

CSL Biotherapies

Medical Device Bureau
Ministry of Health
Malaysia

Friday, 16 July 2010

Dear Sir/Madam,

Product Notification

CSL is advising the MDB of actions taken recently regarding its Reagent Red Blood Cells (RRBC).

Background

CSL Biotherapies Immunohaematology has received customer complaints in June from a small number of customers who received 0.8% RRBC products, reporting sporadic examples of haemolysis in some cells from some batches of RRBC product.

RRBCs are in vitro diagnostic reagents used in pretransfusion and antenatal testing, made from red blood cells and supplied every 4 weeks on a cyclical basis. As such they have a short expiry (10 weeks from date of bleed of the donor units, approximately 6 weeks in the field). The products are issued non-sterile and are used by laboratories in a non-sterile environment.

Investigation

CSL has conducted a thorough review of all customer complaints, tested product returned from the customer, the field, and product held at CSL, conducted trend analysis and reviewed manufacturing records and lot trace information. Subsequent to the investigation we have been able to ascertain:

1. 0.8% RRBCs were affected
2. all results indicate that the haemolysis was sporadic, not all kits within a batch or all tubes within a kit were affected
3. only batches of product manufactured between 5th May and 26th May were affected
4. product not affected performed as per the product leaflet
5. there is a precaution in the product leaflet, advising that product should not be used if signs of haemolysis are observed

Post investigations we have identified the root cause and implemented corrective actions to address this, ensuring that all future batches are not affected. Ongoing investigations to monitor the implemented action are underway and no further reports have been observed or received from product manufactured post the implementation.

Product Shipped to Malaysia

Malaysian customers received two products that were manufactured during this period (Phenocell™ C Batch 9653013 Expiry 09/07/10, and Abtectcell™ III Batch 8245035 Expiry 10/07/10). Customers who received these batches were advised to report any instances of product discolouration and/or haemolysis, and any such product has been replaced. Product which did not show any of these features was still suitable for normal use.

Conclusion

This action was rapid, aimed to inform customers and to instruct them to check product and remind them to follow the product leaflet.

Regards,



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CSL Biotherapies - Immunohaematology
Blood safety | Blood security | Blood quality
Blood supply history | Blood supply continuity | Blood supply reliability

Note: Customer notification letter dated 24/06/2010 attached