

Other Document Form

Number

1395

Title E-mail JUDY MYER (WORKMOT.) to Kavita CHADDA (MHRA)
(Include source and any document number if relevant) *re Diamorphie*

Receiver's instructions urgent action Yes / No _____

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Further actions no(s) _____

Receiver	
Code A	
O/M	SIO
Indexer	

When satisfied all action raised Office Manager to endorse other Document Master Number Form.

Code A

From: Code A
Sent: 10 March 2006 13:54
To: Code A @mhra.gsi.gov.uk
Cc: Code A @wockhardt.co.uk;
 Code A @wockhardt.co.uk
Subject: Diamorphine Hydrochloride for Injection BP, Operation Rochester

Ref: jm/14807/Diam/MHRA

Dear Mrs Chadda

Diamorphine Hydrochloride for Injection BP
 Operation Rochester

Wockhardt UK Limited was contacted, on 27 February 2006, by [Code A] of the Major Crime Department of the Hampshire Constabulary. Operation Rochester is investigating a number of allegations of suspicious deaths at the Gosport War Memorial Hospital.

The period covered by the investigation was specified initially as being between 1990 and 2000, however, yesterday, [Code A] (who spoke to me in the absence of [Code A]) explained that this has been revised to 1996 to 2000. The investigation involves consideration of a number of prescription drugs including diamorphine 5, 10, 30 and 100mg. The prescribing of the drug and the quantity prescribed is under scrutiny. The quality of the drug is not being questioned by the police.

Wockhardt UK Limited (formerly known as CP Pharmaceuticals Limited) was one of the companies supplying diamorphine in the UK between 1996 and 2000. Wockhardt UK Limited has held marketing authorisations (MAs) for Diamorphine Hydrochloride for Injection BP since 1993.

Diamorphine Hydrochloride 5 mg for Injection BP (MA 4543/0303)
 Diamorphine Hydrochloride 10 mg for Injection BP (MA 4543/0304)
 Diamorphine Hydrochloride 30 mg for Injection BP (MA 4543/0305)
 Diamorphine Hydrochloride 100 mg for Injection BP (MA 4543/0306)
 Diamorphine Hydrochloride 250 mg for Injection BP (MA 4543/0307)
 Diamorphine Hydrochloride 500 mg for Injection BP (MA 4543/0308)

The responsibility of an MA holder to inform the Medicines and Healthcare products Regulatory Agency (MHRA) of serious adverse drug reactions (ADRs) including overdose within 15 days is clear, however, in this case, three of the four minimum reporting criteria can not be fulfilled, that is, identifiable patient, reporter/healthcare professional or reaction. In addition, we have not been able to establish conclusively as yet that Wockhardt UK Limited's diamorphine was administered to the patients.

The Coroner involved in the investigation may submit ADR reports but relevant details for the patients may not be available. It seems unlikely that anyone deliberately administering inappropriate doses would keep detailed documentation, however, the controlled drug record system may provide some information.

In light of the limited information available on the individual cases, I would be grateful for your advice please regarding what action (with respect to ADR reporting) you feel ensures compliance with pharmacovigilance legislation.

My contact details as follows:

Tel: [Code A] (direct line with voice mail).
 Fax: 01978 661 702
 Email: [Code A]@cppharma.co.uk
 Office hours: 0830 to 1630, Monday to Friday.

The police officers involved are as follows:

Code A

Tel:

Code A

Mobile:

Fax: +442392892608

Email: **Code A**@hampshire.pnn.police.uk

Major Crime Department

Hampshire Constabulary

Fareham Police Station

Quay Street,

Fareham,

PO16 0NA.

Code A

Email: **Code A**@hampshire.pnn.police.uk

Senior Investigating Officer: Detective Superintendent Williams

Thank you for your help.

Yours sincerely

Jude

Jude Myer (Mrs)

Drug Safety and Information Manager / Qualified Person for Pharmacovigilance Wockhardt
(UK) Limited (incorporating CP Pharmaceuticals Limited & The Wallis Laboratory) United
Kingdom