

Safeguarding public health**Defective Medicines Report Centre****Market Towers****1 Nine Elms Lane****London****SW8 5NQ****Telephone: +44 (0)20 7084 2574****Fax: +44 (0)20 7084 2676****DRUG ALERT****CLASS 4 MEDICINES DEFECT INFORMATION****Caution in Use****For distribution to physicians and pharmacists**

Date: 1 April 2009

EL (09)A/08 Rev 1

Our Ref: MDR 43-02/09

Dear Healthcare Professional,

CP Pharmaceuticals/Wockhardt UK**CP Multiparin / Monoparin Products
Wockhardt Heparin Sodium products****See attached appendix for PL
numbers****See attached appendix for presentations, batch numbers, expiry dates and pack sizes.****Please replace the Drug Alert issued yesterday (31 March 2009) with this revised document. There are two changes present in this update:**

- 1. Wockhardt UK have informed us that some of the batches involved are presented in Wockhardt (unbranded) livery.**
- 2. Wockhardt UK have informed us that two additional batches are involved which have been added to the attached appendix.**

A very low level (0.6%) of over sulphated chondroitin sulphate (OSCS) has recently been identified in the active raw material used in the manufacture of 31 batches of CP Pharmaceuticals and Wockhardt UK heparin sodium injections distributed in the UK. This was identified using a more sensitive test method than was previously available. Wockhardt UK have provided details of affected presentations and batch numbers. Batches are in both CP (branded) and Wockhardt (unbranded) livery. See the attached appendix. No other batches of either product are affected.

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units

Chief Pharmacists: England, Scotland, Wales, Northern Ireland

Prison Health Policy Unit (DH)

Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar

Special Hospitals

Healthcare Commission for distribution to Independent Health Care Establishments

Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency

Market Towers 1 Nine Elms Lane London SW8 5NQ

T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

1 April 2009

EL (09)A/08 Rev 1

MDR 43-02/09

Due to a potential out-of-stock situation which would have adverse clinical consequences, these products are not being recalled. There is no evidence that this very low level of OSCS is associated with the anaphylactoid reactions reported following use of heparin with OSCS levels of 17 to 21% after i.v. administration, which were observed outside of the UK during 2007/8. Nonetheless Healthcare Professionals are advised to exercise particular caution when using the affected batches. Current evidence suggests that the risk of adverse reactions (ADRs) may be reduced by s.c. administration. Patients should be carefully monitored for signs of anaphylactoid or hypotensive reactions both during and after treatment, and standard therapies (ie vasopressor treatment and steroids) should be available as a precaution. Any suspected ADRs observed should be reported to the MHRA and Wockhardt UK in the usual way. As an extra precaution, it is suggested that batch details are recorded routinely in the patient's notes when using any heparin product.

MHRA will continue to liaise with Wockhardt UK to ensure that affected batches of products remain in the supply chain for as short a time as possible.

Recipients of this Drug Alert should bring this information to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to bring this information to the attention of relevant clinics, General Practitioners and Community Pharmacists by copy of this letter.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor, DMRC

Safeguarding public health
Defective Medicines Report Centre
Market Towers
1 Nine Elms Lane
London
SW8 5NQ
Telephone: +44 (0)20 7084 2574

Fax: +44 (0)20 7084 2676

Appendix: Batch details for affected presentations

CP Pharmaceuticals Branded Monoparin and Multiparin

CP PHARMACEUTICALS MONOPARIN 1000u/ml AMPOULES			PL No 04543/0221
Presentation	Batch number	Expiry date	First distribution
10 x 10ML PACK	003088	Aug 2011	17/10/2008
	004088	Aug 2011	19/11/2008
10 x 20ML PACK	PH40273	Jun 2011	25/11/2008
	PH40274	Aug 2011	08/01/2009
	PH40359	Nov 2011	28/02/2009
CP PHARMACEUTICALS MONOPARIN 5000u/ml AMPOULES			PL No 04543/0208
Presentation	Batch number	Expiry date	First distribution
10 x 1ML PACK	003088	Jul 2011	09/12/2008
10 x 5ML PACK	005108	Sep 2011	06/01/2009
CP PHARMACEUTICALS MONOPARIN 25000u/ml AMPOULES			PL No 04543/0210
Presentation	Batch number	Expiry date	First distribution
10 x 0.2ML PACK	PH40345	Sep 2011	04/12/2008
	PH40576	Sep 2011	16/02/2009
10 x 1ML PACK	PH40265	Aug 2011	24/12/2008
CP PHARMACEUTICALS MULTIPARIN 1000u/ml VIALS			PL No 04543/0218
Presentation	Batch number	Expiry date	First distribution
10 x 5ML PACK	011098	Feb 2010	28/11/2008
	012098	Feb 2010	28/11/2008
	013098	Feb 2010	05/12/2008
	014098	Feb 2010	05/12/2008
	015098	Mar 2010	28/11/2008
	016108	Mar 2010	28/11/2008

MHRA Distribution:

Regional Contacts for NHS Trusts and Provider Units
 Chief Pharmacists: England, Scotland, Wales, Northern Ireland
 Prison Health Policy Unit (DH)
 Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
 Special Hospitals
 Healthcare Commission for distribution to Independent Health Care Establishments
 Primary Care Trusts (England)

Medicines and Healthcare products Regulatory Agency
 Market Towers 1 Nine Elms Lane London SW8 5NQ
 T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

An executive agency of the Department of Health

CP PHARMACEUTICALS MULTIPARIN 5000u/ml VIALS PL No 04543/0219			
Presentation	Batch number	Expiry date	First distribution
10 x 5ML PACK	012088	Jan 2010	27/10/2008
	013088	Jan 2010	29/10/2008
	014108	Mar 2010	10/12/2008
	015108	Mar 2010	16/12/2008

Wockhardt UK (Unbranded) Heparin Sodium products

WOCKHARDT UK HEPARIN SODIUM (PRESERVATIVE FREE) 1000u/ml AMPOULES
PL No 29831/0105

Presentation	Batch number	Expiry date	First distribution
10 x 1ML PACK	002118	Oct 2011	12/01/2009
10 x 5ML PACK	009118	Oct 2011	not yet distributed
	010118	Oct 2011	not yet distributed
	011118	Oct 2011	not yet distributed
	012118	Oct 2011	12/03/2009
10 x 10ML PACK	005118	Oct 2011	09/01/2009
	006118	Oct 2011	09/01/2009
	007118	Oct 2011	30/01/2009

WOCKHARDT UK HEPARIN SODIUM (PRESERVATIVE FREE) 5000u/ml AMPOULES
PL No 29831/0107

Presentation	Batch number	Expiry date	First distribution
10 x 1ML PACK	004118	Oct 2011	26/01/2009

WOCKHARDT UK HEPARIN SODIUM (CONTAINS PRESERVATIVE) 1000u/ml VIALS
PL No 29831/0109

Presentation	Batch number	Expiry date	First distribution
10 x 5ML PACK	017118	Apr 2010	16/02/2009
	018118	Apr 2010	17/02/2009