Medicines & Healthcare products
Regulatory Agency

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[redacted]
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NG13 8PJ
UNITED KINGDOM

14/08/2024

Dear [redacted]

NOTIFICATION OF ACCEPTANCE

Our Reference:	PLGB 53632/0006 - 0188
Your Reference:	53632
Product:	Comirnaty 10 micrograms/dose concentrate for dispersion for injection
Type of Procedure:	National
Submission Type:	Information Update
Submission Category:	External Information Update
EU Procedure Number (if applicable):	
Reason:	PAM-LEG-p46-70: Submission of the final clinical study report for paediatric study C4591007.
Territory:	GB
Route:	Direct

Processing is now complete and the above information is accepted.

Please retain this letter with the formal documents relating to the Marketing Authorisation/Registration.

Please note that all Marketing Authorisations and Marketing Authorisation Holders are subject to standard provisions and obligations contained in current medicines regulations, full details of which are published on the MHRA website:

https://www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing

Yours sincerely,

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This letter refers to Collection ID 285968 and covers the following submissions: PLGB 53632/0008 - 0096,PLGB 53632/0030 - 0021,PLGB 53632/0024 - 0025,PLGB 53632/0014 - 0075,PLGB 53632/0034 - 0021,PLGB 53632/0036 - 0024,PLGB 53632/0022 - 0027,PLGB 53632/0032 - 0024,PLGB 53632/0020 - 0030.