EN E-001294/2021 Answer given by Ms Gabriel on behalf of the European Commission (4.5.2021)

Clinical studies are key to identify safe and efficacious treatments. The ERAvsCORONA action plan stresses the need for large EU-wide clinical trials for management of COVID-19 patients¹. As part of Europe's research response², EU-funded clinical trial networks have been established³ and have already successfully identified novel treatments⁴ and treatments that initially seemed promising but were found not to be beneficial⁵. Information on treatment development, evaluation and authorised treatments is systematically collected and provided by the European Medicines Agency⁶.

Medicinal product information is provided via a Summary of Product Characteristics, an annex to the product's marketing authorisation available and published for all authorised medicines to treat COVID-197. It contains information on medicine use, includes contraindications, warnings and precautions for use and side effects. While marketing authorisation requirements and procedures for medicinal products have been harmonised in the EU, treatment guidelines and protocols are the competence of the Member States.

The Commission is concerned about the impact of COVID-19 on the health and wellbeing of persons in long-term care. The Coronavirus Response Investment Initiatives⁸ allowed for great flexibility in the use of the European Regional Development Fund and the European Social Fund, including to support operations to limit the spread of the virus in long-term care residencies, and promote the development of homecare and community-based services as a less risky alternative, in line with the general policy in favour of independent living. The Recovery Assistance for Cohesion and the Territories of Europe provides for additional resources⁹

¹ https://ec.europa.eu/info/sites/info/files/covid-firsteravscorona actions.pdf

 $^{^2\} https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en$

³ https://ec.europa.eu/info/news/commission-supports-international-clinical-research-network-treat-covid-19-2020-sep-18_en

⁴ https://ec.europa.eu/info/news/eu-funded-clinical-trial-finds-new-treatments-be-effective-against-covid-19-2021-jan-08 en

⁵ <u>https://eu-response.eu/results/</u>

⁶ https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-treatments

⁷ https://ec.europa.eu/health/documents/community-register/html/

⁸ https://ec.europa.eu/regional_policy/en/newsroom/coronavirus-response/

⁹ https://ec.europa.eu/regional_policy/en/newsroom/coronavirus-response/react-eu