Dr Morag Horne
Medical Adviser

Novartis Pharmaceuticals UK Ltd.
Novartis, Frimley
Frimley Business Park
Frimley
Surrey
GU16 7SR
Tel +44 (0)1276 698700
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NOVARTIS

H M Coroner
Mr David C Horsley
Guildhall
Guildhall Square
Portsmouth
PO1 2AJ

09 July 2009

Dear Mr Horsley

Our Refs: **S2009GB01043, Mrs E Lavender, Age: 83**
S2009GB01427, Mr B Cunningham, Age: 79
S2009GB01431, Mr R Wilson, Age: 74
S2009GB01437, Mr G Packman, Age: 66
S2009GB01439, Mrs E Devine, Age: 88
S2009GB000875

You may recall we have previously written to you concerning the inquest that was held recently into the deaths of 10 elderly patients who received diamorphine and other drugs at Gosport War Memorial Hospital. The patients included the five named above for whom details were published in media reports. Unfortunately I cannot locate a reply to that letter and hope you do not mind me writing to you again about this.

The safety of patients taking our products is our paramount concern and as marketing authorisation holder for diamorphine we would be very interested to receive further details about these patients. It is only by obtaining detailed information about adverse drug events that we are able to analyse the cumulative data to detect early signals of emerging safety issues. In addition we have a statutory obligation to report adverse events suspected as related to Novartis products to the regulatory authorities (the MHRA in the UK).

I fully appreciate that the investigations into these deaths are complex and that your time is precious, but wonder if it is possible that you will be able to provide us with any further details about these patients and the outcome of the inquest. Equally, I would be grateful if you could advise if you are unable to provide any further details.

I have enclosed copies of our suspect adverse drug reaction form which details the information we would be interested to receive. Please be assured that any information received will be treated in confidence.

NOVARTIS

Thank you for your assistance with this enquiry, and please do not hesitate to contact me if you have any queries.

Yours sincerely

Code A

Dr Morag Horne MB ChB, MSc, FRCPath
Medical Adviser
Drug Safety and Epidemiology

NOVARTIS Adverse Event Report Form

SINA S200YGB01043

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
EZ		/ /	83					

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: *"Muscle pain"*	*01-05-2004*	-	*Yes*	*IMP*

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
- ☐ Persistent or significant disability or incapacity
- ☐ Required hospitalization or prolonged hospitalization
- ☐ Life threatening at the time the event(s) occurred
- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: *Lipitron (lipostatin)*	*Oral*	*75mg*	*01/01/2004-19/04/2004*	*Hypertriglyceridemia*
DIAMORPHINE				

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S2009GB01043

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant?**
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
☐ Novartis drug recommenced ☐ adverse event(s) recurred ☐ adverse events did not recur ☐ other:	☐ Drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Non-drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:

*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper

NOVARTIS Adverse Event Report Form

SINA S200996B01427

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
BC		/ /	79	M				

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: *"Muscle pain"*	*01-05-2004*	-	*Yes*	*IMP*

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
- ☐ Persistent or significant disability or incapacity
- ☐ Required hospitalization or prolonged hospitalization
- ☐ Life threatening at the time the event(s) occurred
- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: *Lipitron (lipostatin)*	*Oral*	*75mg*	*01/01/2004-19/04/2004*	*Hypertriglyceridemia*
DIAMORPHINE				

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S200 9GB01427

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant?**
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
☐ Novartis drug recommenced ☐ adverse event(s) recurred ☐ adverse events did not recur ☐ other:	☐ Drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Non-drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:

*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper

NOVARTIS Adverse Event Report Form

SINA S2009GB01431

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
RW		/ /	74	M				

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: ***"Muscle pain"***	***01-05-2004***	-	***Yes***	***IMP***

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
- ☐ Persistent or significant disability or incapacity
- ☐ Required hospitalization or prolonged hospitalization
- ☐ Life threatening at the time the event(s) occurred
- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: ***Lipitron (lipostatin)***	***Oral***	***75mg***	***01/01/2004-19/04/2004***	***Hypertriglyceridemia***
DIAMORPHINE				

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S2009GB01431

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant?**
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
☐ Novartis drug recommenced ☐ adverse event(s) recurred ☐ adverse events did not recur ☐ other:	☐ Drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Non-drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:

*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper

NOVARTIS Adverse Event Report Form

SINA S2009GB01437

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
GP		/ /	66	M				

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: *"Muscle pain"*	*01-05-2004*	-	*Yes*	*IMP*

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
- ☐ Persistent or significant disability or incapacity
- ☐ Required hospitalization or prolonged hospitalization
- ☐ Life threatening at the time the event(s) occurred
- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: *Lipitron (lipostatin)*	*Oral*	*75mg*	*01/01/2004-19/04/2004*	*Hypertriglyceridemia*
DIAMORPHINE				

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S2009GB01434

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant**?
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
☐ Novartis drug recommenced ☐ adverse event(s) recurred ☐ adverse events did not recur ☐ other:	☐ Drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Non-drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:

*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper

NOVARTIS Adverse Event Report Form

SINA S200 9GB01439

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
ED		/ /	88	F				

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: *"Muscle pain"*	*01-05-2004*	-	*Yes*	*IMP*

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
- ☐ Persistent or significant disability or incapacity
- ☐ Required hospitalization or prolonged hospitalization
- ☐ Life threatening at the time the event(s) occurred
- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: *Lipitron (lipostatin)*	*Oral*	*75mg*	*01/01/2004-19/04/2004*	*Hypertriglyceridemia*
DIAMORPHINE				

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S2009GB01439

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant?**
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
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*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper

NOVARTIS Adverse Event Report Form

SINA S2009GB00875

CPMS NO

Please print clearly and include any additional information on a separate sheet of paper

Please return the completed form to:
Drug Safety & Epidemiology
Novartis Pharmaceuticals UK Ltd
Frimley Business Park
Camberley
Surrey GU16 7SR

Telephone: 08456 011387
Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height (cm)	Weight (kg)	Ethnic Origin	No Patient Details Reported to Novartis
		/ /						

Adverse event(s) information

Adverse event(s)	Onset date of this event	End date for this event	Do you suspect that the Novartis product caused the event?	What was the outcome? **REC** Completely recovered **SEQ** Recovered with sequelae **IMP** Condition improving **UNC** Condition unchanged **DET** Condition deteriorating **FAT** Fatal **UNK** Outcome unknown
For example: *"Muscle pain"*	*01-05-2004*	-	*Yes*	*IMP*

Further description of adverse event(s)

Do any of the following criteria apply?

- ☐ Medically significant hazard
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- ☐ Congenital anomaly or birth defect
- ☐ Patient died due to event(s)

Date of death:
Cause of death:
Please attach a copy of the post mortem report if available

Medication information

Drug(s) suspected of causing adverse event(s)	Route	Daily dose	Dates of treatment	Indication
For example: *Lipitron (lipostatin)*	*Oral*	*75mg*	*01/01/2004-19/04/2004*	*Hypertriglyceridemia*

Other drug(s) taken by the patient	Route	Daily dose	Dates of treatment	Indication

PLEASE CONTINUE OVERLEAF

NOVARTIS Adverse Event Report Form

SINA S2009G8000875

CPMS NO

Further patient information

Relevant medical history including concurrent and pre-existing conditions (please provide dates where possible):

Risk factors:
- ☐ Nicotine
- ☐ Alcohol
- ☐ Drug abuse

If female, is patient **pregnant**?
- ☐ No
- ☐ Yes
  LMP: _____

Additional drug information/measures taken

(more than one may be selected)

☐ Novartis drug continued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Novartis drug discontinued ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Dose reduction Novartis drug* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:
☐ Novartis drug recommenced ☐ adverse event(s) recurred ☐ adverse events did not recur ☐ other:	☐ Drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:	☐ Non-drug treatment of adverse event* ☐ adverse event(s) abated ☐ adverse events did not abate ☐ other:

*Please give any additional drug information here:

I have reported this to the MHRA Yes ☐ No ☐ (please tick)

Lot/Batch number:	Formulation:
Expiry date:	Strength (units):

Relevant laboratory and test data

Test	**Date** dd/mm/yyyy	**Results** (with units)	**Normal values**

Reporter information

Please PRINT or use stamp

Name:		**Address:**	**Telephone:**	
Title:			**Fax:**	
Profession:			**Email:**	
Signature:			**Date:**	

Please include any further information on a separate sheet of paper