National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Recall of Targocid 200mg powder for solution for injection/infusion or oral solution, Aventis Pharma Limited t/a Sanofi, due to the presence of bacterial endotoxins

Date of Issue:	21-Oct-22	Reference No:	NatPSA/2022/008/MHRA

This alert is for action by: primary and secondary care, specifically those involved in pharmacy services, including dispensing general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists, Chief Nurse, Head of Infection Control and Head of Procurement/Supplies or equivalent roles, as well as leaders in general practice and community pharmacy.

DMRC Medicines Defect Classification	NatPSA equivalent to Class 1 Recall Notification

Explanation of identified safety issue:

Sanofi UK is initiating an urgent recall of two batches of Targocid 200mg powder for solution for injection/infusion or oral solution (Batch Number 0J25D1 and Batch Number 0J25D2).

This is due to out of specification results obtained for bacterial endotoxins, which has been confirmed through testing of retain samples. This issue was observed following a medical adverse event, which reported that four patients experienced high grade of fever approximately three hours post-administration of vials from the impacted batches.

Due to the out of specification results observed there is a potential life threatening or serious risk to patient health.

Advice for all healthcare professionals

Healthcare professionals should be aware of the following clinical symptoms related to the potential risk to patient health: a high temperature (fever) or low body temperature, chills and shivering, cold, clammy and pale or mottled skin, a fast heartbeat, fast breathing, severe breathlessness, severe muscle pain, feeling dizzy or faint, a change in mental state – such as confusion or disorientation, loss of consciousness, slurred speech, nausea and vomiting and/or diarrhoea.

In the event the affected batches have been administered to patients, appropriate clinical assessment should be performed, in addition to close monitoring for any adverse reactions. All suspected adverse events should also be reported via the MHRA's Yellow Card scheme immediately.

Actions required

Actions to complete by 26-Oct-22:

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist/Responsible Pharmacist and Dispensing GPs in the first instance.

1. Stop supplying the impacted batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

2. Immediately identify whether your organisation has administered any affected batches to patients and put an action plan in place to ensure appropriate clinical assessment and monitoring

3. Immediately identify whether your organisation has supplied any affected batches to patients to use at home. If batch traceability information is not available, identify any patients dispensed this product since 28 July 2022. Request patients to return any impacted batches for disposal.

4. Contact all patients who may be using the impacted batches. If they have any impacted product help them source alternative supplies, including by ensuring a new prescription is available for the patient when they return their medicine to the pharmacy.

Additional information:

Product Information: Aventis Pharma Limited t/a Sanofi
Targocid 200mg powder for solution for injection/infusion or oral solution (Teicoplanin) **PL 04425/0088**

Batch Number	Expiry Date	Pack Size	First Distributed
0J25D1	30/04/2023	1 vial	28/07/2022
0J25D2	30/04/2023	1 vial	10/08/2022

Defective Medicines Report Centre Reference: MDR 111-10/22

Advice for healthcare professionals in primary care

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. Pharmacists and homecare providers involved in dispensing this product should:

- immediately contact all patients who have been issued the impacted batches and ask them to confirm if they have any affected stock within their possession. If batch traceability information is not available, all patients dispensed this product since 28 July 2022 should be contacted.
- appropriately counsel affected patients to contact their General Practitioners (GPs) or other relevant prescribers to arrange a new prescription.

GPs and other prescribers involved in patient care should also actively seek to identify any patients who have been prescribed the impacted product/batches since 28 July 2022 to ensure that a new prescription is available for the patient when they return their medicine to the pharmacy.

Advice for healthcare professionals in secondary care

Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. In liaison with relevant colleagues, Pharmacy Procurement teams (NHS provider Trust and others) involved in dispensing this product should immediately identify patients who are currently using any impacted batches and source alternative supplies. The Department of Health and Social Care has confirmed that alternative unaffected batches of Targocid and non-proprietary teicoplanin preparations remain available.

Advice for patients

For most patients, this product is administered by healthcare professionals directly in hospitals. If you have concerns about a medicine you may be using, please contact your healthcare professional. If you have been prescribed this medicine to use at home (via intravenous injection/infusion or for use by preparing the solution for oral administration), check to see if you have any of the impacted batches listed above and return to your local pharmacy. If you have received an impacted batch and are currently undergoing medical treatment with an impacted batch, you should discontinue treatment and seek immediate medical advice on alternative supplies and/or monitoring. Alternative teicoplanin medicines can be sourced by speaking to your GP or pharmacist. If they have not contacted you within 24 hours, please contact them directly or an out-of-hours service to discuss.

If you are being treated with Targocid 200mg currently and are concerned after experiencing any of the symptoms listed below, please seek medical assistance or visit the nearest accident and emergency centre: a high temperature (fever) or low body temperature, chills and shivering, cold, clammy and pale or mottled skin, a fast heartbeat, fast breathing, severe breathlessness, severe muscle pain, feeling dizzy or faint, a change in mental state – such as confusion or disorientation, loss of consciousness, slurred speech, nausea and vomiting, diarrhoea and feeling increasingly unwell

Further Information

For more information on licensed stock and resupply queries for the licensed presentation, please contact GB-CustomerServices@sanofi.com; phone number: 0800 854 430. For medical information queries and all other enquiries, please contact uk-medicalinformation@sanofi.com; phone number: 0800 035 25 25.

Reference Information:

1. Class 1 Medicines Recall Notification including patient specific information – Click Here

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Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restrictions are lifted.