



Reports of Cases

Order of the President of the General Court of 26 November 2024 – Advanz Pharma v Commission

(Case T-455/24 R)

(Interim relief – Medicinal products for human use – Orphan medicinal product for human use
‘Ocaliva – obeticholic acid’ – Revocation of a conditional marketing authorisation –
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 – Weighing up of all the interests involved – Order of examination and method of verification – Discretion of the judge 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 15, 17, 18)

2. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Burden of proof borne by the party seeking the interim measure – Need to plead the risk of suffering that damage personally*

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

(see paragraphs 21, 40-42)

3. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Burden of proof – Financial loss – Obligation to show that there are structural or legal obstacles preventing the applicant company from regaining a significant proportion of the market share*

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

(see paragraph 51)

4. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – Serious and irreparable damage – Financial loss – Serious nature of the damage – Situation liable to endanger the existence of the applicant company – Assessment in the light of its size and turnover and the situation of the group to which it belongs – Activity in highly regulated markets – Decision revoking conditional marketing*

authorisation – Risk normally having to be borne by an undertaking operating on such a market – No urgency

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

(see paragraphs 52-54, 59, 60, 64, 67, 73)

5. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Serious and irreparable damage – Damage having already occurred – Reparation outside the purpose of the interim proceedings*

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

(see paragraphs 70, 71)

6. *Interim relief – Suspension of operation of a measure – Interim measures – Conditions for granting – Urgency – 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)

(see paragraph 72)

Operative part

1. The application for interim measures is dismissed.
2. The order of 4 September 2024, *Advanz Pharma v Commission* (T-455/24 R), is cancelled.
3. The costs are reserved.