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Procedure Management and Business Support

EMA procedural advice for marketing authorisation holders/applicants concerned by referral procedures (human medicines)

The European Medicines Agency is changing its practices in informing marketing authorisation holders (MAHs)/applicants involved in a referral procedure.

As of 20 January 2014, all correspondence related to the start of a referral procedure, as well as all subsequent documents provided to the MAHS/applicants during the referral procedure will be sent electronically (via e-mail and/or Eudralink, only).

Therefore, MAHs /applicants need to ensure that the national competent authorities of the Member States where their products are authorised or where the marketing authorisation application is ongoing, are provided with the most up to date contact details.

MAHs/applicants must also inform the national competent authorities of the Member States in cases where the MAHs/applicants cannot be reached electronically.

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