Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Head of Regulatory Affairs
BIONTECH MANUFACTURING GMBH
AN DER GOLDGRUBE 12
MAINZ
D-55131
GERMANY

22/04/2021

Dear Head of Regulatory Affairs,

GRANT / RENEWAL OF MARKETING AUTHORISATION

Our Reference:	PLGB 53632/0002 - 0001
Your Reference:	53632
Product:	Comirnaty concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)
Type of Procedure:	National
Submission Type:	Initial
Submission Category:	New Active Substance
EU Procedure Number (if applicable):	
Territory:	GB
Route:	Not Applicable

The Licensing Authority agrees to the grant or renewal of marketing authorisation for the above submission on the basis of the data provided. This includes any replacement and amendment of the original dossier.

The grant or renewal that has been made is conditional upon the review of the following conditions by 20/12/2021

1. In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data. - Due date July 2021.Interim reports:31 March 2021

2. In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications. Due date July 2021. Interim reports: March 2021

3. In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data. Due date March 2021

4. In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315. Due date July 2021. Interim reports:January 2021, April 2021

5. In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159. Due date July 2021.Interim reports: January 2021, April 2021

6. In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001. Due date December 2023

The formal documents are enclosed. These constitute evidence of authorisation. If you consider them to contain information that is incorrect or not in accordance with the dossier, please return immediately indicating any errors.

All Marketing Authorisations are subject to standard provisions contained in current medicines regulations full details of which are published on the MHRA section of its website:
https://www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing

Yours sincerely,

[redacted]

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The Medicines for Human Use (Marketing Authorisations etc.) Regulations, SI 1994/3144, as amended.

GRANT / RENEWAL OF MARKETING AUTHORISATION

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Submission Type:	Initial
Granted to:	BIONTECH MANUFACTURING GMBH AN DER GOLDGRUBE 12 MAINZ D-55131 GERMANY

This Marketing Authorisation, under the above reference number is hereby granted / renewed in respect of the product named above. The Summary of Product Characteristics of the product is set out in the attached document.

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The application is also subject to the standard provisions set out or referred to in the above Regulations.

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This Marketing Authorisation, as now granted / renewed, unless previously revoked, will continue in force until the expiry date (if applicable) given below.

Grant Date: 01/01/2021

Date of Expiry: 20/12/2021

[redacted]

A person authorised to sign on behalf of the Secretary of State for Health