

1.15. "Cost of Goods" [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

1.16. “COVID Pandemic” has the meaning given in the recitals.

1.17. “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.

[REDACTED]

(b) To the extent that the total Cost of Goods exceed [REDACTED], AstraZeneca shall provide an updated purchase and payment schedule to the Commission, which shall state the delivery schedule of the Initial Europe Doses and the corresponding amounts payable by the Participating Member States, [REDACTED]

(c) If AstraZeneca becomes aware that the estimated Cost of Goods are reasonably expected to exceed [REDACTED] then AstraZeneca shall notify the Commission of such excess and provide the relevant evidence in this respect. Following such notice, AstraZeneca and the Commission shall agree to a payment or other mechanism which will result in AstraZeneca supplying the Participating Member States with a number of Doses without incurring a loss. Such mechanism may include a reduction in the number of Doses and/or a further increase in Price Per Dose.

(d) If following the finalization of the matters contemplated hereby, documentary evidence provided by AstraZeneca indicates that the Cost of Goods for the Initial Europe Doses sold is less [REDACTED]

[REDACTED]

(i) ensure the transfer of all purchased vials and stoppers to the Commission (or its designee) to be repurposed;

(ii) assign the Commission (or its designee) all purchased or reserved drug product manufacturing capacity from the applicable CMO (to the extent permitted by the agreement between AstraZeneca and such CMO); and

(iii) return to the Commission (or its designee), within thirty (30) days after the date of termination of this Agreement, any portion of the Funding that is unspent, if any, after deducting all expenses incurred by AstraZeneca including any non-cancellable expenses relating to the activities under this Agreement.

(d) [REDACTED]

Without prejudice to the indemnification rights of AstraZeneca and the other Indemnified Persons under Article 14, no additional compensation shall be claimed from the Commission or any Participating Member State for any damages AstraZeneca might incur due to the termination.

12.3. Termination for cause.

The Commission on behalf of the Participating Member States may terminate this Agreement in the following circumstances:

(a) if AstraZeneca is in material breach of its obligations (considered as a whole) of this Agreement following notice and an opportunity to cure as set forth below;

(b) if the contractor or any person that assumes unlimited liability for the debts of the contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation³;

³ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046>