

Date: October 2020

## **DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

### **MUSE urethral sticks (alprostadil): Supply of packs with known anti-tamper seal issue**

Dear Healthcare Professional,

**Summary: To ensure on-going market availability of MUSE urethral sticks in the UK, the MHRA have granted a batch specific variation to enable supply of packs with a defective anti-tamper seal.**

The latest batches of 500mcg and 1000mcg (all pack sizes) of MUSE have been produced with anti-tampering devices (transparent seals) which were found to either not adhere correctly to the cartons (popping up) or to be misaligned. Please kindly note that 125mcg and 250mcg packs remain unaffected. Please refer to the Annex for further details of affected batches.

#### **Please note the following:**

- The MUSE urethral sticks themselves are not impacted in any way, so, from a clinical perspective, these batches will perform as licensed.
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.
- Please check the completeness of the products from the batches affected (batch numbers are included in the attached Annex). Please ensure that a patient information leaflet (PIL) is included in each carton. Should the PIL be missing, please print a copy from the emc website (<https://www.medicines.org.uk/emc/search?q=muse>) and report to Mylan UK Healthcare (contact details for product quality complaints are provided below)

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients. Failure of the tamper-evident seal may result in counterfeit products being supplied. Therefore, please report any issues (e.g. product quality complaints including lack of efficacy) to Mylan UK Healthcare Limited using the contact details below and if appropriate (e.g. adverse events or lack of efficacy) to the MHRA.

#### **MHRA Reporting Details - Call for reporting:**

Please continue to report suspected adverse reactions with any medicine or vaccine to the MHRA through the Yellow Card Scheme. It is easiest and quickest to report ADRs online via the Yellow Card website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, you can report via some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) or by calling the Commission on Human Medicines (CHM) free phone line: 0800-731-6789.

Adverse reactions/events should also be reported to MAH at e-mail address:  
[ukpharmacovigilance@mylan.com](mailto:ukpharmacovigilance@mylan.com)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

**Mylan UK Healthcare Limited contact point**

If you have details of an Adverse Event or Pharmacovigilance Relevant Information (including lack of efficacy) to report please email UK Pharmacovigilance TODAY at [ukpharmacovigilance@mylan.com](mailto:ukpharmacovigilance@mylan.com) or by phone: 0800 121 8267

To report a Product Quality Complaint for the UK please email UK Complaints TODAY at [UKComplaints@mylan.co.uk](mailto:UKComplaints@mylan.co.uk)

If you have any questions about this letter or if you have an enquiry for Medical Information please e-mail [info.uk@mylan.co.uk](mailto:info.uk@mylan.co.uk) or if it is urgent please phone +44 (0)1707 853 000

Yours Sincerely,



**Julian De Gabriele**

Head of Medical Affairs UK, Ireland & Malta

Mylan Products Ltd.

**Annex to letter: Table of batches affected by defective tamper evident seal.**

| Batch Number | Man Date | Exp Date | Product Strength                     |
|--------------|----------|----------|--------------------------------------|
| 190423       | Mar-19   | Mar-21   | MUSE URETH STK 1000MCG 1POU GB/IE MY |
| 191273       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 1POU GB/IE MY |
| 191274       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 1POU GB/IE MY |
| 191323       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 1POU GB/IE MY |
| 192327A      | Nov-19   | Nov-21   | MUSE URETH STK 1000MCG 1POU GB/IE MY |
| <b> </b>     |          |          |                                      |
| 190479       | Apr-19   | Apr-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 190488       | May-19   | May-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191048       | May-19   | May-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191120       | May-19   | May-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191121       | May-19   | May-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191162       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191163       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191217       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191218       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191219       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191321       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191322       | Jun-19   | Jun-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191575       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191612       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191613       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191576       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191633       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191634       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191677       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191678       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| 191679       | Aug-19   | Aug-21   | MUSE URETH STK 1000MCG 6POU GB/IE MY |
| <b> </b>     |          |          |                                      |
| 190431       | Apr-19   | Apr-21   | MUSE URETH STK 500MCG 1POU GB MDA    |
| 191105       | May-19   | May-21   | MUSE URETH STK 500MCG 1POU GB MDA    |
| 191170       | May-19   | May-21   | MUSE URETH STK 500MCG 1POU GB MDA    |
| <b> </b>     |          |          |                                      |
| 190138       | Jan-19   | Jan-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |
| 190727       | May-19   | May-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |
| 191049       | May-19   | May-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |
| 191223       | Jun-19   | Jun-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |
| 191687A      | Aug-19   | Aug-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |
| 191911       | Sep-19   | Sep-21   | MUSE URETH STK 500MCG 6POU GB/IE MY  |