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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines

The European Medicines Agency (EMA) together with the responsible scientific committees and their working parties, and in collaboration with the European Commission, operates rapid procedures to support the development and evaluation of treatments and vaccines for COVID-19. The EMA emerging health threats plan foresees that detailed procedures are set-up to adapt different types of review activities to the needs of the health threat/crisis situation. Whilst respecting the regulatory requirements and established review principles (e.g. independence of experts), these procedures aim, within timelines that are appropriate for the public health emergency situation, to provide most efficient management of product-review activities leading to scientifically sound and robust outcomes.

The EMA Emergency Task Force (ETF)[2], coordinates and enables fast regulatory action on the development, authorisation and safety monitoring of treatments and vaccines intended for the treatment and prevention of COVID-19. Working with the best experts from within the EU regulatory network, the ETF's activities include providing guidance on development plans of COVID-19 medicines when formal scientific advice is not yet feasible, advising the Committee for Human Medicinal Products (CHMP) on formal scientific advice (rapid or regular – see section 1) and, ultimately, on product-related assessments, including those on a rolling basis. For such formal development support and evaluation activities rapid procedures have been established. These procedures are available for products intended for prevention or treatment of COVID-19, including both new products and products already authorised in other conditions.

This document provides an overview of EMA's rapid formal review procedures related to COVID-19 and is mainly intended as procedural guide for developers. It complements other documents published under the guidance for medicine developers and companies on COVID-19 and the respective guidance provided for regular procedures published on the EMA website for research and development and for marketing authorisation.

EMA's rapid formal review procedures related to COVID-19 are outlined in the following sections:

1. Rapid scientific advice
2. Rapid agreement of a paediatric investigation plan and rapid compliance check

[1] Revision 4 includes updates arising from entry into force of Regulation (EU) 2022/123, in particular concerning the ETF and its role, and updated contact details.
[2] Before current ETF according to Regulation (EU) 2022/123 came into operation in April 2022, COVID-19 EMA pandemic Task Force (COVID-ETF) was operating under EMA's emerging Health Threats Plan.

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