



Reports of Cases

Order of the President of the General Court of 23 November 2018 – GMPO v Commission

(Case T-733/17 R)

(Interim relief — Medicinal products for human use — Active substance trientine tetrahydrochloride — Commission decision not to classify the medicinal product Cuprior-trientine as an orphan medicinal product — Regulation (EC) No 141/2000 — Application for suspension of operation of a measure — Lack of urgency)

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

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

(see paras 13, 15, 16)

2. *Application for interim measures — Suspension of operation of a measure — Interim measures — Conditions for granting — Urgency — Serious and irreparable damage — Burden of proof — Financial loss — Obligation to provide concrete and precise indications, supported by detailed documentary evidence — Situation liable to endanger the existence of the applicant company — Assessment having regard to the situation of the group to which the applicant company belongs*

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

(see paras 19, 20, 27, 30-34, 36)

3. *Application for interim measures — Formal requirements — Submission of applications — Brief summary of the pleas in law on which the application is based — Insufficient explanation of the grounds constituting a prima facie case — General reference to other documents — Inadmissibility*

(Arts 278 TFEU and 279 TFEU; Rules of Procedure of the General Court, Art. 156(4) and (5))

(see paras 22-24)

4. *Application for interim measures — Suspension of operation of a measure — Interim measures — Conditions for granting — Urgency — Serious and irreparable damage — Financial loss — Serious nature of (the) harm — Assessment in the absence of information concerning the size of the undertaking concerned — Financial harm which is objectively significant sustained by an undertaking owing to an alleged obligation to make a commercial choice within a disadvantageous timescale — Risk that should normally be borne by an undertaking operating in a highly regulated market — No urgency*

(Arts 278 TFEU and 279 TFEU)

(see paras 45, 46)

5. *Application for interim measures — Suspension of operation of a measure — Interim measures — Conditions for granting — Urgency — Lack of diligence by the applicant taken into account*

(Arts 278 TFEU and 279 TFEU; Rules of Procedure of the General Court, Art. 156(3))

(see para. 49)

6. *Application for interim measures — Suspension of operation of a measure — Conditions for granting — Serious and irreparable damage — Financial loss — Commission decision refusing to categorise a medicinal product as an orphan medicinal product — Risk that should normally be borne by an undertaking operating in the relevant market — No urgency*

(Art. 278 TFEU; Rules of Procedure of the General Court, Art. 156(4); European Parliament and Council Regulation No 141/2000, Art. 5(12)(b))

(see para. 76)

7. *Application for interim measures — Suspension of operation of a measure — Interim measures — Conditions for granting — Urgency — Serious and irreparable damage — Burden of proof — Financial loss — Loss capable of being subsequently remedied by means of an action for compensation — Damage which cannot be regarded as irreparable*

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

(see paras 79, 80)

8. *Application for interim measures — Suspension of operation of a measure — Interim measures — Conditions for granting — Serious and irreparable damage — Irreparable nature of the damage — Damage which cannot be quantified — Assessment solely on the basis of the uncertainty as to compensation for pecuniary damage in an action for damages — Not permissible*

(Arts 268 TFEU, 278 TFEU, 279 TFEU, 339 TFEU and 340 TFEU)

(see paras 97-99)

Re:

Application under Articles 278 and 279 TFEU for suspension of operation of Article 5 of Commission Implementing Decision C(2017) 6102 final of 5 September 2017 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1) for 'Cuprior-trientine', a medicinal product for human use.

Operative part

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