

**Lines to take on testing AstraZeneca**

Commission to the Members of the Steering Board

08 September 2020

Please find below some lines to take from the Commission regarding today's press articles on the AstraZeneca clinical trials:

- The Commission is of course following this very closely. We remain in very close collaboration with the European Medicines Agency as they analyse the current state of play in detail.
- It is important to note that the postponement of clinical trials in this instance is **something that could normally happen in any clinical trial and a single event is not sufficient for drawing any firm conclusion.**
- While a vaccine represents the surest exit strategy from the COVID-19 pandemic, the safety of citizens is the top priority. The Commission would never compromise on this nor would it cut any corners with regards to the information that needs to be submitted regarding both safety and efficacy, or with the time required to ensure this in clinical trials.
- Safety is a fundamental requirement for any vaccine to reach EU markets. Before being made available for purchase and use, any COVID-19 vaccine candidate will need to meet the requirements and evidence thresholds of the European Medicines Agency's scientific assessment to receive market authorisation. It is clear that if serious side effects are detected, the vaccine will not be made available for use in the EU.
- Moreover, comprehensive arrangements are in place to monitor the vaccine after market authorisation.
- The Commission remains committed to investing in a diverse and broad portfolio of vaccine candidates, built with diversified technologies and platforms to ensure the best possible chance of finding a safe and effective vaccine, which will be key to put an end to this unprecedented health crisis.