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Press release

European medicines regulatory network fully mobilised in fight against COVID-19

The development and availability of medicines and vaccines for all patients in the European Union, including those with COVID-19, is the number one priority for the <u>European medicines regulatory</u> <u>network</u>. EMA, together with EU Member States and the European Commission, has published a <u>plan</u> outlining principles for how the network will ensure that core public and animal health regulatory activities, such as the authorisation, maintenance and supervision of human and veterinary medicines will continue to be carried out during the ongoing COVID-19 pandemic.

This includes, in the first instance, procedures related to potential treatments for COVID-19 and vaccines against the virus, those related to medicines needed to treat COVID-19 patients (including crucial medicines used in intensive care units) and procedures to minimise shortages due to COVID-19. The plan also ensures that the EU regulatory system continues to address all other patients' needs. It therefore sets out how the assessment of non-COVID-19-related medicines will be undertaken during the COVID-19 pandemic, especially when challenges are encountered, for example, with the unavailability of experts due to illness or the need to look after family members.

The plan aims to support the continued functioning of the network as a whole through a consistent approach for all medicines, irrespective of whether they are centrally or nationally authorised.

It includes how Member States could provide back-up for each other, if the disruptions caused by COVID-19 affects their ability to carry out assigned assessments.

Under no circumstances can the assessment of medicines used to treat or prevent COVID-19 be delayed, and Member States must consider their resources and capacity, when putting themselves forward to deal with such an assessment on behalf of the EU.

Delays to the assessment of non-COVID-19-related medicines must also be mitigated as far as possible. Should delays occur for a non-COVID-19 procedure, these will be dealt with according to the details set out in the annexes. Details for medicines subject to the centralised authorisation procedure are outlined in Annex 1 of the document. Arrangements for nationally authorised human medicines are described in Annex 2 and those specific to nationally authorised veterinary medicines are outlined in Annex 3.

More details are provided in the plan, which will be reviewed regularly and revised as needed. EMA and the network will provide further updates and guidance on its implementation as necessary.



An agency of the European Union

Notes

- 1. This press release, together with all related documents, is available on the Agency's website.
- 2. The European medicines regulatory network is the network of national competent authorities of the EU Member States, and of the European Economic Area (EEA) working together with EMA and the European Commission.
- 3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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