Statement

On European Commission Implementing Regulation (EU) .../... of XXX as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6

GIRP welcomes the opportunity to comment on the revised drafts of the "COMMISSION IMPLEMENTING REGULATION (EU) .../... of XXX as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6.

GIRP member associations and products for human use in compliance with the regulatory requirements of the EU-GDP Guidelines with medicinal products for human use. In addition, some GIRP members supply pharmacies and veterinarians with starting materials for veterinary medicines.

We warmly welcome the approach of the European Commission in their draft implementing regulation on European Commission Implementing Regulation (EU) .../... of XXX as regards measures on good distribution practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 to avoid unnecessary administrative burdens and costs, as wholesale distributors store and deliver human and veterinary medicines and some of them also starting materials for veterinary medicinal products, it is therefore not practicable to deviate from the GDP Guidelines of 19 March 2015 on active substances for medicinal products for human use. In order not to adversely affect the availability of starting materials for veterinary medicinal products, no more stringent requirements should be imposed on GDP for active substances used as starting materials in veterinary medicinal products other than those that already hold for active substances for medicinal products for human use.

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

Alignment with Good Distribution Practices for active substances used as starting materials in for 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 Article 15(5). GIRP invites the European Commission to align the measures on GDP for active substances used as starting materials in veterinary medicinal products with the GDP for medicinal products for human use insofar as the latter always provides for physical **or** electronic segregation and that except the current Article 15(5), all the provisions of the GDP for active substances used as starting materials in veterinary medicinal products incorporate the alternative condition as regards segregation of products.

GIRP invites the Commission to amend Articles 15(5) and to replace 'physically and electronically' by 'physically **or** electronically'.

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.

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