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Press release

EMA establishes task force to take quick and coordinated regulatory action related to COVID-19 medicines

As part of its health threat plan activated to fight COVID-19, the Agency has finalised and published the composition and objectives of its COVID-19 EMA pandemic Task Force (COVID-ETF), which assists Member States and the European Commission in dealing with development, authorisation and safety monitoring of therapeutics and vaccines intended for treatment or prevention of COVID-19.

The main purpose of the COVID-ETF is to draw on the expertise of the European medicines regulatory network and ensure a fast and coordinated response to the COVID-19 pandemic. The task force is accountable to EMA's human medicines committee (CHMP) for all its activities. Strict rules are in place to assure the independence of all members.

The COVID-ETF is chaired by EMA and composed of the chair and vice-chair of the CHMP, the Agency's safety committee (PRAC), the Paediatric Committee (PDCO) and relevant working parties, as well as the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and the Clinical Trials Facilitation and Coordination Group (CTFG). It will include CHMP rapporteurs and co-rapporteurs for all COVID-19 medicines and vaccines, as well as additional experts as needed, including those involved in the review of applications received at national level. Additional observers will be invited on a case-by-case basis.

As stated in its mandate, the COVID-ETF will, among others:

- review the available scientific data on COVID-19 medicinal products and identify promising candidates;
- request data from developers and engage with them in preliminary discussions;
- offer scientific support in collaboration with the CTFG to facilitate clinical trials conducted in the EU for the most promising medicinal products for COVID-19;
- provide feedback on development plans of COVID-19 medicinal products when formal rapid scientific advice is not feasible;

- act as advisor to the Scientific Advice Working Party (SAWP) or the CHMP for formal scientific advice and product-related assessment and contribute to the PRAC activities on emerging safety issues related to COVID-19;
- ensure close cooperation with stakeholders and relevant European and international organisations.

The composition and rules of procedure of the COVID-ETF are detailed in the group's mandate.

EMA developed a health threats plan to describe how the Agency, together with the European medicines network, plans for, responds to and communicates on serious health threats. The health threat plan builds on the experience from the 2009 influenza H1N1 pandemic and includes experience gained since then in responding to emergencies such as the Ebola outbreak in Western Africa in 2014-2016.

As part of this plan, specific expert groups such as the EMA task force and scientific advisory groups can be swiftly convened to assist EMA's scientific committees or take part on behalf of the scientific committees in early scientific discussions and medicines' reviews.

In the context of the COVID-19 pandemic, the mandate of the EMA task force has been revised to adapt to the unprecedented challenges and specificities of the ongoing health threat crisis and to better support the regulatory activities and public health needs of the Member States and the European Commission during this pandemic.

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