



## Precautionary measures regarding access to unauthorized medicinal products

**Orders of the Contentious Administrative Court I of Castellon de la Plana of 10, 13 and 27 August 2021**

### Background

In August 2021, following a request from the relatives of a patient in serious condition for Covid-19, a Spanish Court adopted precautionary measures forcing the application of an unauthorized ozone therapy in a public hospital. Whatever one's views about such type of treatment, these Court orders are relevant to the extent they deal with matters that frequently pop up when patients claim access to unauthorized medicinal products.

### Contents of the Court orders

The Court issued precautionary measures *inaudita parte*, i.e. without hearing other parties, because it concluded that *periculum in mora* was present in this case, i.e. an irreparable harm to patient's life due to his serious medical condition. The Court also assessed the lack of alternatives (the transfer of the patient to another hospital where he could receive the treatment was not possible); and the absence of relevant damages to general or third parties' interests (probably, although this is not expressly indicated in the Orders, because the relatives of the patient assumed the cost of the treatment). The fact that the situation was very critical ("the life of a person is at stake" the Court states) was as well taken into account.

Once the precautionary measures were issued, the administration objected to such measures on the grounds that ozone therapies are not included in the guides or protocols for Covid-19

treatments, and that no evidence exists with respect the efficacy and safety of such therapies. Despite this, the Court kept the precautionary measures alleging that its role was not to assess the efficacy or safety of the therapy, but only to assess the existence of the requisites contemplated in the law to issue precautionary measures. Finally, the measures were lifted once the Court considered that the patient was well enough to be transferred to another hospital where he could receive the treatment.

### Conclusions

When precautionary measures are requested in order to get access to unauthorized medicinal products, the right to life is a key element to consider, particularly when dealing with serious and imminent risks to human life, and when patients do not have any alternative. These Court orders, as well as other case law, show that denying access to a treatment on the grounds that its efficacy is not well-proven may be difficult unless there are clear concerns about the safety the treatment. On another note, the administration may oppose to such access on the grounds that paying the treatment with public funds may affect general interests. If the administration does so, however, it will have to be very careful because the Constitutional Court has declared (order of 12 December 2012) that the "right to life has singular constitutional relevance that cannot be undermined by an unspecified and eventual economic saving".