

Amsterdam, 30 November 2020
EMA/CHMP/641827/2020
Committee for Medicinal Products for Human Use (CHMP)

CHMP interim opinion on a rolling review

In support of an emergency procedure for a pandemic vaccine, in view of a planned marketing authorisation application

Medicinal product

(Invented) Name:	COVID-19 mRNA Vaccine BioNTech
Common name:	COVID-19 mRNA vaccine (nucleoside-modified)
Pharmaceutical form(s):	See Annex A
Strength(s):	See Annex A
Route(s) of administration:	See Annex A
Packaging and package size(s):	See Annex A

Basis for opinion

In support of a planned application for marketing authorisation, pursuant to Article 6 of Regulation (EC) No 726/2004, BioNTech Manufacturing GmbH submitted to the Agency on 06 November 2020 a quality data package within the rolling review cycle EMEA/H/C/5735/RR/02.

The procedure started on 7 November 2020. The steps taken for the assessment are laid out in the attached overview.

Scope of the rolling cycle review

eCTD modules sequence 0001.

Interim Opinion

The CHMP completed its assessment of the data submitted and adopted by consensus the CHMP overview and list of questions as attached.

The Icelandic and the Norwegian CHMP members agree with the above-mentioned interim opinion of the CHMP.

This interim opinion is forwarded to the rolling review applicant, together with its annex and attachment.

Annex A

<u>EMA Number</u>	<u>(Invented) name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Route of Administration</u>	<u>Immediate Packaging</u>	<u>Content (concentration)</u>	<u>Pack size</u>
EMA/H/C/005735/001	COVID-19 mRNA Vaccine BioNTech	--1	Concentrate for suspension for injection	Intramuscular use	vial (glass)	0.45 ml (5 doses)	195 vials

--1

1 vial (0.45 mL) contains 225 micrograms mRNA* (embedded in lipid nanoparticles).

* highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike protein of SARS-CoV-2.