FSN Ref: RC-2022-RN-01012-1 FSCA Ref: 20306/22

MediPharm Labs

Date: 05-10-2022

Urgent Field Safety Notice
ELM SYRINGES DISTRIBUTED WITH MEDICINAL CANNABIS PRODUCTS

For Attention of*:Compounding Pharmacist

Contact details of local representative (name, e-mail, telephone, address etc.)*
Medipharm Labs Australia, +61 433 254 037, 2 Cyclone Street, Wonthaggi, Victoria, Australia.

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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Dosing Pipette. Medical Device Class Im
1.	2. Commercial name(s)
	NA
1.	3. Unique Device Identifier(s) (UDI-DI)
	UMDNS 15-166
1.	4. Primary clinical purpose of device(s)*
	DISPENSER
1.	5. Device Model/Catalogue/part number(s)*
	901700-01
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	03007-01
1.	8. Associated devices
	NA

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Elm dosing pipettes have been breaking with repeated patient use. Affected Batches: BB3017-01.
2.	2. Hazard giving rise to the FSCA*
	MediPharm Labs has found that a very small number of Elm dosing pipettes have been breaking with repeated patient use. Affected Batches: BB3017-01.
2.	3. Probability of problem arising
	Please note that the corrective action is currently in place, customers are receiving a different medical device.
2.	4. Predicted risk to patient/users
	The frequency of this occurrence is low. The assessed impact to patient safety is low due to the potential disruption to treatment and dosing of medicine from the accessory, not due to any issue with the medicine. This low risk is mitigated by the proactive replacement of pipette
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	Multiple complains were raised by Australian Client, after investigation, an incompatibility of the device with the finished product was found.
2.	7. Other information relevant to FSCA
	NA

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	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

MediPharm Labs ask customers to
1. Inspect stock and quarantine affected stock on hand to prevent further use.
2. Contact the company to be provided with a replacement.

3.	2. By when should the action be completed?	Please consider that the only batch affected expires next 01st Nov 2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? NA NA	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No

3. 5. Action Being Taken by the Manufacturer

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

Elm pipette has already been replaced by an alternative device on which we have performed a R&D compatibility study

3	6. By when should the action be completed?	NA
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Medipharm Labs Australia
	b. Address	2 Cyclone Street, Wonthaggi, 3995, Victoria Australia
	c. Website address	NA
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Therapeutics Goods Administration (TGA) has been informed	
4.	9. List of attachments/appendices:	NA
4.	10. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.