Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: February 24, 2015

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Sagent Pharmaceuticals, Inc. – RECALL [Drug]

AFFECTED PRODUCT: **Atracurium Besylate Injection, USP (50mg/5ml and 100mg/10ml)**

SUMMARY: **Unclassified Recall; The products are being recalled due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility.**

The lot numbers being recalled are VATA012, VATA015 (50mg/5mL) and VATB012, VATB013, VATB014, VATB017 (100mg/10mL). Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL is indicated, as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation, and is supplied in single-dose and multi-dose vials.

The recalled product was distributed to hospitals, wholesalers and distributors nationwide from February 2014 through February 2015.

SUGGESTED ACTION: **For consumer inquiry only. Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Sagent Pharmaceuticals Initiates a Nationwide Voluntary Recall of Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL due to FDA Observations Pertaining toAseptic and GMP Practices at the Manufacturer's Site Potentially Impacting Product Sterility

Contact:
Consumer:
(866) 625-1618

FOR IMMEDIATE RELEASE — February 23, 2015 — Schaumburg, IL,Sagent Pharmaceuticals, Inc. today announced the voluntary nationwide recall of two lots of Atracurium Besylate Injection, USP, 50mg/5mL single-dose vials (NDC 25021-659-05) and four lots of Atracurium Besylate Injection, USP, 100mg/10mL multi-dose

vials (NDC 25021-672-10) manufactured by Emcure Pharmaceuticals Ltd. and distributed by Sagent. Sagent has initiated this voluntary recall of Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL to the user level due to FDA observations pertaining to aseptic and GMP practices at the manufacturer's site potentially impacting product sterility. Non-sterility of a drug administered via the intravenous route has the potential to result in infections, which could be fatal, especially in patients who are immunocompromised. Sagent has transferred the manufacture of this product to its own facility and this product manufactured at the Sagent facility will not be impacted by the recall.

Sagent is not aware of any adverse patient events resulting from the use of the subject product lots.

The lot numbers being recalled are VATA012, VATA015 (50mg/5mL) and VATB012, VATB013, VATB014, VATB017 (100mg/10mL) which were distributed to hospitals, wholesalers and distributors nationwide from February 2014 through February 2015. Atracurium Besylate Injection, USP, 50mg/5mL and 100mg/10mL is indicated, as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation, and is supplied in single-dose and multi-dose vials.

Customers are being notified by fax, email, FedEx, and/or certified mail that includes arrangements for return of all recalled product. Customers have been instructed to examine their inventory immediately and to quarantine, discontinue distribution of and return the recalled lots of product. Customers who may have further distributed this product have been requested to identify their customers and notify them at once of this product recall. The necessary form by which to document this information as well as other information regarding this recall is available at www.Sagentpharma.com.

Any questions about returning unused product should be directed to the customer call center at (866) 625-1618 M-F 8am-7pm CST. Healthcare workers who have medical questions about Atracurium Besylate Injection, USP may contact Sagent Medical Affairs (866-625-1618, Option 3) M-F 8am-5pm CST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Program either online, by regular mail or by fax.

- • Online: www.fda.gov/medwatch/report.htm
- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA3500 available at www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Sagent Pharmaceuticals, Inc.

Sagent Pharmaceuticals, Inc., founded in 2006, is a specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing pharmaceutical products, with a specific emphasis on injectables. Sagent has created a unique global network of resources, comprising rapid development capabilities, sophisticated manufacturing and innovative drug delivery technologies, resulting in an extensive and rapidly expanding pharmaceutical product portfolio that fulfills the evolving needs of patients.

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