



Medicines Authority

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Drug Alert

CLASS III MEDICINES RECALL

ACTION WITHIN 5 DAYS

Date: 10th August 2012

Our Ref: MDR_08/2012

Dear Healthcare Professional,

**CLASS III Recall of
THYMOGLOBULINE PDR FOR SOLN FOR INFUSION 25MG
LOT No. C0102H11**

Genzyme, a Sanofi company, is performing a voluntary, preventive recall of lot C0102H11 of the above mentioned product which has been distributed in Malta. This recall is being performed to hospital/ward level under the supervision of the Medicines Authority.

This lot is still compliant with specification but presents similar stability profiles to lot C0072 (only distributed in the United States) which has an out of specification result (OOS) for molecular size distribution (polymers, aggregates and fragments) of Thymoglobuline.

The proposed recall is not expected to impact supply to patients.

Kind Regards,

S Serge
Medicines Inspector