EUROPEAN MEDICINES AGENCY
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Press release

COVID-19: how EMA fast-tracks development support and approval of medicines and vaccines

As researchers race to develop vaccines and therapeutics against COVID-19, EMA has published an overview of how the Agency will accelerate its regulatory procedures so that marketing authorisations of safe, effective and high-quality COVID-19 related medicines can be granted as soon as possible. The rapid procedures described in the inventory can accelerate every step of a medicine's regulatory pathway and the Agency is fully mobilised to deliver these fast-track assessments in the shortest possible timeframes while ensuring robust scientific opinions are reached.

"Supporting the development and marketing authorisation of safe, effective and high-quality therapeutics and vaccines as soon as possible is one of EMA's top priorities in the COVID-19 public health emergency. Together with our scientific committees and working parties, we have adapted our procedures in order to significantly shorten our own regulatory timelines for the review of new medicines and vaccines against COVID-19," said Executive Director Guido Rasi. "However, the rapid approval of therapeutics and vaccines will only be possible if applications are supported by robust and sound scientific evidence that allows EMA to conclude on a positive benefit-risk balance for these products."

These 'rapid' procedures stem from EMA's emerging health threats plan. The flexible and fast review of medicines is supported by **EMA's pandemic Task Force (COVID-ETF)**, which brings together in one group the best scientific experts from the EU regulatory network. It will work closely with EMA's human medicines committee (CHMP) for optimal and fast coordination of activities related to the development, authorisation and safety monitoring of medicines and vaccines against COVID-19.

Accelerated support during research and development

For products under development, in early stages and/or before the submission of a marketing authorisation application, mechanisms put in place by EMA include:

- **Rapid scientific advice**, through which developers can receive prompt guidance and direction on the best methods and study designs to generate robust data on how well a medicine or vaccine works, how safe it is, as well as on the manufacturing and control process to establish

its quality. In the context of COVID-19, fees for scientific advice are waived and the procedure is reduced to a maximum of **20 days**, compared to normally 40-70 days.

- **Rapid agreement of paediatric investigation plans (PIPs) and rapid compliance check**. The total review time for a PIP for COVID-19 products will be reduced to **20 days**, compared to normally up to 120 days active review time. In case needed, EMA also carries out a check to ensure companies comply with the agreed measures listed in each PIP before a marketing authorisation can be submitted, which will now also be reduced to **4 days**.

All these accelerated mechanisms will require developers to submit well-prepared dossiers to EMA. The Agency therefore continues to encourage developers of vaccines or therapeutics against COVID-19 to make contact as soon as possible, to discuss their strategy for evidence-generation, by emailing 2019-ncov@ema.europa.eu. Depending on the maturity of the development, initial discussions on the various mechanisms to fast-track development and approval will take place, with priority given to the most relevant proposals.

Accelerated evaluation in authorisation and post-authorisation procedures

According to the EU pharmaceutical legislation, the standard timeline for the evaluation of a medicine is a maximum of 210 active days. However applications for marketing authorisation for COVID-19 products will be treated in an expedited manner:

- **Rolling review**. This procedure, used in a public health emergency, allows EMA to assess data for a promising medicine as they become available on a rolling basis. Under normal circumstances, all data supporting a marketing authorisation application must be submitted at the start of the evaluation procedure. In the case of a rolling review, CHMP rapporteurs are appointed whilst development is still ongoing and the Agency reviews data as they become available. Several rolling review cycles can be carried out during the evaluation of one product as data continue to emerge, with each cycle requiring around **two weeks**, depending on the amount of data to be assessed. Once the data package is considered complete, a developer submits a formal marketing authorisation application to EMA which is then processed under a shortened timetable.
- **Accelerated assessment**. This procedure can reduce the review time of products of major interest for public health from 210 days to less than 150 days. In practice, where there is an urgent public health need, assessment timelines will be reduced to the absolute minimum.
- EMA is ready to apply further flexibility, where it is established that shortening of any other procedural step could have an important public health impact in dealing with the COVID-19 pandemic.

The various rapid procedures are also available in the context of extensions of indications for already approved medicines, which are being repurposed in the fight against COVID-19.

The inventory also describes the support EMA can provide in the context of **compassionate use** programmes. Such programmes are set up at the level of individual EU Member States, to give patients access to treatments that are still under development and that have not yet received a marketing authorisation. EMA can provide scientific recommendations as to how these medicines should be used in this context, to support a harmonised EU-wide approach.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Information on EMA's contribution in the COVID-19 pandemic is available here.

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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