

EN
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Answer given by Ms Lahbib
on behalf of the European Commission
(27.8.2025)

The (Advance) Purchase Agreements for the supply of COVID-19 vaccines were neither negotiated nor signed independently. The negotiations were concluded in full transparency with the Member States and carried out by a Joint Negotiation Team¹. This team reported regularly to a Vaccines Steering Board co-chaired by the Commission and a Participating Member State, which provided guidance. When the final text of the contract was negotiated, the signature was executed by the Commissioner in charge, not independently, but after approval by the College. Therefore, the process was based on a joint effort and collective decision-making, both in the negotiation and the signature of the contracts.

The first COVID-19 vaccines were granted a conditional marketing authorisation (CMA), a specific type of marketing authorisation to facilitate access to medicines that fulfil an unmet medical need, including in emergency situations such as the COVID-19 pandemic, whilst a comprehensive data dossier is not yet available. It allows regulators to authorise such medicines as soon as sufficient data demonstrate that the medicine's benefits outweigh its risks, with robust safeguards and controls in place post-authorisation: the marketing authorisation holder must fulfil specific obligations (e.g. conduct further studies and provide more data to confirm efficacy or safety) within defined timelines. CMAs are valid for one year and can be renewed annually. If the specific obligations are fulfilled, CMAs can be converted in full marketing authorisation, as it happened for COVID-19 vaccines.

The updated product information² and assessment reports³ of COVID-19 vaccines have always been made timely publicly available.

¹ Joint Negotiation Team consisted of the Commission and of several Member States:
https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_1662.

² https://ec.europa.eu/health/documents/community-register/html/index_en.htm.

³ <https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when/european-public-assessment-reports-background-context>.