

Request to marketing authorisation holders to send the approved version of the risk management plan

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The Vigilance Division of the FAMHP requests marketing authorisation holders to send the approved version of the risk management plan for medicinal products for human use with a national marketing authorisation.

In order to have a better overview of the approved risk management plans (RMP), the FAMHP asks marketing authorisation holders to send the most recently approved risk management plan and any subsequent changes to vig@fagg-afmps.be.

From now on, the email sent to marketing authorisation holders upon the closing of a variation procedure will also ask that when the risk management plan is updated, the approved version of that plan in PDF format, as well as any questions, be sent to vig@fagg-afmps.be.

Back

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