Rolling review
Covid-19 vaccines

A rolling review is a regulatory tool used by National Regulatory Authorities (NRAs) to speed up the assessment of a promising medical product during a public health emergency.

Usually, a regulatory agency would not receive a dossier until all the quality, non-clinical and clinical parts are complete to support an application for marketing authorization. However, during a public health emergency, in order to advance the review of existing information as the product and clinical development progresses, NRAs are accepting rolling submissions.

WHO is also accepting rolling submissions from applicants simultaneously or soon after these are sent to the NRA of record, in order to conduct a parallel review and formulate a decision on listing soon after the product has received an Emergency Use Authorization or equivalent, granted by the NRA of record.

A rolling submission is to be understood as the submission of a discrete number of complete packages (i.e. 3 to 5) of information and data of the Common Technical Document (CTD) and not as a continuous update of the application by submitting pieces of information on an ongoing basis. For example, a company may submit the non-clinical section of a dossier, or completed phase 1 and phase 2 clinical trials, as well as the core dossier for the production and manufacturing control, and later send interim reports of phase 3 clinical trials, Risk Management Plan (RMP) and production and quality control data for commercial scale production in facilities designated for supply through COVAX, or updated stability data to support the claimed shelf life. All documents submitted must be in English.

WHO may accept less than a complete section only if it is determined that such a subsection constitutes a reviewable unit that will make the review process more efficient. Examples include CMC section for commercial scale production, with ongoing comparability studies for Process Performance Qualification - PPQ batches, initiated long-term stability with defined timelines for update reports, a toxicology section lacking chronic toxicology data, interim study reports for some or all of the principal controlled trials without integrated summaries.

The applicant should, before the initial submission, advise WHO of the timelines to submit the complete data packages and possible subsections. This will allow WHO to coordinate the use of resources and estimate the completion of the assessment.

Should an initial submission be composed of incomplete sections and subsections for the stage of development of the product, WHO may decide to not start the review until substantial information is submitted to conduct an efficient assessment.