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EMA Fast-Tracking Procedures for COVID-19 Medicines

The European Medicines Agency (EMA) has published an overview of initiatives for acceleration of the regulatory procedures. This is aimed at making COVID-19-related medicines' marketing authorisation available in the shortest possible timeframes.

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To support the development and evaluation of treatments and vaccines for COVID-19, the EMA emerging health threats plan allows for adaptation of different types of review activities to the needs of the health threat/crisis situation. This is expected to optimise the management of product-review activities while upholding scientific standards.

The accelerated review of potential COVID-19 treatments and vaccines is supported by the COVID-19 EMA pandemic Task Force (COVID-ETF), which will advise the Scientific Advice Working Party (SAWP) and the Committee for Human Medicinal Products (CHMP) on co-ordination of activities related to the development, authorisation and safety monitoring of COVID-19-related medicines.

In this regard, specific rapid procedures have been established for both new products and products already authorised in other conditions. The overview of these procedures, intended as procedural guide for developers, complements other documents published under the guidance for medicine developers and companies on COVID-19 and the respective guidance provided for regular procedures (research and development and marketing authorisation).

While acknowledging the importance of such adjustments during the COVID-19 public health emergency, EMA Executive Director Guido Rasi noted that "the rapid approval of therapeutics and vaccines will only be possible if applications are supported by robust and sound scientific evidence that allows the EMA to conclude on a positive benefit-risk balance for these products."

The overview of EMA's rapid formal review procedures related to COVID-19 includes the following:

1. **Rapid scientific advice** – a procedure, which follows the general principles of the regular scientific advice but is adapted to accelerate COVID-19-related research (eg with flexibility in type and extent of the briefing dossier, waiving fees for scientific advice or reduction of the procedure to 20 days instead of 40-70).

2. **Rapid agreement of a paediatric investigation plan and rapid compliance check** – review time is reduced to 20 days instead of up to 120 days, and compliance check in advance of a marketing authorisation application can be reduced to 4 days if necessary.

3. **Rolling review** – another special procedure, which allows the EMA to assess data for a promising medicine on a rolling basis, ie while development is still ongoing. There can be several rolling review cycles with each cycle normally requiring a two-week review.

4. **Marketing authorisation** – the applications will be treated in an expedited manner with a possibility of a rolling review.

5. **Extension of indication and extension of marketing authorisation** – the application of the abovementioned measures for already authorised products that are being developed (repurposed) for treatment or prevention of COVID-19.

6. **Compassionate Use** – while such programmes remain competence of the national authorities, EMA can provide through the CHMP recommendations for a 'group of patients' on a medicinal product eligible to the centralised procedure.

7. **Other considerations** (eg Priority medicines (PRIME) scheme).

Source: European Pharmaceutical Review

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