COMMISSION DECISION (EU) 2021/1125

of 8 July 2021

refusing to include the medicinal product subject to prescription Zinc-D-gluconate in the list of medicinal products that shall not bear the safety features referred to in Article 54, point (o), of Directive 2001/83/EC of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular Article 54a(4) thereof,

Having regard to Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use ([2]),

Whereas:

(1) Article 54a(1) of Directive 2001/83/EC provides that medical products subject to prescription are to bear safety features referred to in Article 54, point (o), of that Directive, unless they have been listed in accordance with the procedure pursuant to Article 54a(2), point b, of that Directive. Annex I to Delegated Regulation (EU) 2016/161 sets out a list of medicinal products or product categories subject to prescription that shall not bear the safety features, based on the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products. The medicinal product subject to prescription Zinc-D-gluconate is not included in that list.

(2) On 15 February 2019, the German competent authority, in accordance with Article 54a(4) of Directive 2001/83/EC and Article 46(2) of Delegated Regulation (EU) 2016/161, informed the Commission by email that they do not deem the medicinal product subject to prescription Zinc-D-gluconate to be at risk of falsification according to the criteria set out in Article 54a(2), point b, of Directive 2001/83/EC. The German competent authority considered that Zinc-D-gluconate should therefore be exempted from the requirement to bear the safety features referred to in Article 54, point (o), of Directive 2001/83/EC.

(3) The Commission assessed the risk of and the risk arising from falsification relating to the medicinal product concerned, taking into account the criteria listed in Article 54a(2), point (b), of Directive 2001/83/EC. As the medicinal product is authorised for the treatment of severe conditions such as Wilson's disease and Acrodermatitis enteropathica disorder, the Commission assessed, in particular, the severity of the conditions intended to be treated, referred to in Article 54a(2), point (b), subpoint (iv), of that Directive and found that the risks from falsification were not negligible. Therefore, the criteria were not considered to be met.

(4) It is, therefore, not appropriate to include the medicinal product Zinc-D-gluconate in Annex I to Delegated Regulation (EU) 2016/161 and it should not be exempted from the requirement to bear the safety features referred to in Article 54, point (o), of Directive 2001/83/EC.

(5) The measures provided for in this Decision are in accordance with the assessment of the European Commission Expert Group 'Delegated act on safety features for medicinal products for human use',

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) OJ L 32, 9.2.2016, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product subject to prescription Zinc-D-gluconate shall not be included in Annex I to Delegated Regulation (EU) 2016/161 and shall not be exempted from the requirement to bear the safety features referred to in Article 54, point (o), of Directive 2001/83/EC.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 8 July 2021.

For the Commission
The President
Ursula VON DER LEYEN