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Covid-19 : Guidance on more regulatory flexibility for medicines

The European Commission, EMA and the European medicines regulatory network have developed a Q&A document to provide guidance to stakeholders on adaptations to the regulatory framework to address challenges arising from the COVID-19 pandemic, with a particular focus on crucial medicines for use in COVID-19 patients.

The document explains some regulatory flexibilities that can be applied to help pharmaceutical companies cope with the consequences of the pandemic, while ensuring a high level of quality, safety and efficacy for medicinal products made available to patients in the EU.

The document published today outlines areas where regulatory flexibility is possible to address some of the constraints marketing authorisation holders may be faced with in the context of COVID-19. The measures introduced cover different areas of the regulation of medicines such as marketing authorisations and regulatory procedures, manufacturing and importation of active pharmaceutical ingredients (APIs) and finished products, quality variations, and labelling and packaging requirements with flexibility to facilitate the movement of medicinal products within the EU. Some of the measures described are reserved for crucial medicines for use in COVID-19 patients.