Romanian Ministry of Health approves protocol for coronavirus treatment Romanian health authorities to prioritise approval of COVID-19 clinical trials

In response to the COVID-19 pandemic, the Romanian National Agency for Medicines and Medical Devices (ANMDM) announced that it will prioritise approval of clinical trials of those medicines earmarked for treatment of coronavirus infections.

Depending on the number of applications and the phase of the study, ANMDM estimates a maximum seven-day term to complete the authorisation assessment. Phase III studies will be given top priority.

By laws governing national clinical trials, the general term for the ANMDM to complete a valuation of an application and authorise a clinical trial is a maximum of 60 days from the submission of the complete dossier.

At the same time, the ANMDM encourages the coordinated assessment at the EU level through the Voluntary Harmonisation Procedure (VHP). This procedure allows a sponsor that wishes to carry out a clinical trial in two or more EU member states to obtain a coordinated assessment of its application as an alternative to submitting a separate clinical-trial application to each competent national authority.

For more information on the ANMDM's announcement and Romania's pharmaceutical and pharma research industries, contact your regular CMS advisor or local CMS expert ***Valentina Parvu****.*