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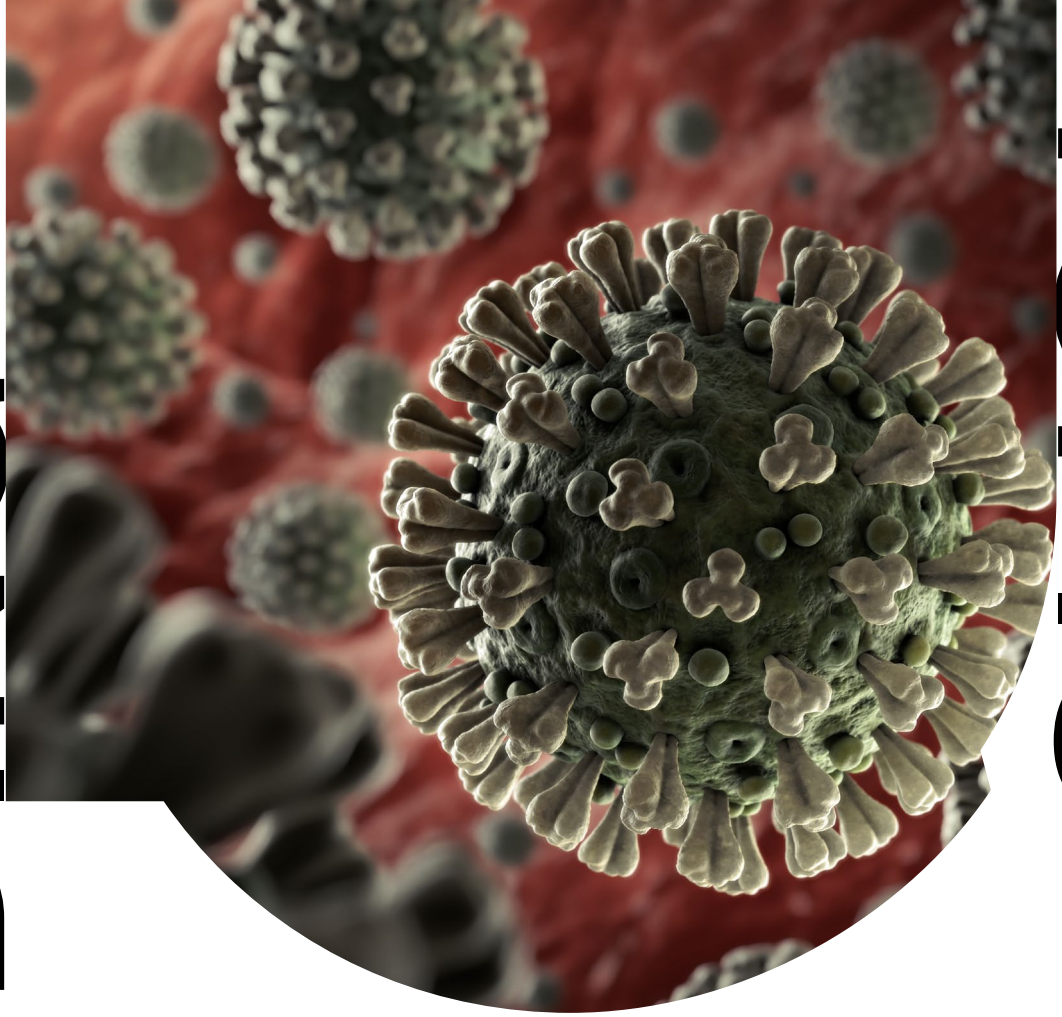

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HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Coronavirus: Restrictions on exports of vaccines against COVID-19

Brief notes on Commission Regulation 2021/111 of 29 January 2021

Following the differences that came to light with AstraZeneca at the end of last week, the European Commission approved Implementing Regulation (EU) 2021/111 of 29 January 2021, which came into force on Saturday, 30 January. The Regulation prohibits the unauthorised exportation of vaccines against SARS-CoV-2 outside the European Union.

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"Regulation 2021/111 raises a number of important practical questions in terms of administrative law – and in particular regarding the procedural and litigation guarantees for private parties."

Regulation 2021/111 raises a number of important practical questions, from the point of view of administrative law – and in particular from the point of view of the procedural and litigation guarantees for private parties.

Scope and legal nature of the procedure under Regulation 2021/111

Regulation 2011/111 prohibits the exportation of vaccines against COVID-19 without the production of a valid export authorisation. This authorisation must be produced when the vaccines are declared for export and up to the time of their release[1]. The justification given for this admittedly harsh measure is the fear that there may be a risk of breach of contractual commitments entered into by vaccine producers under Advance Purchase Agreements (APAs) with the European Commission[2]. In addition, the Commission stresses the need to ensure transparency on the quantities of vaccines produced and their destination[3].

Not all destination countries for the export of vaccines are covered by the prior authorisation requirement. Invoking the "principle of international solidarity", the Regulation excludes exports to a long list of countries and regions outside the European Union from the scope of the authorisation procedure. These countries include Iceland, Switzerland, Egypt and Ukraine[4]. Besides these countries, low and middle-income countries on the COVAX AMC list, including most sub-Saharan African states, several of the poorest states in Latin America, and India and Indonesia, are also excluded from the authorisation requirement.

Destination countries that are not exempt from the prior authorisation requirement include several non-EU high-income countries such as the United States, Canada, New Zealand and the United Kingdom.

The authorisation procedure consists of several stages. It starts with an application to the national competent authority by the company wishing to export COVID-19 vaccines (including the active substances and master and working cell banks used in the production of these vaccines) outside the European Union. The national competent authority will be the authority of the Member State where the vaccines are produced. The national authority should assess whether or not the volume of exports is likely to pose a threat to the performance of any APAs made between the EU and vaccine producers[5].

According to Recital 8 of the Regulation, "The administrative modalities for these authorisations should be left to the discretion of the Member States". In other words, the normal systems of national administrative law will apply. If the procedure is started in Portugal, the provisions of general Portuguese administrative law, in particular those of the Portuguese Code of Administrative Procedure ("CAP") will apply.

1 Article 1(2) and (3).
2 Recitals 2 and 3.
3 Recitals 4 and 5.
4 Article 1(4).
5 Article 1(4).

As soon as the competent national authority has finished preparing a draft decision, it must submit it to the European Commission. From that moment on, a phase begins at the level of the European Union's own administration: the Commission must deliver an opinion within one working day of receiving the draft decision assessing the impact of the targeted exports on the implementation of the APAs made with the EU. The Commission's opinion is required "In order to ensure an adequate coordinated decision at Union level"[6] and this solution is understandable because a number of authorities in several different Member States could be assessing applications for authorisation.

In the terminology of Portuguese administrative law, the Commission's opinion can be described as *mandatory*, because it must be requested by the national authority before it makes the final decision, and *binding*, because the final decision that the national authority takes will have to comply with the positive or negative assessment of that draft decision by the European Commission[7].

The administrative procedure described falls within the dogmatic category of composite administrative procedures. In other words, it is one of those administrative procedures established by European legislation that consist of different stages which are interdependent at national and European Union level[8]. There are many procedures with such a multi-level structure. In fact, they are becoming increasingly common in a wide variety of areas from drug regulation to banking supervision[9]. However, it is precisely this multi-level structure which creates serious practical difficulties from the point of view of the guarantees of private parties, both in terms of procedural rights and litigation.

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Administrative and litigation guarantees for private parties

The procedure described first raises doubts from the point of view of the procedural guarantees of private parties (in this case, the companies exporting vaccines). As is unfortunately common in legislation creating compound procedures, the European legislature has omitted any reference to procedural guarantees and, in particular, to the right to a prior hearing.

Under the Portuguese Code of Administrative Procedure, it seems clear that the company should be asked to decide on the probable outcome of the decision to be taken (article 121(1) of the CAP) before sending the draft decision to the European Commission, that is, whether the draft decision is to reject the authorisation, because if the authorisation is granted in full, no prior hearing will be necessary (article 124(1)(f) of the CAP). It is possible that the draft decision will be in favour of the authorisation, thus dispensing with the need for a prior hearing in Portugal and several other Member States, but that the Commission will subsequently issue a binding opinion against the administrative act of authorisation by the competent authority. In such circumstances, before finalising its opinion, should the Commission hold a prior hearing of the company concerned?

6 Recital 7.

7 Article 2(5).

8 Filipe Brito Bastos, "Derivative illegality in European composite administrative procedures", in: *Common Market Law Review*, 55:1, 2018, pp. 101-134.

9 Filipe Brito Bastos, "Judicial review of composite administrative procedures in the Single Supervisory Mechanism", in: *Common Market Law Review*, 56:5, 2019, pp. 1355-1378

Despite the fact that Regulation 2021/111 is silent on this point, the answer must be yes. While it is true that the distribution of the duty to have a prior hearing between national and European authorities in compound procedures is a matter of great complexity,[10] according to the case law of the Court of Justice, that right has to be respected even if it is not specifically provided for in the European legislation establishing an administrative procedure[11].

Some difficulties can also be identified regarding litigation. Which courts – national or European – should review a rejection decision taken upon completion of a procedure in which national authorities and the Commission make a joint decision?

Naturally, the first thought would be to consider that, if the final decision in the procedure is taken at national level, the national courts would have jurisdiction. Once the European Commission has issued a binding negative opinion, it would then be possible to seek a preliminary ruling on the validity of the opinion on which the administrative act of definitive refusal[12]. This is a viable solution to ensure companies are protected in terms their ability to litigate, but there seems to be at least one other alternative.

The exporting company will be able to meets the conditions to have legal standing to bring an action to challenge the Commission's opinion before the General Court of the European Union. The Commission's opinion is formally addressed to the competent national authority. However, as that authority is bound to decide in accordance with what the Commission has determined, in practice, the opinion inevitably affects the legal sphere of the company in the same way it would if the company were actually the addressee of the decision. Thus, the exporting company will be able to bring an action for annulment under article 263 of the TFUE. In fact, this may prove to be a more direct alternative to going down the road of a challenge before the national courts with a subsequent reference from the national court to the Court of Justice for a preliminary ruling on the validity of the Commission's binding opinion.

Furthermore, attention should be paid to the Court of Justice's TWD case. Here, the Court held that questions as to the invalidity of EU decisions raised by the national court in proceedings to challenge national implementing measures will be inadmissible if the appellant manifestly has standing to bring an action for annulment before the CJEU and has not done so within the time limit[13]. In practical terms, if the exporting undertaking brings an action for annulment under the general terms of the code that governs procedure in the administrative courts against the national authority's decision to refuse authorisation on the basis of a negative opinion of the Commission, it will no longer be possible to raise a preliminary question as to the validity of that opinion if the two-month period for its challenge before the European courts has expired. ■

10 Christina Eckes/Joana Mendes, "The right to be heard in composite administrative procedures: lost in between protection?", in: *European Law Review*, 36:5, 2011, pp. 651-670 e Paul Craig, *EU Administrative Law*, 3.ª ed., Oxford University Press, Oxford, 2018.

11 See, among others *Judgment of the General Court of 19 November 2009, Case T-334/07, Denka*, point 127.

12 Judgment of the Court of Justice of 21 March 2000, Case C-6/99, *Association Greenpeace France*, points 54 and 55.

13 Judgment of the Court of 9 March 1994, Case C-188/92, *Textilwerke Deggendorf*.