



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Retraction of the “Letter of support for drug-induced liver injury (DILI) biomarker” (EMA/423870/2016).

This letter of support was retracted from the EMA website on 15 April 2019.

The decision to retract was based on information received by the IMI TransBioLine consortium, which is the successor of the former IMI SAFE-T consortium, which itself was the applicant of the aforementioned “Letter of Support”. The consortium informed that, due to a case of scientific misconduct at one of the collaboration partner centers of the consortium, the IMI TransBioLine consortium is no longer recommending the exploratory use of hyperacetylated HMGB1 isoforms in clinical studies.

Whereas it is likely that the other markers included in the Letter of Support are not affected, the overall promising nature of the biomarkers was considered to be highly dependent on the outstanding results for the incriminated biomarker hyperacetylated HMGB1. The CHMP/EMA has therefore decided to retract this Letter of Support.

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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