



Eng. Mohammed Yahya Majrashi
Head, follow up and communications section,
Surveillance and biometric executive management,
Medical Devices Sector,
Saudi Food & Drug Authority

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www.mastgrp.com

28th May 2013

Dear Eng. Majrashi,

With regards to the following Field Safety Notice (FSN) that we have recently issued:

CIPROFLOXACIN 1ug CARTRIDGE DISCS, CIP1C, lot: 316356 expiry 30/04/2016

This relates to Mast CIPROFLOXACIN 1ug CARTRIDGE DISCS, please see the enclosed document.

I can confirm that we have not sold any of the affected products to customers or any other parties in The Kingdom of Saudi Arabia. Also our investigations to date show that no other batches of CIP1C appear to be affected.

We have already contacted any customers who have received the affected product, and have sent out replacements.

Once again, I can confirm that **no products relating to this incident** have been sold to any customers in The Kingdom of Saudi Arabia.

Yours sincerely

A handwritten signature in blue ink, appearing to read "Jon Hobson", written over a faint, illegible printed name.

JON HOBSON
LABORATORY MANAGER



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**Urgent FIELD SAFETY NOTICE (FSN)
CIPROFLOXACIN 1ug CARTRIDGE DISCS, CIP1C, lot: 316356 expiry 30/04/2016**

Dear Customer,

Mast is issuing Field Safety Corrective Action (FSCA). This has also been reported to the Medicines and Healthcare products Regulatory Agency (MHRA) for the reason detailed below.

Mast has identified a potential problem with the above batch of CIPROFLOXACIN 1ug CARTRIDGE DISCS. As a consequence of recent follow-up QC testing we have identified a potential problem with the above batch of Ciprofloxacin 1ug Cartridge Discs. The investigation revealed that this batch of discs may be producing zones of inhibition that exceed the expected quality control limits stated in current British Society for Antimicrobial Chemotherapy (BSAC) methodology for antimicrobial susceptibility testing (Version 12, January 2013). Although additional "in house" testing has not shown any evidence of misinterpretation of resistant or intermediate organisms there is a possibility that use of this batch may result in isolates being falsely reported as susceptible to Ciprofloxacin. Monitoring of performance of antimicrobial susceptibility tests with appropriate control strains, as specified in BSAC methodology would detect any issue in test performance so it is unlikely that patient safety would be compromised as a result.

It is recommended that use of this batch of discs within your laboratory is discontinued immediately whether or not any unexpected results have been noted.

Mast records show that we despatched X packs to you on [date of depatch]. Mast will dispatch the outstanding replacements to you from current stock of an alternative lot. Please check if you have any packs of this batch left in your stock and if so please discard them/quarantine them awaiting disposal, and confirm the action you have taken on the reconciliation table below and we kindly request that you return this form back to us within 48 hours of receipt. We request that you pass a copy of this FSN onto any relevant users and or customers and or alert any organisation to which incorrect test results arising from the use of this device have been sent.

Please accept our sincere apologies for any inconvenience caused, if you would like to discuss this matter any further, please do not hesitate to contact me (see details above) or your usual Mast contact.

Yours sincerely

Jon Hobson
Laboratory Manager

CIPROFLOXACIN 1ug CARTRIDGE DISCS, CIP1C, lot: 316356 expiry 30/04/2016		
Number of packs we sent you	Number of packs destroyed	Number of packs already used
X		
Comments:		
Contact name:	Signed:	Date:

