Belgian Court orders AstraZeneca to deliver vaccine doses to the EU – Questions and Answers

Brussels, 19 June 2021

Why did the European Commission start this Court proceeding and what did it intend to obtain?

The company announced in January that it would not be in a position to deliver the number of doses laid down in the contract. The Commission and the Member States immediately took this matter up with the company with a view to ensure a speedy delivery of sufficient number of doses, urgently needed for the vaccination campaigns in the Member States.

In the absence of a satisfactory arrangement, the Commission started on 19 March a dispute resolution procedure to reach an agreement on the way forward.

However, as this procedure did not entail an increase of the number of deliveries and as the company did not manage to develop a credible strategy to ensure compliance with its contractual commitments, the Commission had no other choice than to start legal proceedings.

These proceedings followed a double track, both with the same purpose, notably the delivery of doses.

First, the Commission started an emergency injunction procedure (procedure en référé). The objective of this procedure was to have the Court acknowledge the urgency of the deliveries, given the vaccination needs in the countries, and order the company to deliver the necessary doses.

The second procedure is a procedure on the merits, in the context of which the Court is requested to assess the mutual rights and obligations of the two parties. The Commission requests in this procedure that the Court acknowledges that the company did not respect its contractual obligations vis-à-vis the Commission and Member States.

But again the purpose of both legal actions is in the end to ensure the delivery of a sufficient number of doses.

What is the main message of the court ruling?

AstraZeneca grossly and intentionally breached the agreement with the EU.

On substance, what are the main points the court makes?

First, the case was urgent and needed to be handled in emergency proceedings – quote: "prima facie, the delays of the vaccination may have damaging consequences on individual freedoms of the EU citizens and, as a consequence, on the economic life of the EU and the Member States. Those are downsides that are sufficiently serious to justify an immediate decision on the number of doses of vaccine that AstraZeneca had to deliver to the EU" (p. 36, n° 17).

Second, AstraZeneca breached the agreement by:

- choosing not to use the all the manufacturing sites at its disposal to manufacture and deliver the vaccines to the Member States, especially the site located in the UK - quote: "AstraZeneca **intentionally** chose not to use the means at its disposal to manufacture and deliver the vaccines (…)" (p. 50, n° 46).
- prioritising the UK over the EU and thereby violating its warranty that it was not under any obligation that conflicts with the terms of the agreement with the EU - quote: "the delays can be explained by the obligations towards the UK prioritised by AstraZeneca, which substantially conflicted with the agreement with the EU and impeded the complete fulfillment thereof. Therebyn AstraZeneca has – apparently – **deliberately** breached its contractual warranty,

contained in Article 13.1(e) of the APA" (p. 51, n° 48).

Because of those breaches, AstraZeneca was ordered today by the Court of First Instance of Brussels to deliver to the EU and its Member States 50 million doses in three installments until September 27th with a 10 Euro penalty for each dose not delivered in due time. Quote: "In view of its behavior since the negotiations and the multiple aborted communications, one can fear that AstraZeneca will not comply with this judgment or, at least, not in a reasonable time to preserve the rights of the EU. It is justified to pair the aforementioned sentencing with a penalty. (…) To compel AstraZeneca to perform its obligations, we pair the sentencing with a penalty (…) of 10 € per missing dose at each deadline (…) Therefore, of AstraZeneca does not deliver any dose at each of the three deadlines, it will be liable towards the EU for a penalty of 500.000.000 €, this amount being the de facto cap of the penalty" (p. 63, nos 75 and 76).

What did the court decide on the question of the UK sites?

According to the Belgian judge, AZ committed a serious breach of the contract by not using the UK site, which should have been used as stipulated in the contract quote: "The choice to monopolize the Oxford Biomedica site for the UK and therefore to deprive the EU from a manufacturing site mentioned in the agreement is even more damaging that its yield is twice as high as the yield of Novsaep, Catalent and Halix (…).

In view of the magnitude of the delays experienced by AZ and the difficulties of the manufacturing sites of Novasep and Catalent a pharmaceutical company normally diligent and prudent placed under the same circumstances of a health crisis would not have deliberately chosen to deprive the European Union of all the supplies from the contractual manufacturing site with the highest yield – as AZ did" (pp. 50 and 51, n° 46).

Why is this interim order important?

The Court has laid the tracks for the delivery of future doses on the basis of clear contractual principles. The company will have to follow these tracks, and it can no longer argue that it cannot use the UK plants for the production of vaccines for the European Union. This is very important to scale up the production of the doses due under the contract. The Belgian Court will again hear the case on 24 and 29 September to assess whether the company has indeed respected these obligations.

The Court considered that it must be assumed that AstraZeneca will now comply with its contractual obligations, including the use of the Oxford Biomedica manufacturing site, but that should it fail to do so, this would be debated during the hearings scheduled in September quote: "Even if AstraZenca seems to have breached its obligations in the past, there is no evidence that after this judgment, AstraZenecea will continue to breach them and/or will refuse to take measures to remedy the breach in the future. We cannot decide anticipatory measures in emergency proceedings for breaches that are future and potential and for which no evidence exists that they will occur. This claim is premature. It is even more so that the parties will debate before the judge on the merits of the case relating to the delays in September 2021 and that the EU will have the possibility, on this occasion, to explain the potential breaches since this judgment" (pp. 64 and 65, n° 78).

What amount of doses actually has to be delivered now?

The contract remains fully in force, which means that AstraZeneca must make its best reasonable efforts to deliver all the remaining doses of the vaccine of the agreement as soon as possible. In this respect, AstraZeneca will have to abide by the contract as interpreted by the Court, and therefore also use the manufacturing site of Oxford Biomedica located in the UK. Should it fail to do so, a new order can be issued after the hearings of September (p. 64, n° 78).

Moreover, the Court has ordered AstraZeneca to deliver 50 million doses, which come on top of the 30,2 million doses which were delivered in the first quarter.

The doses delivered by AZ between the end of March and the date of the judgement will be taken into account. Anticipating on the court order, AstraZeneca has indeed already delivered more than 40 million doses since the end of March (on top of the 30 million doses delivered until end of March).

What did the European Commission not obtain from the Court?

The Court ordered AstraZeneca to urgently deliver 50 million doses of vaccine by 27 September 2021. The Commission had requested 90 million to be delivered by the end of Q2.

However, and more importantly, the Court has also laid the tracks for the delivery of future doses on the basis of clear contractual principles. The company will now have to follow these tracks, and it can no longer argue that it cannot use the UK plants for the production of vaccines for the European Union.

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