Canada: Phenytoin Sodium Injection USP 50 mg/ml (Sandoz Canada Inc) - potential for particulate matter in 2 ml and 5 ml vials

Sandoz Canada Inc, in consultation with Health Canada, has announced the possible presence of particulate matter in some 2ml and 5ml vials of Phenytoin Sodium Injection USP 50 mg/ml (potentially affected batches are listed below). Low levels of sub-visible particulate matter, determined to be inert carbon related to the vial manufacturing process, have been noted during a recent investigation. The possible presence of visible particulate matter in these batches cannot be excluded.

Description	Batch
PHENYTOIN NA 50MG/ML 5ML 10LIVI CA	BT9159, CG2519, CH9389, CK9567, CX9724, DA2448, DE5293
PHENYTOIN NA 50MG/ML 2ML 10LIVI CA	BG1193, BL9015, CB1255, CG0113, CJ8539, CN3870, DA4554, DE2788, DP2639

Inadvertent injection of particulate matter into a patient could result in patient injury, such as local inflammation, phlebitis, allergic response and/or embolization in the body. Since the release of the potentially affected batches, no adverse event reports related to this issue were received at Sandoz Canada Inc.

Healthcare professionals are recommended, as per standard practice, to inspect all phenytoin injectable products before use (or after dilution). The use of a 0.22 micron in-line filter is recommended when administering the listed batches. Where it is not possible to use an in-line filter for intravenous administration, alternative therapies should be considered.

Please refer to the following website in Health Canada for details:
http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/37369a-eng.php

In Hong Kong, the above product is not a registered pharmaceutical product.

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