

Critical EU-Pfizer Agreement Leaked

Advanced Purchase Agreement for COVID-19 Vaccines for EU Member States

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Italian activists sent me the signed November 2020 Advance Purchase Agreement (APA) between the EU member states and Pfizer/BioNTech. This appears to be genuine, but has not been independently verified.

The 59 page contract and the 45 pages of attachments can be found [here](#).

Due to the vast amount of information in this document, I am not going to try to analyze it all today. In fact, I am hoping that my readers, other reporters, attorneys and analysts will help with this task. I do ask (not required in any way) that if you write up your results and want to link the document, that you link back to the Malone Institute landing page and the PDF documents found there.



EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT (“APA”)¹ for the development, production, priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member States

SANTE/2020/C3/043 - SI2.838335

Please use this document responsibly – I have not altered anything in it.

Rather than try to recreate what is in the document, please read for yourself. Over the course of time, expect more analysis.

Quoted text directly from the Agreement:

1.1.1 Quality tests and checks The Contractor shall perform all bulk holding stability, manufacturing trials, validation (including, but not limited to, method, process and equipment cleaning validation), raw material, in-process, bulk finished product and stability (chemical or microbial) tests or checks required to assure the quality of the Product and tests or checks required by the Specifications and Good Manufacturing

11.6.4 Limits on liability

(i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that the Contractor and its Affiliates cannot be held liable for any damages except for proven damages which are suffered by the Commission or the Participating Member States as a direct consequence of a breach by the Contractor or its Affiliates of its obligations under this APA or a Vaccine Order Form, and that the Contractor and its Affiliates shall in any case not be liable for late deliveries (subject to the Contractor's obligation to use Best Reasonable Efforts as contained in Article 1.6.3), loss of revenue, loss of anticipated savings, loss of business, loss of profit, loss of goodwill, reputational damages, losses from economic disruption or cost of alternative supply.

11.6.4 No limitation of liability

(i) Nothing in this APA excludes or limits the liability of either party for:

(a) wilful intent, fraud or fraudulent misrepresentation;

(b) any breach of Article 11.9 (Confidentiality);

(i) Nothing in this APA excludes or limits the liability of either party for:

(a) wilful intent, fraud or fraudulent misrepresentation;

(b) any breach of Article 11.9 (Confidentiality);

(1.12.1) The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this APA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. Hence, each Participating Member State shall indemnify and hold harmless the Contractor, their Affiliates, sub contractors, licensors and sub-licensees, and officers, directors, employees and other agents and representatives of each (together, the "Indemnified Persons") from and against any and all liabilities incurred, settlements as per Article I.12.6, and reasonable direct external legal costs incurred in the defence of Third Party Claims (including reasonable attorney's fees and other expenses) relating to harm, damages and losses as defined in Article I.12.2 (together, the "Losses") arising from or relating to the use and deployment of the Vaccines in the jurisdiction of the Participating Member State in question.

1.12.8 The parties explicitly agree that:

(i) any warranties given by the Contractor, whether express or implied, under this APA as regards compliance with Good Manufacturing Practice or conformity of the Product with the Specifications shall be without prejudice to the provisions of this Article I.12, which shall apply independently of and prevail over such warranties, including any (claimed) breach of such warranty; and

a Participating Member State does not have the right to suspend and/or otherwise not perform its obligations under this clause

except where the Participating Member State puts forward reasonable evidence that one of the situations listed in this Article I.12.1(i) and (ii) is applicable and the matter is brought for dispute resolution under Article I.13

ANNEX III: PARTICIPATING MEMBER STATES

Germany France Italy Spain Austria Greece Cyprus Malta Denmark Sweden Finland Ireland Portugal Belgium Luxembourg Netherlands Poland Romania Bulgaria Slovenia Croatia, Czech Republic Hungary Slovakia Lithuania Latvia Estonia

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