



URGENT FOLLOW-UP TO FIELD SAFETY NOTICE – MSS-15-637 FA dated September 2015

Voluntary Medical Device Safety Advisory Notice BD Plastipak / Oral Syringes

Date: 16 November 2016

For the Attention of:

- Procurement, Medical Director, Risk Manager, Chief Pharmacist, Health & Safety Officer

Description of the problem:

BD communicated in September 2015, via an Urgent Field Safety Notice (MSS-15-637 FA) that customers had reported reduced potency of certain medications when stored in BD plastic disposable syringes, made with a stopper provided by an alternate supplier.

The purpose of this Follow-up is to inform our customers about the corrective actions implemented by BD:

- 1- All syringes currently distributed in Ireland by BD are manufactured with a stopper provided by our primary supplier (not affected by the issue), except for the 4 products listed in table A.
- 2- The syringes in table A are currently manufactured with the stopper from the alternate supplier and are still in distribution in Ireland.
- 3- BD is committed to converting all syringes sold in the EU back to the primary stopper supplier and expects that from July 2017, all syringes supplied to the marketplace will contain the primary stopper only.

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Registered Office: The Danby Building, Edmund Halley Road Oxford Science Park, Oxford OX4 4DQ

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Table A:

Syringe Size	Product Type	Catalog No.
20mL	Eccentric Tip syringe	300613
	Bulk non sterile Eccentric Tip syringe	300220
50 ml	Catheter Tip	300867
	Bulk non sterile catheter tip	300228

In addition, BD will modify our labeling of the BD Syringes listed in table B to include the following statement:

Pharmaceutical products prepared in these syringes should be administered as soon as possible.

This statement will appear on the shelf pack, it will not be included on the case pack or individual blister pack.

Table B:

Syringe Size	Product Type	Catalog No.
3 ml	Luer-Lok™ syringe	309658
	Bulk non-sterile syringe	301073
	With BD SafetyGlide™ needle	305904
	Oral syringe	305210 305220 305853
5mL	Luer-Lok™ syringe	309649
	Bulk non-sterile syringe	301027
	With BD Eclipse™ needle	305785
	With BD SafetyGlide™ needle	305907
	Oral syringe	305855 305218
20mL	Eccentric Tip syringe	300613 301183 301190
	Bulk non sterile Eccentric Tip syringe	300220
30mL	Luer-Lok™ syringe	302832
+50 ml	Catheter Tip	300867
	Bulk non sterile catheter tip	300228

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Potential hazard and potential risk to patients

In early 2015, BD has received a limited number of reports from customers globally (not from European customers) related to loss of drug potency when some drug products were stored for periods of time (exact timeframes unknown) in BD syringes with alternate stoppers. There have been no reports of serious deterioration in state of health.

Actions:

Please be aware of the information provided in this Field Safety Notice.

Transmission of this Field Safety Notice

Please maintain awareness of this notice and resulting actions to ensure effectiveness of the corrective action.

Please complete and return the enclosed Acknowledgement Form by email or fax to val.mummery@bd.com or + 44 1865 781501 or by post using the enclosed FREEPOST addressed envelope.

Contact Reference Person

If you have any questions or would like to discuss this issue further, please contact your local BD Account Manager, Tina Cregan, on 86 82 07869 or tina.cregan@bd.com.

Yours sincerely,



Dr. Bernd Peschke
Director Regulatory Compliance CE and MPS WE-EMA
Corporate / Shared Services

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