Submission of Applications where Italy acts as Reference Member State (RMS)

Any new request to AIFA to acts as RMS as well as any other application where Italy acts as RMS should be submitted according to the following procedure:

- **For any marketing authorization application** (including Line Extension and Repeat Use procedures) where Italy acts as RMS, please fill the forms “FORM_AIFA.RMS” and “Mod.309/2” and send them to the Head of the RMS&VAR Unit, Laura Braghiroli (l.braghiroli@aifa.gov.it). If the request is related to a biological product please send it in copy also to the Head of the MB Unit, Lorenzo Montrasio (l.Montrasio@aifa.gov.it).

- **For variations**, the Applicant is requested to inform the RMS in advance, by e-mail (at least 10 days before submission for type I and 20 days before submission for type II), sending the draft Application Form (AF) and the table of contents (ToC) and indicating the planned time for submission. All information should be sent to the contact point of the medicinal product, if already available, or otherwise to the Head of the IT-RMS and Variation Unit, Laura Braghiroli (l.braghiroli@aifa.gov.it) or, for biological product, to the Head of the MB Unit, Lorenzo Montrasio (l.Montrasio@aifa.gov.it).