From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, May 16, 2017 8:25 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Coronary Catheters by Abbott: Recall - Difficulty in Removing Balloon Sheath

Includes specific lots of:
NC Trek RX Coronary Dilatation Catheter
NC Traveler Coronary Dilatation Catheter
NC Tenku RX PTCA Balloon Catheter

ISSUE: Abbott has initiated a voluntary recall of specific lots of three catheters: NC Trek RX Coronary Dilatation Catheter, NC Traveler Coronary Dilatation Catheter, and NC Tenku RX PTCA Balloon Catheter. Specific lots of affected product were manufactured between Jan. 1, 2015 – Jan. 2, 2017, and were distributed between Jan. 13, 2015 – March 14, 2017. For more information, please see Abbott's field safety notice.
Products from the identified lots may exhibit difficulty in removing the protective balloon sheath, which could cause problems with inflating or deflating the balloon. Potential risks associated with balloon inflation and deflation difficulties include air embolism, additional intervention, thrombosis, and myocardial infarction. In one reported case, failure to deflate the balloon necessitated surgery, which resulted in multiple post-surgical complications leading to death.

BACKGROUND: The total number of distributed units from identified lots potentially affected is 449,661. This recall does not affect patients who have successfully undergone cardiac procedures using these devices. Abbott has already implemented corrective actions to ensure the products perform as intended.

RECOMMENDATION: Abbott began contacting customers in March who received coronary catheters from the affected lots, and is arranging the return and replacement of all remaining products.
Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

Read the MedWatch safety alert, including links to the press release and Abbott field safety notice, at:
https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm558737.htm