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WHO informal consultation on regulatory considerations for evaluation of the quality, safety and efficacy of RNA-based prophylactic vaccines for infectious diseases, 20-22 April 2021

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Abstract

This paper presents the key outcomes of the above WHO informal consultation with global stakeholders including regulatory authorities, vaccine developers and manufacturers, academia and other international health organizations and institutions involved in the development, evaluation and use of messenger RNA (mRNA) vaccines. The aim of the consultation was to further clarify the main principles to be presented in an upcoming WHO guidance document on the regulatory considerations in evaluating the quality, safety and efficacy of mRNA prophylactic vaccines for infectious diseases. This WHO guidance document is intended to facilitate global mRNA vaccine development and regulatory convergence in the assessment of such vaccines. The urgent need to develop such a document as a new WHO written standard is outlined in this report along with the key scientific and regulatory challenges. A number of key conclusions are provided at the end of this report along with an update on the steps taken following this meeting.

Keywords: COVID-19; WHO; infectious diseases; mRNA vaccines; prophylactic vaccines; regulatory considerations.

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