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Press release

EMA to support development of vaccines and treatments for novel coronavirus

To contribute to the global response to the outbreak of the novel coronavirus (2019-nCoV) infections, EMA is taking concrete actions to accelerate the development and availability of medicinal products for the treatment and prevention of the new coronavirus.

"EMA has activated its plan for managing emerging health threats," says Guido Rasi, the Agency's Executive Director. "The new coronavirus has been declared a public health emergency of international concern by the World Health Organization, and we are drawing on the strong expertise of the European medicines network to provide fast-track scientific advice and give prompt feedback on any proposed medicine developments."

The Agency is surveying the landscape for potential antivirals or vaccines to treat or prevent novel coronavirus infections. EMA is also analysing all available information on developers' drug pipelines. As with any emerging public health threat, EMA collaborates and exchanges information with EU public health authorities, notably the European Commission, the Health Security Committee and the European Centre for Disease Prevention and Control (ECDC), the World Health Organization and other international regulators, in particular through the International Coalition of Regulatory Authorities (ICMRA).

There are currently no commercially available medicinal products that are authorised to detect, treat or prevent infections with the novel coronavirus. EMA is ready to support medicine developers with all available regulatory tools to advance and expedite the development of effective measures to fight and prevent the spread of this virus.

Developers working on medicinal products or vaccines that could be used for treatment or prevention of novel coronavirus 2019-nCoV infections are encouraged to contact the Agency and discuss their strategy for evidence generation as soon as possible. They can contact EMA by sending an email to 2019-nCoV@ema.europa.eu for initial discussions with EU regulators.

The 2019-nCoV identified in Wuhan, China in December 2019 is a new strain of coronavirus that has not been previously seen in humans. Although the most likely primary source of this outbreak is of animal origin, human-to-human transmission is confirmed and investigations are ongoing to determine all sources and modes of transmission of the 2019-nCoV virus. Cases have now been detected in



several countries in Asia, Australia, Europe and North America. Further global spread is likely. EU authorities will provide further updates as more information becomes available.

EMA published more information on the novel coronavirus on its <u>website</u> that also lists the Agency's efforts in response to this outbreak and provides key information on processes and procedures in place to help developers.

Notes

- 1. This press release, together with all related documents, is available on the Agency's website.
- 2. EMA has a range of support measures that can help to facilitate and speed up the development of medicines, which include scientific advice, the PRIME scheme, the accelerated assessment, and conditional marketing authorisation procedures.
- 3. The epidemiological situation in relation to the outbreak is monitored by the ECDC who is providing regular risk assessments and situation updates (https://www.ecdc.europa.eu/en/novel-coronavirus-china).
- 4. For more information on the EU's response on coronavirus 2019-nCoV see: https://ec.europa.eu/health/coronavirus en

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