Dr Morag Horne
Medical Adviser

Novartis Pharmaceuticals UK Ltd.
Novartis, Frimley
Frimley Business Park
Frimley
Surrey
GU16 7SR
Tel +44 (0)1276 698700
Fax +44 (0)1276 698319

NOVARTIS

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

23 March 2009

Dear Mr Horsley

Our Ref: S2009GB00875 and S2009GB01043, Mrs E Lavender, Age: 83

We have been made aware by a media report that an inquest is being held into the deaths of 10 elderly patients at Gosport War Memorial Hospital in regard to concerns about prescribing levels of diamorphine and other drugs. In the media report, one of the 10 patients was identified as Mrs Elsie Lavender, age 83.

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 and the outcome of the inquest. 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 would therefore be very grateful if you could provide further details about these patients including copies of the post mortem reports, if available. I have enclosed a copy of our suspect adverse drug reaction form for Mrs Lavender which details the information we would be interested to receive and further copies can be provided for the other patients, if appropriate. Please be assured that any information received will be treated in confidence.

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
Medical Adviser
Drug Safety and Epidemiology

25 MAR

NOVARTIS Adverse Event Report Form

SINA S200 9G801043

CPMS NO

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

Please return the completed form to:
IMS PVO
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
EL		/ /	83	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***

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

PLEASE CONTINUE OVERLEAF

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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:

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