



Department of

Health, Social Services and Public Safety

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer

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For Action: Directors of Pharmaceutical Services of the HSC Board & BSO
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/26/09
Date: 19 August 2009

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

Karib Kemi Pharm Ltd

Please note - Ciprofloxacin tablets are in both Karib Kemi Pharm and Sandoz Liveries. All other products are solely in Karib Kemi Pharm Livery.

Multiple product Drug Alert

Product Name	PL No.
Amoxicillin Caps 250mg	18224/0004
Amoxicillin Caps 500mg	18224/0005
Atenolol Tabs 50mg	18224/0018
Atenolol Tablets 100mg	18244/0019
Ciprofloxacin Tablets 250mg	18224/0008
Ciprofloxacin Tablets 500mg	18244/0009
Fluoxetine Caps 20mg	18224/0059
Paracetamol Tabs 500mg	18224/0003
Phenoxymethylpenicillin Potassium Tabs 250mg	18224/0049
Ranitidine Tabs 75mg	18224/0028
Ranitidine Tabs 150mg	18224/0006

Ranitidine Tabs 300mg	18224/0007
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Details of over one hundred batches are attached to this document as Appendix 1. Please note the Sandoz livery products are listed in line numbers 68, 70 and 72 of Appendix 1.

Karib Kemi Pharm Ltd, the marketing authorisation holder, is recalling all unexpired stock of the above products due to unsatisfactory shipment conditions during sea transit from their overseas contract manufacturers.

All **unexpired** stock of the listed products and batches should be quarantined and returned for credit. However, care needs to be taken to ensure only those specific batches listed in this drug alert are returned. There are a number of other batches and products which have been transported by air and are not subject to recall action.

For any Medical Information enquiries related to this case please call Karib Kemi Pharm Ltd on 07732 166641 or 07732 166891

For enquiries related to stock returns and credit please call Karib Kemi Pharm Ltd on the numbers in the previous paragraph.

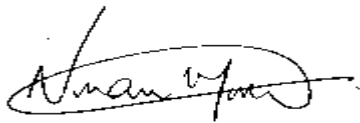
Further details of the products and liveries involved are attached as Appendix 1. This list has been provided by Karib Kemi Pharm Ltd as all remaining in-date stock which has been shipped by sea.

Further information is attached as Questions and Answers in Appendix 2

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:
CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPLD

Appendix 1 (111 line listing)

No.	Product Name	PL No.	Batch Number	Livery	Pack Size
1	Amoxicillin Caps 250mg	18224/0004	KASC 7002	Karib Kemi	21
2	Amoxicillin Caps 250mg	18224/0004	KASC 7003	Karib Kemi	21
3	Amoxicillin Caps 250mg	18224/0004	KASC 7004	Karib Kemi	21
4	Amoxicillin Caps 250mg	18224/0004	KASC 7005	Karib Kemi	21
5	Amoxicillin Caps 250mg	18224/0004	KASC 7007	Karib Kemi	21
6	Amoxicillin Caps 250mg	18224/0004	KASC 7008	Karib Kemi	21
7	Amoxicillin Caps 250mg	18224/0004	KASC 7009	Karib Kemi	21
8	Amoxicillin Caps 250mg	18224/0004	KASC 7010	Karib Kemi	21
9	Amoxicillin Caps 250mg	18224/0004	KASC 7011	Karib Kemi	21
10	Amoxicillin Caps 250mg	18224/0004	KASC 7012	Karib Kemi	21
11	Amoxicillin Caps 250mg	18224/0004	KASC 7013	Karib Kemi	21
12	Amoxicillin Caps 250mg	18224/0004	KASC 7014	Karib Kemi	21
13	Amoxicillin Caps 250mg	18224/0004	KASC 7015	Karib Kemi	21
14	Amoxicillin Caps 250mg	18224/0004	KASC 7016	Karib Kemi	21
15	Amoxicillin Caps 250mg	18224/0004	KASC 7017	Karib Kemi	21
16	Amoxicillin Caps 250mg	18224/0004	KASC 7018	Karib Kemi	21
17	Amoxicillin Caps 250mg	18224/0004	KASC 7019	Karib Kemi	21
18	Amoxicillin Caps 500mg	18224/0005	KADC 7003	Karib Kemi	21
19	Amoxicillin Caps 500mg	18224/0005	KADC 7004	Karib Kemi	21
20	Amoxicillin Caps 500mg	18224/0005	KADC 7005	Karib Kemi	21
21	Amoxicillin Caps 500mg	18224/0005	KADC 7008	Karib Kemi	21
22	Amoxicillin Caps 500mg	18224/0005	KADC 7009	Karib Kemi	21
23	Amoxicillin Caps 500mg	18224/0005	KADC 7010	Karib Kemi	21
24	Amoxicillin Caps 500mg	18224/0005	KADC 7011	Karib Kemi	21
25	Amoxicillin Caps 500mg	18224/0005	KADC 7012	Karib Kemi	21
26	Amoxicillin Caps 500mg	18224/0005	KADC 7013	Karib Kemi	21
27	Amoxicillin Caps 500mg	18224/0005	KADC 7014	Karib Kemi	21
28	Amoxicillin Caps 500mg	18224/0005	KADC 7015	Karib Kemi	21
29	Amoxicillin Caps 500mg	18224/0005	KADC 7016	Karib Kemi	21
30	Amoxicillin Caps 500mg	18224/0005	KADC 7017	Karib Kemi	21
31	Amoxicillin Caps 500mg	18224/0005	KADC 7018	Karib Kemi	21
32	Amoxicillin Caps 500mg	18224/0005	KADC 7019	Karib Kemi	21

No.	Product Name	PL No.	Batch Number	Livery	Pack Size
33	Amoxicillin Caps 500mg	18224/0005	KADC 7020	Karib Kemi	21
34	Amoxicillin Caps 500mg	18224/0005	KADC 7021	Karib Kemi	21
35	Amoxicillin Caps 500mg	18224/0005	KADC 7022	Karib Kemi	21
36	Amoxicillin Caps 500mg	18224/0005	KADC 7023	Karib Kemi	21
37	Amoxicillin Caps 500mg	18224/0005	KADC 7024	Karib Kemi	21
38	Amoxicillin Caps 500mg	18224/0005	KADC 7025	Karib Kemi	21
39	Amoxicillin Caps 500mg	18224/0005	KADC 7026	Karib Kemi	21
40	Amoxicillin Caps 500mg	18224/0005	KADC 7027	Karib Kemi	21
41	Amoxicillin Caps 500mg	18224/0005	KADC 7028	Karib Kemi	21
42	Amoxicillin Caps 500mg	18224/0005	KADC 7029	Karib Kemi	21
43	Amoxicillin Caps 500mg	18224/0005	KADC 7030	Karib Kemi	21
44	Amoxicillin Caps 500mg	18224/0005	KADC 7031	Karib Kemi	21
45	Amoxicillin Caps 500mg	18224/0005	KADC 7032	Karib Kemi	21
46	Amoxicillin Caps 500mg	18224/0005	KADC 7033	Karib Kemi	21
47	Amoxicillin Caps 500mg	18224/0005	KADC 7034	Karib Kemi	21
48	Amoxicillin Caps 500mg	18224/0005	KADC 7035	Karib Kemi	21
49	Amoxicillin Caps 500mg	18224/0005	KADC 7036	Karib Kemi	21
50	Amoxicillin Caps 500mg	18224/0005	KADC 7037	Karib Kemi	21
51	Amoxicillin Caps 500mg	18224/0005	KADC 7038	Karib Kemi	21
52	Amoxicillin Caps 500mg	18224/0005	KADC 7039	Karib Kemi	21
53	Amoxicillin Caps 500mg	18224/0005	KADC 7040	Karib Kemi	21
54	Amoxicillin Caps 500mg	18224/0005	KADC 7041	Karib Kemi	21
55	Amoxicillin Caps 500mg	18224/0005	KADC 7042	Karib Kemi	21
56	Amoxicillin Caps 500mg	18224/0005	KADC 7043	Karib Kemi	21
57	Amoxicillin Caps 500mg	18224/0005	KADC 7044	Karib Kemi	21
58	Amoxicillin Caps 500mg	18224/0005	KADC 7045	Karib Kemi	21
59	Amoxicillin Caps 500mg	18224/0005	KADC 7046	Karib Kemi	21
60	Amoxicillin Caps 500mg	18224/0005	KADC 7047	Karib Kemi	21
61	Atenolol Tabs 50mg	18224/0018	KA5 701	Karib Kemi	28
62	Atenolol Tabs 50mg	18224/0018	KA5 702	Karib Kemi	28
63	Atenolol Tabs 50mg	18224/0018	KA5 703	Karib Kemi	28

No.	Product Name	PL No.	Batch Number	Livery	Pack Size
64	Atenolol Tabs 100mg	18224/0019	KA1 702	Karib Kemi	28
65	Atenolol Tabs 100mg	18224/0019	KA1 701	Karib Kemi	28
66	Atenolol Tabs 100mg	18224/0019	KA1 703	Karib Kemi	28
67	Ciprofloxacin Tabs 250mg	18224/0008	KF2 601ML	Karib Kemi	20
68	Ciprofloxacin Tabs 250mg	18224/0008	SF2 602ML	Sandoz	10
69	Ciprofloxacin Tabs 500mg	18224/0009	KF5 601ML	Karib Kemi	10
70	Ciprofloxacin Tabs 500mg	18224/0009	SF5 602ML	Sandoz	10
71	Ciprofloxacin Tabs 500mg	18224/0009	KF5 701	Karib Kemi	10
72	Ciprofloxacin Tabs 500mg	18224/0009	SF5 702	Sandoz	10
73	Fluoxetine Caps 20mg	18224/0059	DH 10108	Karib Kemi	30
74	Fluoxetine Caps 20mg	18224/0059	DH 10208	Karib Kemi	30
75	Fluoxetine Caps 20mg	18224/0059	DH 10308	Karib Kemi	30
76	Paracetamol Tabs 500mg	18224/0003	DL 10708	Karib Kemi	100
77	Paracetamol Tabs 500mg	18224/0003	DL 10808	Karib Kemi	100
78	Paracetamol Tabs 500mg	18224/0003	DL 10908	Karib Kemi	100
79	Penicillin VK Tabs 250mg	18224/0049	SPT 7004	Karib Kemi	28
80	Penicillin VK Tabs 250mg	18224/0049	SPT 7005	Karib Kemi	28
81	Penicillin VK Tabs 250mg	18224/0049	SPT 7006	Karib Kemi	28
82	Penicillin VK Tabs 250mg	18224/0049	SPT 7007	Karib Kemi	28
83	Penicillin VK Tabs 250mg	18224/0049	SPT 7008	Karib Kemi	28
84	Penicillin VK Tabs 250mg	18224/0049	SPT 7009	Karib Kemi	28
85	Penicillin VK Tabs 250mg	18224/0049	SPT 7010	Karib Kemi	28
86	Penicillin VK Tabs 250mg	18224/0049	SPT 8002	Karib Kemi	28
87	Penicillin VK Tabs 250mg	18224/0049	SPT 8003	Karib Kemi	28
88	Penicillin VK Tabs 250mg	18224/0049	SPT 8004	Karib Kemi	28
89	Penicillin VK Tabs 250mg	18224/0049	SPT 8005	Karib Kemi	28
90	Penicillin VK Tabs 250mg	18224/0049	SPT 8006	Karib Kemi	28
91	Penicillin VK Tabs 250mg	18224/0049	SPT 8007	Karib Kemi	28
92	Ranitidine Tabs 75mg	18224/0028	KR7 701	Karib Kemi	12
93	Ranitidine Tabs 150mg	18224/0006	KR1 704	Karib Kemi	60
94	Ranitidine Tabs 150mg	18224/0006	KR1 705	Karib Kemi	60
95	Ranitidine Tabs 150mg	18224/0006	KR1 706	Karib Kemi	60

No.	Product Name	PL No.	Batch Number	Livery	Pack Size
96	Ranitidine Tabs 150mg	18224/0006	KR1 707	Karib Kemi	60
97	Ranitidine Tabs 150mg	18224/0006	KR1 708	Karib Kemi	60
98	Ranitidine Tabs 150mg	18224/0006	KR1 709	Karib Kemi	60
99	Ranitidine Tabs 150mg	18224/0006	KR1 710	Karib Kemi	60
100	Ranitidine Tabs 150mg	18224/0006	KR1 711	Karib Kemi	60
101	Ranitidine Tabs 150mg	18224/0006	KR1 712	Karib Kemi	60
102	Ranitidine Tabs 150mg	18224/0006	KR1 713	Karib Kemi	60
103	Ranitidine Tabs 150mg	18224/0006	KR1 714	Karib Kemi	60
104	Ranitidine Tabs 150mg	18224/0006	KR1 715	Karib Kemi	60
105	Ranitidine Tabs 150mg	18224/0006	KR1 716	Karib Kemi	60
106	Ranitidine Tabs 150mg	18224/0006	KR1 717	Karib Kemi	60
107	Ranitidine Tabs 150mg	18224/0006	KR1 801	Karib Kemi	60
108	Ranitidine Tabs 150mg	18224/0006	KR1 802	Karib Kemi	60
109	Ranitidine Tabs 300mg	18224/0007	KR3 705	Karib Kemi	30
110	Ranitidine Tabs 300mg	18224/0007	KR3 706	Karib Kemi	30
111	Ranitidine Tabs 300mg	18224/0007	KR3 707	Karib Kemi	30

Appendix 1 Ends

Appendix 2 Questions and Answers – follows on next page

Appendix 2 Questions and Answers

Questions and Answers

Why is a product recall being carried out?

These products have been subjected to unsatisfactory conditions during shipment from their overseas manufacturing sites to the UK.

Is the temperature monitored during shipment?

Yes, but the Qualified Person took no action to review the data, ensure shipment conditions were acceptable or to find a better shipment system. This explains why all remaining in-date stock of these products is being recalled.

Why are you not recalling the product to patient level?

Products imported from non-EU countries have to be tested on import to the EU. These medicines have been tested on import and passed the required tests. However, testing is a sampling activity which examines a limited proportion of the batch and only reflects the condition at the time of testing. We are adopting a precautionary approach at this stage. If any of the additional testing, mentioned below, indicates a higher risk then we will reconsider this position.

Is any more work going on to obtain more information about the risks and potential problems?

Yes, laboratory testing is being carried out and should provide more information. This obviously takes time and some problems might only be detected as the product ages. The recall action taken now should minimise risk to the patient.

Are all products from this marketing authorisation holder shipped by sea?

No. The above listing excludes some recent products which have been shipped by air.

Are you anticipating any product shortages following these recalls?

No. These products are widely used generics with several active suppliers.

What should a company do if they think their products may have been subjected to unsatisfactory conditions during shipment?

They should call the MHRA Defect Centre on 0207 084 2574 or inform their local medicines inspector.

Appendix 2 Ends