Le Agenzie Regolatorie sono state all'altezza della sfida posta dall'approvazione dei vaccini anti CODIV-19?

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The COVID-19 pandemic has put the capability of regulatory agencies to provide a prompt response to unmet medical needs arising in an emergency under strain. Indeed, the assurance of Quality, Safety and Efficacy of medicinal products, which is normally guaranteed, for industrial products, through a Manufacturing authorisation and a Marketing authorisation, usually takes time: 10 to 15 years for products based on new active substances to hit the market from the initial R&D phase (less for generics or biosimilars or for new indications of old drugs).

However, in some cases, competent Authorities worldwide may put in place faster routes to market for medicinal products to be used in the prevention or treatment of pathologies. In particular, during the present emergency, the US Food and Drug Administration resorted to the Emergency Use Authorization (EUA) and the European Medicines Agency to a series of tools comprising the Conditional Authorisation and the rolling review, to accelerate the time to market of vaccines for preventing COVID-19. These regulatory pathways imply that, at the date of authorisation, clinical data are less comprehensive than usually required and have to be completed at a subsequent time.