentially increase the prices of veterinary medicines and possibly reduce their accessibility as medicinal products for human and veterinary use are transported in the same vehicles. In addition, such requirements are not to be found in the GDP of medicinal products for human use.

GIRP invites the Commission to delete Article 37(4)(b).

Brussels, 09 June 2021

European Healthcare Distribution Association (GIRP) ([website](#))

GIRP, the European Healthcare Distribution Association, is the umbrella organisation for pharmaceutical full-line wholesalers and distributors of healthcare products and services in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 34 European countries, as well as major international and pan-European healthcare distribution companies. GIRP members employ over 140,000 people and distribute around 15 billion packs of medicines as well as a wide range of healthcare products per year. As the vital link in healthcare, they are committed to developing and providing innovative and efficient healthcare products and services to improve health and wellbeing of patients across Europe.