



11 May 2016

Dear Colleague

The Medicines and Healthcare products Regulatory Agency (MHRA) has been made aware of an issue involving the QRISK[®]2 Calculator in SystmOne, run by TPP which has resulted in incorrect results for some patients. This only affects TPP.

If you run TPP in your practice please do not use this QRISK[®]2 Calculator option until further notice. If necessary you can use the QRISK[®]2-2016 Calculator on the www.qrisk.org website which is not affected by this issue.

MHRA is working with TPP, as a matter of urgency, to make sure the identified issue is resolved and that any affected patients are identified.

The calculator is a predictive algorithm used to support medical practitioners, mainly in GP practices, to help assess the potential risk of cardiovascular disease (CVD) in patients, as part of their overall evaluation. This issue has resulted in incorrect results being produced for a proportion of patients. For the affected patients, the potential risk of CVD could have been under or overstated.

Clinical advice received by MHRA indicates the risk to individual patients is small and affects only a limited group of patients who should be re-evaluated at their next routine appointment. TPP will be in communication with practices to inform them of any patients who may be affected.

If you have any further enquiries please contact DSS-TM@mhra.gsi.gov.uk.

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MHRA