

[REDACTED]

From: [REDACTED]
Sent: 29 April 2014 12:55
To: All Human PHARMACOVIGILANCE
Cc: [REDACTED]
Subject: [REDACTED] comments Gardasil, EMEA/H/C/703 LEG 079 - Rapp Assessment Report - Case number 401422

Dear PRAC Members,
Dear colleagues,

Please be informed that we fully endorse the conclusions of the Rapporteur and agree that the review of data provide sufficient evidence to list ADEM as an ADR in the section 4.8 of the EU SmPC.

Best regards,

On behalf of the PRAC Rapporteur [REDACTED]

[REDACTED]