



## **Astra-Zeneca v EU – the vaccine row explained in straight forward terms**

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On 1 February, AstraZeneca told the EU that it would deliver around 50% of the 80 million COVID-19 vaccine doses that it had previously told the EU for the first quarter of 2021.

Teething problems at manufacturing facilities in Belgium have led to the delay. As Pascal Soriot, AstraZeneca's CEO, told a press conference last Friday, making a vaccine is "not like doing an orange juice".

The manufacture of the vaccine involves a complicated two-stage process. First, there is the production stage where the antigen drug substance must be produced in large quantities. It may need to be combined with other substances to make it more effective. Second, the finished vaccine needs to be put into vials and tubes. These different production processes take place at different facilities.

AstraZeneca has run into problems at its Belgian facility. The production of the vaccine antigen drug substance is lower than expected. AstraZeneca experienced similar issues at its UK facilities. However, AstraZeneca signed its supply agreement with the UK Government three months earlier than it did with the EU. This gave AstraZeneca time to sort out the manufacturing problems at its facilities in the UK. It expects to meet all its commitments in relation to supplying the UK Government.

However, the EU is now demanding that AstraZeneca take some of the vaccine it is manufacturing at its UK facilities and supply this to the EU to make up for the shortfall in the deliveries that the EU had expected in the first quarter of 2021.

The question arises, what are AstraZeneca's legal obligations towards the EU? On Friday, the EU published a redacted version of the contract that it has signed with AstraZeneca (available at the following link: [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_302](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_302)).

First, clause 18.4 states that the contract will be governed by the laws of Belgium.

In sum, there appear to be two legal issues that are of interest:

- (i) That AstraZeneca must use its "reasonable best efforts" to manufacture the vaccine;  
and
- (ii) Good faith – Belgian civil law imports a term that the parties must act in accordance with good faith and fair dealing.

### **Issue 1: AstraZeneca must use its reasonable best efforts to manufacture the vaccine**

Clause 5 (particularly clauses 5.1 and 5.4) – AstraZeneca must use its "reasonable best efforts" to manufacture the vaccine at sites within the EU. The UK is expressly stated to be part of the EU for the purposes of this clause and this clause only.

The term "reasonable best efforts" is one that is used in UK common law jurisdictions. It is a term quite familiar to Belgian lawyers and is generally assimilated to what is known as an "obligation of means" in Belgian law. In Belgian law, this means that generally the EU must prove negligence on the part of AstraZeneca in the manufacture of the vaccine, although AstraZeneca must cooperate in terms of providing evidence and leave no stone unturned, otherwise an adverse inference against AstraZeneca may be drawn. Based on publicly available information, there is nothing that suggests that AstraZeneca has been negligent. However, "reasonable best efforts" on the part of AstraZeneca is defined at clause 1.9(a) to take account of the need that the European Commission need this vaccine urgently. The EU therefore has an argument that AstraZeneca may have failed to use its "reasonable best efforts" by failing to build up adequate manufacturing capacity for the first quarter of 2021. The answer is not clear.

### **Issue 2: AstraZeneca must act in accordance with good faith and fair dealing**

There is no express duty in the contract that the parties must co-operate and perform their obligations in good faith. However, article 1134(3) of the Belgium Civil Code imports a term into all Belgian commercial contracts and states:

Good Faith and Fair Dealing

- (1) Each party must act in accordance with good faith and fair dealing.

(2) The parties may not exclude or limit this duty.

The Vienna Convention also likely applies as the Advanced Purchase Agreement is a qualifying contract between AstraZeneca AB, having a place of business in Sweden, and the European Commission, having a place of business in Belgium. The Vienna Convention also imports duties that the parties must act in good faith in performing their contractual obligations. The application of the duties of good faith arising under both Belgian law and the Vienna Convention is that the parties are required to collaborate and work together in achieving the objectives of the contract. This includes working together to overcome unforeseen contingencies. The concept of good faith in Belgian law is very complicated. There is some subjectivity as to what the duty of "acting in good faith" requires. The position is not clear cut.

The fact that AstraZeneca agreed at clause 5.1 that it would manufacture the vaccine at sites that included the UK creates an unwanted difficulty for AstraZeneca. There is an argument that some of the production at its UK facilities should be used to honour its commitment to provide vaccine to the EU where there are problems with production at its Belgian factory. This is even though:

- (i) AstraZeneca signed its agreement three months after the agreement that it signed with the UK; and
- (ii) the agreement Astra Zeneca signed does not specify when the doses should be delivered.

If the contract AstraZeneca entered into had specified the laws of England and Wales applied, it is unlikely any duty of good faith and fair dealing would have been implied into the contract.

Only time will tell how this dispute plays out.

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