Press Release

Dr.Reddy's

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Dr. Reddy's Laboratories Issues Voluntary Nationwide Recall of Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules Due To Ampules Breaking And Shattering Upon Opening

Hyderabad, India, March 26, 2020 **For Immediate Release**

Hyderabad, India and Princeton, NJ, USA. March 26, 2020—Dr. Reddy's Laboratories Ltd. (along with its subsidiaries together referred to as "Dr. Reddy's") announced today that it is voluntarily recalling four lots (ACB902, ACB903, ACB904, ACB905) of Phytonadione Injectable Emulsion USP, 10 mg/mL, Single-Dose Ampules to the hospital level. The product is being recalled due to product complaints received due to ampules breaking and shattering, upon opening, during compounding.

The company has received reports of cuts in skin and lacerations to health care professionals. There may be a reasonable probability of flying glass injuring skin, eye and/or other parts which could result in either temporary or permanent injury.

Phytonadione injectable emulsion, is indicated in the following coagulation disorders which are due to faulty formation of factors II, VII, IX and X when caused by Vitamin K deficiency or interference with Vitamin K activity.

Phytonadione injectable emulsion is indicated in:

- anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives;
- prophylaxis and therapy of hemorrhagic disease of the newborn;
- hypoprothrombinemia due to antibacterial therapy;
- hypoprothrombinemia secondary to factors limiting absorption or synthesis of Vitamin K, e.g., obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas, and regional enteritis;
- other drug-induced hypoprothrombinemia where it is definitely shown that the result is due to interference with phytonadione metabolism, e.g., salicylates.

The product is packaged in a carton with 25 X 1 mL Single-Dose Ampules. The batches were distributed nationwide, in U.S. only, between June 21, 2019 and February 26, 2020, to wholesalers, distributors, hospitals and pharmacies.

The recalled lot details are as follows:

Item Description	Lot Number	Expiration date	NDC Number
Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules.	ACB902	03/2021	43598-405-16

Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules.	ACB903	03/2021	43598-405-16
Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules.	ACB904	04/2021	43598-405-16
Phytonadione Injectable Emulsion USP, 10 mg/mL Single-Dose Ampules.	ACB905	06/2021	43598-405-16

Dr Reddy's Laboratories, Inc has notified its distributors to arrange for return of any recalled product. Wholesalers, distributors, hospitals and pharmacies with an existing inventory of the lot being recalled, should stop use and distribution of the product and quarantine the product immediately for return or replacement of all recalled products. Wholesalers, distributors and pharmacies that have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For instructions on returning product or additional assistance, call Inmar at 1-800-967-5952 between the hours of 8 a.m. to 5 p.m. EST, Monday through Friday.

Consumers with general questions can contact Dr. Reddy's Laboratories 1-866-733-3952 between the hours of 8 a.m. to 5 p.m. EST, Monday through Friday. For MedicalInformation or to report an Adverse Event and/or Product Complaint, please contact Dr. Reddy's Laboratories at 1-888-375-3784 between the hours of 9 a.m. to 7 p.m. EST, Monday through Friday. Patients should also contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality concerns experienced with the use of this product may also 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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form 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 executed in cooperation with U.S. Food and Drug Administration.

WARNING - INTRAVENOUS AND INTRAMUSCULAR USE

Severe reactions, including fatalities, have occurred during and immediately after INTRAVENOUS injection of phytonadione, even when precautions have been taken to dilute the phytonadione and to avoid rapid infusion. Severe reactions, including fatalities, have also been reported following INTRAMUSCULAR administration. Typically these severe reactions have resembled hypersensitivity or anaphylaxis, including shock and cardiac and/or respiratory arrest. Some patients have exhibited these severe reactions on receiving phytonadione for the first time. Therefore the INTRAVENOUS and INTRAMUSCULAR routes should be restricted to those situations where the subcutaneous route is not feasible and the serious risk involved is considered justified.

Please refer to the Package Insert for full prescribing information and box warning.

RDY-0320-284

pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com

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The company assumes no obligation to update any information contained herein.