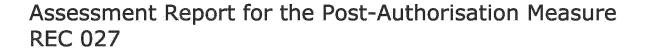


EMA/CHMP/284816/2021 Committee for Medicinal Products for Human Use (CHMP)



Comirnaty

International non-proprietary name: COVID-19 mRNA vaccine (nucleoside-modified)

EMEA/H/C/005735/PAM-ANX REC027

Marketing authorisation holder: BioNTech Manufacturing GmbH



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1. Introduction

This report covers the following post-authorisation commitment undertaken by the MAH:

REC7: The MAH should provide the results of the studies performed to enhance the robustness of the DNase digestion step in the active substance manufacturing process.

1.1. Steps taken for the assessment

Submission date:	30 March 2021
Start of procedure:	21 April 2021
Rapporteur's preliminary assessment report circulated on:	27 April 2021
MS comments:	10 May 2021
Rapporteur's updated assessment report circulated on:	n/a
CHMP adoption of conclusions:	20 May 2021

2. Summary of data submitted

An		in	residual DNA	A was pre	eviously of	bserved in	the PPQ3	batch as co	mpared to	the PPQ1	and
PPC	22 batch	es.									
	As	a l	mitigation a	pproacn,	studies w	ere initiat	ea to enna	ince the robi	ustness or	tne DNase	2
dig	estion st	ep.	As the stud	dies were	progressi	ing, additi	onal manu	facturing ex	p <u>erience p</u>	resented a	a
like	ly root c	aus	se for the	resid	Jual DNA.	As outlin	ed in the f	igure below,			

The likely root cause	Pfizer is
implementing activity testing on incoming enzymes by the end of second quarter 2021, per	_
Recommendation 3, which should help prevent future issues.	

3. Scientific discussion

No detailed report for the studies initiated to enhance the robustness of the DNase digestion step is provided. However, the MAH shows data indicating that the likely root cause for the residual DNA is the likely root cause for the residual It is also confirmed that activity testing on incoming enzymes will be implemented by the end of second quarter 2021 as requested in Recommendation 3. It is expected that a detailed summary of the results from the studies performed to enhance the robustness of the DNase digestion step will be included in Module 3.2.S.2.5 of the dossier by the end of second quarter 2021.

Recommendation 3 requesting implementation of an in-house functional activity analytical method for release testing of enzymes used in the manufacturing process at all relevant manufacturing sites was initially expected by Q1 2021 but it was agreed with EMA by e-mail to extend the due date to Q2-2021. It is recommended that Recommendations 3 and 7 are grouped.

4. Overall conclusion

The Recommendation number 7 is only considered as partly fulfilled.

□ PAM fulfilled (all commitments fulfilled) - No further action required

Recommendation number 7 to provide the results of the studies performed to enhance the robustness of the DNase digestion step has only been partly fulfilled. Further actions are required to fulfil Recommendation 7 including submission of a detailed summary of the results from the studies and inclusion of these data in Module 3.2.S.2.5 of the dossier by the end of second quarter 2021. It also recommended that Recommendations 3 and 7 are grouped.