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1.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	UNITED STATES

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
sudden death of a 13-year-old (place)child who had a second dose of Pfizer vaccine	Sudden death	Sudden death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a non-contactable consumer (columnist). A 13-year-old male patient received second dose of BNT162b2 (FIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number was not reported), via an unspecified route of administration on an unspecified date as single dose for COVID-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that remained strangely silent over the sudden death of a 13-year-old child who had a second dose of Pfizer vaccine. The patient died on an unspecified date. It was not reported if an autopsy was performed.

No follow-up attempts are possible, information about lot/batch number cannot be obtained.

Lab Data: Unknown — **Lab Data**

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA	2		

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Sudden death	N	Unknown	N/A	N/A	N/A

Patient Medical History

1.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Sudden death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				20-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
FEMALE	13 YEARS			NO DATA - NO DATA	UNITED STATES

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
dead from second dose of Pfizer Covid 19 vaccine	Unknown cause of death	Death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a Pfizer-sponsored program COVAX US Support by a non-contactable consumer. This report reported same event for two patients. This is the first dose of two reports. A 13-year-old female patient received bnt162b2 (BNT162B2), dose 2 via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as DOSE 2, SINGLE at the age of 13-year-old for covid-19 immunisation. The patient medical history and concomitant medications were not reported. The patient previously received the first dose of bnt162b2 (BNT162B2) for covid-19 immunisation. A 13 years old female is dead from second dose of Pfizer Covid 19 vaccine. Both had no prior conditions with the heart and now are dead. The patient died on an unspecified date. It was unknown if an autopsy was performed.

No follow-up attempts are possible; information about lot/batch number cannot be obtained

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA	2		

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

Patient Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Cause of Death/Autopsy

2.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				23-AUG-2021	

References

Reference Type	Reference ID	Reference Notes
MEDICAL INFORMATION NO.	(b) (6)	(b) (6)
NO. CASE COPIES	(b) (6)	(b) (6)
E2B LINKED REPORT	(b) (6)	(b) (6)
NCSP	(b) (6)	
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

3.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	UNITED STATES

Event Information and Narrative

Verbatim Term	Lowest Level Term	Preferred Term	Onset Date	Event Seriousness	Clinical Outcome	Procedure Causality Per Company	Procedure Causality Per Reporter
died three days after Covid vaccination	Unknown cause of death	Death		SERIOUS	FATAL	NO DATA	NO DATA
Autopsy showed enlarged heart and fluid surrounding the heart	Pericardial effusion	Pericardial effusion		SERIOUS	FATAL	NO DATA	NO DATA
Autopsy showed enlarged heart and fluid surrounding the heart	Enlargement heart	Cardiomegaly		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable consumer or other non-health care professional in response to mail trail sent regarding the confirmation of below mentioned query. A 13-year-old male patient received second dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number and Expiration date not reported) via an unspecified route of administration in an unspecified anatomical location on an unspecified date as dose 2, single for COVID-19 immunization. The patient medical history and concomitant medications were not reported. The patient previously received first dose of bnt162b2 (PFIZER-BIONTECH COVID-19 mRNA VACCINE, Formulation: Solution for injection, Batch/Lot number and Expiration date not reported) via an unspecified route of administration in an unspecified anatomical location on an unspecified date as dose 1, single for COVID-19 immunization. On an unspecified date, three days after receiving his second Covid vaccine, the patient died. Autopsy result showed enlarged heart and fluid surrounding the heart caused by the Covid vaccination. The outcome of the events was fatal.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Follow-up (25Jun2021): This is a follow up spontaneous report in response to ma

il trail sent regarding the confirmation of below mentioned query. New information included: Updated narrative.

No follow-up attempts are possible; information about lot/batch number cannot be obtained.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	Normal Value	Test Date	Test Result	Lab Comments

Suspect Product(s) Therapy Information

Suspect Product(s)	Unit Dose	Total Daily Dose	Regimen Dose	Route of Admin	Therapy Date(s)	Therapy Duration	Anatomical Location	Vaccination Dose No.	Lot No.	Batch No.
BNT162B2				NO DATA	-		NO DATA	2		

Section Page: 2

3.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Suspect Product(s) Information

Suspect Product(s)	Indication(s)	Form of Admin	First Total Daily Dose	Action Taken	Dechallenge	Rechallenge	Interacting Drug
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Death	N	Unknown	N/A	N/A	N/A
BNT162B2	Pericardial effusion	N	Unknown	N/A	N/A	N/A
BNT162B2	Cardiomegaly	N	Unknown	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
AUTOPSY	PATIENT	Cardiomegaly	
AUTOPSY	PATIENT	Pericardial effusion	
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				22-JUN-2021	

3.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

References		
Reference Type	**Reference ID**	**Reference Notes**
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History					
Patient/Parent Indicator	**Coded Condition**	**Start Date**	**Stop Date**	**Ongoing**	**Notes**

Section Page: 1

4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	UNITED STATES

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
died in his sleep 3 days after taking the Pfizer covid vaccine	Died in sleep	Death	16-JUN-2021	SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable consumer. A 13-year-old male patient received the second dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) via an unspecified route of administration on an unspecified date (Batch/Lot number was not reported) as dose 2, single for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. Historical Vaccine included the first dose of BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE) for COVID-19 immunisation. The patient experienced died in his sleep, 3 days after taking Pfizer COVID vaccine on 16Jun2021. This is coincidental, this is not causative. Cause of death was unknown. No investigation assessment. The patient died on 16Jun2021. The county health department confirmed the investigation and the autopsy was being performed. The information is being sent the CDC to see if there is a correlation. The reporter mentions that we all know a lot of 13-year-old falling over for that.

Information on the lot/batch number has been requested.

Follow-up (05Aug2021): This follow-up is being submitted to notify that the batch/lot number is not available despite the follow-up attempts made. Follow-up attempts have been completed and no further information is expected.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA	2		

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

Product(s) and Event(s) Information						
Suspect Product(s)	**Event(s)**	**CDS**	**Latency Group**	**Rechallenge**	**Causality per Reporter**	**Causality per Company**
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

4.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death,Medically Significant

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				02-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
LOCAL REFERENCE NO.	(b) (6)	(b) (6)
CALL CENTER NO.	(b) (6)	
NO. CASE COPIES	(b) (6)	(b) (6)
CROSS-REFERENCE NO.	(b) (6)	(b) (6)
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Section Page: 1

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Patient Demographic					
Sex	**Age**	**Height (cm)**	**Weight (kg)**	**Race**	**Country Where Event Occured**
MALE	13 YEARS			NO DATA - NO DATA	UNITED STATES

Event Information and Narrative							
Verbatim Term	**Lowest Level Term**	**Preferred Term**	**Onset Date**	**Event Seriousness**	**Clinical Outcome**	**Procedure Causality Per Company**	**Procedure Causality Per Reporter**
I read a Newsweek headline online that said a thirteen year old died in his sleep after taking the Pfizer vaccine and the CDC is investigating. Another article headline may have said it was a boy but	Unknown cause of death	Death		SERIOUS	FATAL	NO DATA	NO DATA

This is a spontaneous report from a contactable consumer via Pfizer Colleague. A 13-year-old male patient received BNT162B2 (PFIZER-BIONTECH COVID-19 VACCINE, Solution for injection, Batch/Lot number was not reported) via an unspecified route of administration on an unspecified date as dose number unknown, single for covid-19 immunisation. The patient medical history and concomitant medications were not reported. On an unspecified date, the reporter read a Newsweek headline online that said a thirteen-year-old died in his sleep after taking the Pfizer vaccine and the CDC was investigating. Another article headline may have said it was a boy, but reporter can't find that article again. The reporter don't have a subscription to newsweek so could not read the article and get more specifics.The patient died on an unspecified date. It was unknown if an autopsy was performed. The outcome of event was reported as fatal.

Follow up needed, further information was requested.

Follow-up (05Aug2021): This follow-up is being submitted to notify that the lot/batch number is not available despite the follow-up attempts made. Follow-up attempts completed. No further information is expected.

Lab Data:	Unknown	**Lab Data**

Lab Narrative:

Test Name	**Normal Value**	**Test Date**	**Test Result**	**Lab Comments**

Suspect Product(s) Therapy Information										
Suspect Product(s)	**Unit Dose**	**Total Daily Dose**	**Regimen Dose**	**Route of Admin**	**Therapy Date(s)**	**Therapy Duration**	**Anatomical Location**	**Vaccination Dose No.**	**Lot No.**	**Batch No.**
BNT162B2				NO DATA	-		NO DATA			

Suspect Product(s) Information							
Suspect Product(s)	**Indication(s)**	**Form of Admin**	**First Total Daily Dose**	**Action Taken**	**Dechallenge**	**Rechallenge**	**Interacting Drug**
BNT162B2	COVID-19 immunisation	SOLUTION FOR INJECTION		NOT APPLICABLE	N/A	N/A	NO DATA

5.AER Number (b) (6) **Case Seriousness:** SERIOUS **Seriousness Criteria:** Death

Product(s) and Event(s) Information

Suspect Product(s)	Event(s)	CDS	Latency Group	Rechallenge	Causality per Reporter	Causality per Company
BNT162B2	Death	N	Unknown	N/A	N/A	N/A

Patient Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes

Cause of Death/Autopsy

Other Death Information:

Type	Patient/Parent Indicator	Coded Condition	Notes
DEATH	PATIENT	Death	

ConMed: Unknown

Concomitant Product(s)

Concomitant Product(s)	Conmed Tradename As Reported	Therapy Date(s)	Route of Admin
		-	

Suspect or Conmed Devices

Suspect Devices

Device Type	Device Indicator	Model No.	Serial No.	NDC No.	Date of Manufacture	Catalog No.	Device Operator	Device Available for Evaluation	Device Evaluated by Manufacturer	Single Use	Evaluation Type	Evaluation Code
NO DATA							NO DATA	NO DATA	NO DATA			

Report History

Source	HP/Medically Confirmed	Case Report Type	Reporter Occupation	Protocol/Study No.	Center ID & Other ID	Patient ID	Initial Safety Receipt Date	EUDRACT No.
Spontaneous	N	SPONTANEOUS	NA				04-JUL-2021	

References

Reference Type	Reference ID	Reference Notes
COVAES REFERENCE NO.	(b) (6)	
E2B COMPANY NUMBER	(b) (6)	

Parent Medical History

Patient/Parent Indicator	Coded Condition	Start Date	Stop Date	Ongoing	Notes