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Committee for Medicinal Products for Human Use

# A call to pool EU research resources into large-scale, multi-centre, multi-arm clinical trials against COVID-19

The World Health Organization (WHO) declared a COVID19 pandemic on 11 March 2020, for which no specific vaccine or treatment is currently authorised in the European Union (EU). With a daily increasing number of people being hospitalised and needing treatment, it is essential that Member States (MSs) in Europe implement a harmonised and robust methodology for data collection. The Committee for Medicinal Products for Human Use (CHMP) is aware that several hospitals and academic institutions are planning to start investigational studies locally or to treat patients as matter of urgency under compassionate use protocols or similar emergency protocols.

The CHMP, after having discussed the current situation, considers it critical to generate robust and interpretable evidence that would allow prompt definition of which investigational or repurposed medicinal products are effective and safe for the treatment of COVID-19. Randomised controlled studies with a control arm without antivirals or other experimental agents, as none yet has proven efficacy, would allow generation of data that could lead to timely regulatory decisions and could promptly guide clinicians in defining best treatment options for COVID-19. Such studies need to be prioritised, considering that they would allow the best use of available supply of investigational agents.

The CHMP is concerned about the amount of planned small studies or compassionate use programmes across Europe that are unlikely to be able to generate the required level of evidence to allow clear-cut recommendations. Such studies would not be in the best interests of patients.

Multi-arm clinical trials investigating different agents simultaneously have the potential to deliver results as rapidly as possible across a range of therapeutic options according to the same evaluation criteria. This concept has been developed for COVID-19 by institutions in the EU and by WHO and is generally supported. It would be important that all EU countries are considered for inclusion in such trials.

While it appears that COVID-19 is mainly affecting older adults with cardiovascular or respiratory co-morbidities, it is acknowledged that the paediatric population is also affected. It is therefore supported that at least adolescent subjects be considered for inclusion in the large adult clinical trials. Coordinated studies of adequate size to inform on safety and pharmacokinetics in the paediatric population should be conducted.

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The European Medicines Agency (EMA) is engaging with different stakeholders and can further support clinical trial sites in MSs to liaise with study sponsors.

It is therefore strongly recommended that a more coordinated approach across the EU is pursued and that efforts are put in place to prioritise larger multi-country randomised clinical trials (RCTs) that have the potential to generate confirmatory evidence.