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



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

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 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.



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



SINA	\$200 PGB01043
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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 Telephone: 08456 011387

Frimley Business Park

Facsimile: 08456 011418/01276 698454

Camberley Surrey GU16 7SR

Patient details Initials Date of birth Weight (kg) Country Height (cm) **Ethnic Origin** No Patient Details Age Sex Reported to Novartis 67 Adverse event(s) information What was the outcome? **REC** Completely recovered Do you SEQ Recovered with End date for Onset date of suspect that sequelae the Novartis Adverse event(s) this event this event IMP Condition improving product **UNC** Condition unchanged caused the **DET** Condition deteriorating event? FAT Fatal **UNK** Outcome unknown Yes IMP For example: "Muscle pain" 01-05-2004 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 П 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



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CPMS NO

	Further pa	tient information		
(more than one may be selected) Novartis drug continued	Additional drug info	rmation/measure	Risk factors: Nicotine Alcohol Drug abu If female, is p No Yes LMP: Dose reduction	patient pregnant? Novartis drug*
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	Reporte	r information		
Name:	Address:	RINT or use stamp	Telephone:	
Title:			Fax:	
Profession:			Email:	
Signature:			Date:	



SINA \$20096B01427

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 Telephone: 08456 011387

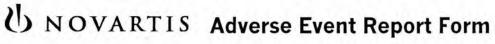
Frimley Business Park

Facsimile: 08456 011418/01276 698454

Camberley

Surrey GU16 7SR Patient details Initials Weight (kg) No Patient Details Date of birth Height (cm) **Ethnic Origin** Country Sex Age Reported to Novartis BC Adverse event(s) information What was the outcome? **REC** Completely recovered Do you suspect that SEQ Recovered with End date for Onset date of sequelae the Novartis Adverse event(s) this event this event IMP Condition improving product UNC Condition unchanged caused the **DET** Condition deteriorating event? FAT Fatal **UNK** Outcome unknown IMP 01-05-2004 Yes For example: "Muscle pain" 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 Indication Other drug(s) taken by the patient Daily dose Dates of treatment

PLEASE CONTINUE OVERLEAF



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			CPMS	NO		
*	Further pa	tient information				
Relevant medical history including cor			provide dates	where po	ssible):	
			Risk	factors: Nicotine Alcohol Drug abus male, is pa No		
Add	itional drug info	rmation/measure	s taken	3.00		
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7			, c.cpiioi	7.2		
Title:			Fax:			
Profession:			Email:			

Please include any further information on a separate sheet of paper

Date:

Signature:



SINA \$2009 6B 1431

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 Telephone: 08456 011387

Facsimile: 08456 011418/01276 698454

Frimley Business Park Camberley Surrey GU16 7SR

Patient details

Initials	Country	Date of birth	Age 74	Sex	Height	(cm)	Weight ((kg) Ethnic		rigin	No Patient Details Reported to Novartis
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Other drug(s)	taken by the pati	ient	Route	Daily do	ose D	ates of t	reatment		Indication	on	



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301431

	Further pa	tient information			
Relevant medical history inclu		sting conditions (please	Risk	factors: Nicotine Alcohol Drug abuse nale, is patie	ent pregnant?
(more than one may be selected)					
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Name:	Address:		Telephone	e:	
Title:			Fax:		
Profession:			Email:		
Signature:			Date:		



SINA \$20096B01437

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 Telephone: 08456 011387 Facsimile: 08456 011418.

Facsimile: 08456 011418/01276 698454

Frimley Business Park

Camberley Surrey GU16 7SR

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Initials	Country	Date of birth	Age 66	Sex	Heigh	t (cm)	Weight (kg)	Ethnic O	rigin	No Patient Details Reported to Novartis
	Adverse	event(s) infor	mation .								
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Other drug(s)	taken by the pati	ent	Route	Daily o	dose C	ates of t	reatment		Indication	on	

PLEASE CONTINUE OVERLEAF

UNOVARTIS Adverse Event Report Form

SINA	S2009 GB 314 34
SINA	S20096B01434

CPMS NO

	Further p	atient information				
	Additional drug inf	isting conditions (please	Risk facto Nicot Alcoh Drug If female, No Yes LMP:	ors: ine ol abuse is patient pregnant ?		
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Name:	Please F Address:	PRINT or use stamp	Telephone:			
Title:			Fax:			
Profession:			Email:			
Signature:			Date:			



SINA \$200 9GB 01439

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 Telephone: 08456 011387

Frimley Business Park

Camberley Surrey GU16 7SR Facsimile: 08456 011418/01276 698454

Patient details

Initials	Country	Date of birth	Age	Sex	Height	(cm) Weig	ght (kg)	Ethnic O	rigin	No Patient Details Reported to Novartis
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Other drug(s)	taken by the pat	ient	Route	Daily dos	e Da	tes of treatme	nt	Indicati	on	



SINA \$2009 G B01439
CPMS NO

	Further pa	tient information					
Relevant medical history includi			provide dates	where po	ossible):		
			Risk factors: Nicotine Alcohol Drug abuse				
				Vo	tient pregnant?		
	Additional drug info	ormation/measure	s taken		STATE OF THE PARTY		
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Title:				Fax:			
Profession:			Email:				
Signature:			Date:				



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Camberley Surrey GU16 7SR

Patient details

Initials	Country	Date of birth	Age	Sex	Height	(cm) Weight ((kg)	Ethnic O	rigin	No Patient Details Reported to Novartis
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Other drug(s)	taken by the pat	ient	Route	Daily dos	se Da	tes of treatment		Indication	on	



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	Further pa	tient information			
Relevant medical history inclu			Risk f N N A N N N N N N N	actors: icotine cohol rug abuse ale, is patient pregnant? o	
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	Reporte Please Pl	er information RINT or use stamp			
Name:	Address:				
Title:					
Profession:			Email:		
Signature:			Date:		