Health Canada Santé Canada

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NOTICE

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Update for Clinical Trial Sponsors: Requirements for Tuberculosis Screening of Healthy Volunteers in Phase I Clinical Trials involving Immunosuppressant Drugs or Drugs with Immunosuppressant Properties.

On July 23, 2006 the Therapeutic Products Directorate's (TPD) and Biologics and Genetic Therapies Directorate's (BGTD) posted a notice related to the requirements for tuberculosis screening for certain Phase I clinical trials in healthy volunteers (see http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/tuberc_notice_avis_e.html for more information).

Since the posting of this notice, two *in-vitro* T-cell based assays that measure interferon gamma production have been licensed in Canada for the diagnosis of latent tuberculosis infection. These assays are known as the QuantiFERON®-TB Gold In-Tube and T-Spot TB®.

While these two assays present possible alternatives to the tuberculin skin test (TST), sponsors are encouraged to continue complying with the information provided in the July 23, 2006, notice for Phase I clinical trials involving immunosuppressant drugs or drugs with immunosuppressant properties, which includes the use of the TST.

Please note that the two assays may be considered as a tool for further assessment by a specialist, such as in instances where the TST result is 5 mm or more, but they should not, at the present time, replace the TST. This recommendation is supported by the recent Canadian Tuberculosis Advisory Committee Statement published in Volume 33 (November 1, 2007) of the Canadian Communicable Disease Report regarding the clinical use of QuantiFERON®-TB Gold In-Tube and T-Spot TB®. To review the Advisory Committee Statement, please visit the following web link: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/07vol33/acs-10/index-eng.html.

Should you have any additional questions regarding the content of the notice, please contact:

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