



Reports of Cases

Order of the President of the General Court of 18 October 2022 – Fresenius Kabi Austria and Others v Commission

(Case T-416/22 R)

(Interim relief – Medicinal products for human use – Directive 2001/83/EC – Marketing authorisations for medicinal products containing the active substance ‘hydroxyethyl starch (HES), solutions for infusion’ – Application for suspension of operation of a measure – No urgency)

1. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Prima facie case – Urgency – Serious and irreparable damage – Cumulative nature – Balancing of all the interests involved – Order of examination and method of verification – Discretion of the court hearing the application for interim relief*

(Arts 256(1), 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4))

(see paragraphs 14, 15)

2. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Burden of proof – Obligation to provide concrete and precise indications, supported by detailed documentary evidence*

(Arts 256(1), 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4))

(see paragraphs 18-21, 38-40)

3. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Serious and irreparable damage – Financial loss – Serious nature of the harm – Situation liable to endanger the existence of the applicant company – Irremediable effect on its market share – Assessment in the light of the size and turnover of the undertaking and the situation of the group to which it belongs – Obligation to demonstrate the existence of obstacles of a structural or legal nature preventing that company from regaining a significant proportion of its market share*

(Arts 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4))

(see paragraphs 29, 30, 32, 41-43, 45)

4. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Serious and irreparable damage – Financial loss – Loss capable of being subsequently remedied by means of an action for compensation – Damage which cannot be regarded as irreparable*
(Arts 268, 278, 279 and 340 TFEU)
(see paragraphs 31, 47)
5. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Non-material damage not capable of being better remedied at the interim stage than in the main proceedings – No urgency*
(Arts 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4))
(see paragraph 46)
6. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Burden of proof – Financial loss – Irreparable alteration in market share – Taking into account of the risk of loss of market shares in non-member countries – Precluded*
(Arts 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4))
(see paragraph 48)
7. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Financial loss – Commission decision concerning the suspension of the marketing authorisation of a product – Reliance on the adoption of measures suspending authorisations for the product at issue by third States – No effect on the assessment of the seriousness of the harm*
(Arts 278 and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4); European Parliament and Council Directive 2001/83)
(see paragraph 49)

Operative part

1. The application for interim measures is dismissed.
2. The costs are reserved.