2 Background Information on the Procedure

2.1 Applicant's Request(s)

New Active Substance status
The applicant requested the status of a new active entity for the active substance CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2) of the medicinal product mentioned above.

Rolling authorisation procedure (FTP)
The applicant requested a rolling authorisation procedure. According to the Guidance document "Authorisation procedures for COVID-19 medicinal products during a pandemic, HMV4", for the exceptional case of a pandemic, and at the request of the applicant during a Presubmission Advice meeting, an authorisation application may be submitted as a "Rolling Submission". The "Rolling Submission" procedure represents a special form of a first authorisation procedure or a variation procedure.

Marketing authorisation for human medical products
The applicant requested a marketing authorisation in accordance with Art. 9a, para. 1 TPA. However, based on the submitted clinical data material and the results of the evaluation, Swissmedic granted a temporary authorisation in accordance with Art. 9a TPA and with regard to the guidance document "*Authorisation procedures for COVID-19 medicinal products during a pandemic, HMV4*"

OPEN project EMA
In the context of the EMA's OPEN project, Swissmedic has been participating in the meetings of the CHMP. Further information at: *EMA COVID-19 assessments 'OPEN' to non-EU regulators | European Medicines Agency (europa.eu).*

2.2 Indication and Dosage

2.2.1 Requested Indication

COVID-19 Vaccine Moderna is indicated for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 18 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.2 Approved Indication

COVID-19 Vaccine Moderna is indicated for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus in individuals 18 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.3 Requested Dosage

COVID-19 Vaccine Moderna is a two-dose regimen. The second dose should be administered one month after the first dose (see Warnings and Precautions).
To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.

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