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Memo

Date:	17 August 2020
To:	Steven Hippe
From:	Christel Brion, Kathleen De hornois en Hendrik Viaene
Subject:	Advance Purchase Agreement on COVID-19 vaccines - AstraZeneca

VERTROUWELIJK & GEPRIVILEGIEERD
CORRESPONDENTIE ADVOCAAT-CLIËNT

Beste Steven,

In navolging van onze eerste bemerkingen op de draft Advance Purchase Agreement dat zou worden gesloten met AstraZeneca, kan u hieronder onze verdere uitgewerkte commentaren vinden.

Met vriendelijke groeten,

Christel Brion, Kathleen de Hornois en Hendrik Viaene

Article number	Comments	Suggested alternative wording
Art. 1.17	'Defect' is interpreted pursuant to art. 6 of the EU Product Liability Directive. For clarity's sake, it could be beneficial to also refer to the Belgian provisions regarding product liability.	"Defect" means the characteristic of a product that does not provide the safety which a person is entitled to expect taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation, in each case as such term is interpreted consistently with the term "defective" under Article 6 of the EU Product Liability Directive 85/374/EEC and the provisions of the Belgian law of 25 February 1991 on the liability for defective products.
Art. 5.1	Article 5.1 lists a schedule of quantities and time of delivery. Public information points to vaccines being available by end of Q2 2021 at the earliest. We assume that there are good reasons to expect that the foreseen delivery schedule will be respected. However, the APA does not provide for sanctions when the delivery dates and quantities are not respected: • Is it a breach of contract which will warrant termination (with compensation for the member states) (Art. 12.3); or • Will it merely imply the time table being pushed backwards, but a continuing obligation on the member states to acquire the quantities ordered, regardless of when they will be delivered and whether at that point in time there is still a need for the vaccine? – that seems to be the consequence of Article 12.1 where the term of the agreement is until delivery of the Additional Doses, if ordered. (Art. 8.2	

Article number	Comments	Suggested alternative wording
	only mentions the possibility to suspend payment in case of non-delivery or late delivery past the firm delivery date by AstraZeneca.)	
Art. 6.1	Article 6.1 requires Belgium to assist AZ in being able to timely supply the Initial Europe Doses. This may for example encompass delivery of vials or other materials. We know from other files that Belgium struggled (as did many other member states and third countries) to find sufficient supplies of certain materials during the first wave. It is unclear whether Belgium will want to commit to such a Best Reasonable Effort for these materials under this contract (sanction appears to be limited and difficult to prove no Best Reasonable Effort) as it may be struggling again in the future to find sufficient materials.	
Art. 6.2 Capacity limitations	The interplay with other vaccine APAs should be carefully considered. It is also difficult to judge Belgium's liability/responsibility under this clause. This is the Commission's responsibility, but at the same time Belgium will bear the consequences if the APA is then terminated or executed later/for lower quantities. Another issue that may be important are the agreements AZ will conclude with third countries. It is assumed that sufficient quantities will be in place? It may be warranted to include a sanction for AZ if it is unable to comply with its contract obligations as a result of supply agreements with third countries.	
Art. 7.6 (b)	[redacted]	
Section 8, Delivery	Art. 8.1, states that delivery at each Distribution Hub will occur [redacted]	

Article number	Comments	Suggested alternative wording
	[redacted] [redacted] There seems to be no conformity assessment procedure in place. Once the products have been delivered to the Distribution Hubs, what is the procedure for verification of conformity?What happens in the event of non-conformity of the Vaccine (to product specifications)? Does this fall under "material breach", cfr. Art. 12.3?	
Art. 8.5	Please consider the practical feasibility of these delivery terms.	
Art. 12.1	See commentary art. 5.1	
	The Agreement does not contain specific wording with respect to the contractual consequences of a scenario where a recall of (certain batches of) the Vaccine would be ordered at a certain point in time by EMA/a Regulatory Authority such as FAGG, or the event where AZ's marketing authorization would be revoked, for instance if post-launch safety and risk management studies would show that there are safety or efficacy concerns (EMA can indeed recommend the withdrawal of centralized EU marketing authorizations to the European Commission which then issues a	

Article number	Comments	Suggested alternative wording
	decision which is legally binding to the member states).	
Art. 12.2(a)	No strict criteria for Abandonment seem to be included – it seems to be a "unilateral" option for AZ.	
Art. 12.2(b)	Grounds for Commission termination based on Abandonment are very limited. • It could be considered to give the initiative under Article 12.2(a) not only to AZ, but also to the Commission, if it feels that the project better be abandoned. • One could also expand the scope of this clause to also include other scenarios, such as the situation where an EU marketing authorization is granted but subsequently withdrawn – wording may be as follows:	12.2 (b) In addition, the Commission can terminate this Agreement at any time if: • AstraZeneca reasonably determines that the ongoing or planned clinical trials by AZ and its partners are not likely to be sufficient for approval of the Vaccine as set out in Section 10.2 of this Agreement, or • further to submission by AstraZeneca for regulatory approval of the Vaccine, the regulatory approvals for the Vaccine are not granted, or the regulatory approvals for the Vaccine are subsequently withdrawn, or • a recall of the Vaccine is ordered.
Art. 14.1	The indemnification by the Member States is extremely broad. Member States will have to hold AZ harmless in case of Third Party Claims. [redacted] [redacted].	[redacted]

Article number	Comments	Suggested alternative wording
Art. 14.2	[redacted]	
Art. 15.1	[redacted] Art. 8.1 provides that the delivery at each Distribution Hub will occur [redacted]	

Article number	Comments	Suggested alternative wording
	[redacted]	
Art. 15.2	[redacted]	
Art. 18.7	This clause is defined in a very broad way and also refers to "epidemics", "shortages" and "quarantines". It would be advisable to expressly exclude COVID-19 from the situations in which force majeure can be invoked. COVID-19 Pandemic is defined in Article 1.16 so arguably this should not fall under the wording "epidemics", "quarantines" and "shortages".	
/	Shall the Parties conclude a separate quality agreement? (Also see Section 8. Delivery and the lack of a conformity assessment procedure therein)	