From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, September 07, 2017 2:20 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Genentech Issues Voluntary Nationwide Recall of Three Lots of Activase® (Alteplase)-100 mg Due to Lack of Sterility Assurance of the Sterile Water for Injection

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), is voluntarily recalling three lots of Activase® (alteplase) 100mg vials, that were co-packaged with Sterile Water for Injection, to the hospital level. The vials of Sterile Water for Injection, manufactured by Hospira Inc., a Pfizer company, and packaged with Activase 100 mg, may be cracked or chipped at the neck of the vial and leaking.

The use of impacted Sterile Water for Injection could result in adverse events such as fever, chills, phlebitis, and granuloma or more severe adverse events such as sepsis or invasive systemic infections. To date, Genentech has not received reports of adverse events associated with use of impacted Sterile Water for Injection.

Activase is supplied directly to hospitals and used in a hospital setting. Activase is indicated for treating patients with acute ischemic stroke (AIS), which is caused by a blood clot in the brain's blood vessels, for treating an acute myocardial infarction (AMI), also known as a heart attack and to break apart an acute massive pulmonary embolism (PE), which is a large blood clot lodged in the blood vessels of the lung. Activase is supplied as a sterile, lyophilized powder in 100 mg vials without vacuum. Each 100 mg Activase vial (58 million IU) is packaged with diluent for reconstitution (100 mL Sterile Water for Injection, USP), and one transfer device: NDC 50242-085-27. The product was distributed nationwide to hospitals.

The affected lots are:

Product Description **UPC**	**NDC**	**Lot #** **Expiration Date**	**Genentech Distribution Dates**
Activase® (alteplase) vial - 100 mg UPC 50242008527	50242-0085-27	3128243 9/30/2018	01/06/2017 – 05/19/2017
		3141239 9/30/2018	
		3166728 2/28/2019	

Genentech is notifying its distributors and customers by issuing a "Dear Customer" letter and arranging for the return of all recalled products. Healthcare providers that have lots of Activase that have been recalled should stop using the product and should return the affected lots to Genentech.

Consumers with questions regarding this recall can contact Genentech:

Medical Inquiries: Please contact Genentech Medical Communications (5am-5pm PT) at 1-800-821-8590 or the Patient Resource Center (6am-5pm PT) at 1-877-436-3683.

Drug Safety/Adverse Events: In the event of any adverse health effects associated with this product recall, contact Genentech Drug Safety/Adverse Events (available 24 hours) at 1-888-835-2555.

Cost Recovery: Genentech will issue a credit to your account for product that you return as part of this recall.

Return Processing Questions: Please contact FedEx Supply Chain at 1-877-674-2081.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: http://www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax** : Download form http://www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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