MPS 2509
MMS 1855

HSC Business Services Organisation

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy and Clinic Level

Dear Healthcare Professional

Techdow Europe AB

Inhixa solution for injection in pre-filled syringe 2,000 IU (20 mg) in 0.2 mL; 4,000 IU (40 mg) in 0.4 mL; 6,000 IU (60 mg) in 0.6 mL; 8,000 IU (80 mg) in 0.8 mL; 10,000 IU (100 mg) in 1.0 mL **(Enoxaparin Sodium)**	**EU/1/16/1132/012** **EU/1/16/1132/014** **EU/1/16/1132/016** **EU/1/16/1132/018** **EU/1/16/1132/020**

Brief description of the problem

Techdow Europe AB has issued the Direct Healthcare Professional Communication (DHCP) attached due to rare cases of premature self-activation of the safety device in unused, unopened pre-filled Inhixa syringes as shown in the DHCP diagrams. When premature activation has occurred, administration is not possible.

Advice for healthcare professionals

To minimise the risk of missed doses:

- Pharmacists should visually check all Inhixa syringes before dispensing to check if they are affected by the self-activation defect as shown in the DHCP diagrams. Do not open the syringe blisters.
- Individual syringes that are affected by the self-activation defect should not be dispensed to patients.

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- Pharmacists should make sure they have sufficient stock of Inhixa available as replacements.

Company contact information

Techdow Pharma England Limited can be contacted on 01271 334 609.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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Direct Healthcare Professional Communication from Techdow Europe AB

▼Inhixa (enoxaparin sodium) solution for injection: rare cases of self-activation of safety device in unopened, unused pre-filled syringes.

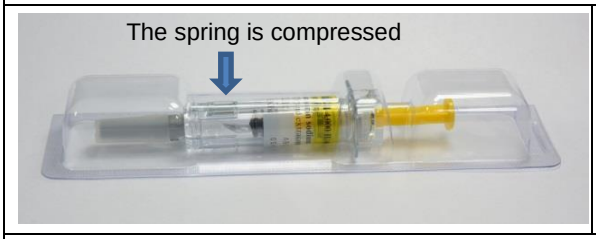
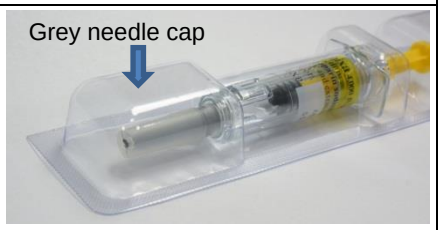
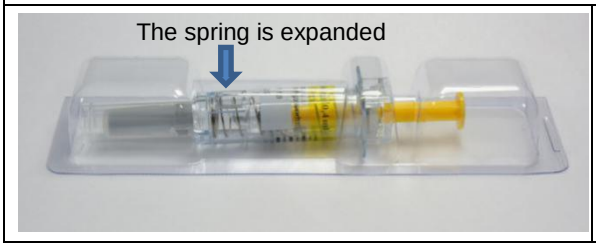
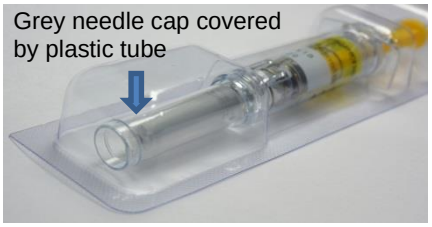
Dear Healthcare professional,

Techdow Europe AB in agreement with the European Medicines Agency and relevant local Competent Authorities would like to inform you of the following:

Summary

- In very rare cases, premature self-activation of the safety device has been observed in unused, unopened pre-filled Inhixa syringes (see Figure 1 below); when premature activation has occurred, medicine administration is not possible.
- **Pharmacists should visually check all devices before dispensing Inhixa and make sure they have sufficient stock of Inhixa available as replacements.**
- There is negligible risk of needle stick injury when handling these pre-filled syringes, since the safety device ensures full coverage of the needle; the risk of a patient missing a dose can be minimised by the above checks and advice to patients.

Figure 1. Pre-activation is easily detectable:

Normal pre-filled syringes	
	
Pre-activated pre-filled syringes	
	

Activated safety device effectively covers the needle

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Background on the safety concern

Self-activation of the safety device has been observed rarely in unused, unopened blisters containing Inhixa pre-filled syringes. An analysis has shown that the incidence of self-activation is 0.001%. To date, the issue has not been associated with any adverse event or risk to public health.
The possibility of needle stick injury is negligible as the safety device ensures full coverage of the needle. With regard to the potential risk of missing a dose, this is easily manageable: as the product is presented in transparent blisters, self-activation is visually apparent and easily detectable before dispensing and use. Moreover it is not necessary for pharmacists to open the blister packs to perform a visual check of syringes blisters before dispensing.
Detailed investigation by the manufacturer has pinpointed the root cause, corrective and preventive actions have been implemented to prevent recurrence of the issue.

Call for reporting

We kindly ask you to notify the manufacturer or local representative of the Marketing Authorization Holder of any pre-activation events. In your notification, we would be grateful if you could provide your contact details (specifically your name, postal address, phone number, email address). Please do not forget to include the product name, strength and batch details (e.g., batch number and expiry date).
Inhixa is subject to additional monitoring. Please report any suspected adverse reactions.

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Company contact point

To access to further information, please contact:

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