REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press Release

EMA receives application for marketing authorisation of Dexamethasone Taw for COVID-19

EMA has started evaluating an application for the authorisation of Dexamethasone Taw for treating hospitalised adult patients with COVID-19. The application, from Taw Pharma, will be evaluated by EMA's human medicines committee (CHMP) according to an accelerated assessment timetable. This will enable the CHMP to issue an opinion on the benefits and risks of Dexamethasone Taw within the shortest possible timeframe.

In July 2020, published results from the RECOVERY trial found that in patients receiving hospital treatment for severe respiratory complications of COVID-19, there were fewer deaths in those treated with dexamethasone. In patients on invasive mechanical ventilation, 29% of those treated with dexamethasone died within 28 days of starting dexamethasone treatment compared with 41% of patients receiving usual care, a relative reduction of about 35%. In patients receiving oxygen without mechanical ventilation, the figures were 23% with dexamethasone and 26% with usual care. No reductions in death occurred in patients who were not receiving oxygen therapy or mechanical ventilation.

Before receiving this application, the CHMP had started reviewing the results of the RECOVERY trial in order to provide an opinion on the use of dexamethasone medicines for COVID-19. The outcome of this review will be considered in the evaluation of Dexamethasone Taw.

Should the available data show that the benefits of Dexamethasone Taw outweigh its risks in the treatment of hospitalised adults with COVID-19, EMA will issue a positive recommendation on the medicine's new use in patients with

COVID-19. The agency will then liaise with the European Commission to fast-track the authorisation.

Dexamethasone medicines have been authorised for several decades for treating various conditions on the basis of their anti-inflammatory properties. This application has no impact on the use of other dexamethasone medicines.

More about the medicine

Dexamethasone Taw is being developed as a hybrid medicine. This means that it is similar to a 'reference medicine' (in this case Fortecortin Inject) containing the same active substance, but differs in certain respects, such as strength, use or pharmaceutical form. Like Fortecortin Inject, Dexamethasone Taw will be available as an injectable medicine and, if authorised, will be used to treat the same conditions with the addition of COVID-19.

More about the procedure

Further information on how EMA fast-tracks its regulatory procedures so that marketing authorisations of safe, effective and high-quality COVID-19 related medicines can be granted as soon as possible is available on EMA's website.

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Ministry of Health

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