

Guidance on submission of Marketing Authorization/Extension, MA Variation and Renewal applications, MAH Transfer, ASMF up to the end of the restrictions related to COVID-19 emergency

Please be informed that, due to COVID-19 emergency and the difficulties that some MA holders are facing, as exception to the provisions given in the guidance published on 7th May 2019

(https://www.aifa.gov.it/documents/20142/0/CESP_EN_07.05.2019.pdf)

and in the guidance published on 29th May 2019 concerning MAH Transfer applications

(https://www.aifa.gov.it/documents/20142/1123276/MAH_Transfer_24.04.2018.pdf)

the Marketing Authorizations Department will accept:

1. the submission of MA variation and renewal applications/notifications through the relevant portals pending the submission of what required in the guidance dated 7th May 2019
2. the submission through CESP of MA/extension applications (N,MR,DC) pending the submission of what required in the guidance dated 7th May 2019
3. the submission of MAH Transfer applications of marketing authorization granted through national, DC and MR according to the below instructions:
 - the applications shall be sent to protocollo@pec.aifa.gov.it
 - all documents that would require submission as original or legalized copies can be sent as scanned copies, including cover letter with original signature
 - statement that product information is in line with the latest approved one should be attached, together with details concerning parallel variations submitted on the variation portal, if any

At the end of the restrictions related to COVID-19 emergency, in order to complete the submission and obtain the MAH transfer, the Applicant shall submit the original paper documents supporting the MAH transfer; copy of the receipt of PEC submission shall be included together with the € 16.00 revenue stamp, if not yet already done.

4. the submission of ASMF and subsequent updates according to the below instructions:
 - submission through CESP
 - notification of the submission through CESP to the mailbox asmf@aifa.gov.it

At the end of the restrictions related to COVID-19 emergency, ASMF and ASMF updates shall be sent in accordance with what established in the guidance dated 7th May 2019; copy of the CESP submission notification should be included in the package.

5. The submission of proposed changes in accordance with artt.78 e 79 del D.Lgs. N°219/2006 (articles 61(3) and 62 of the Directive 2001/83) in line with the below instructions:
 - the applications shall be sent to protocollo@pec.aifa.gov.it
 - - all documents that would require submission as original or legalized copies can be sent as scanned copies

At the end of the restrictions related to COVID-19 emergency, the Applicant shall submit the original paper documents together with the copy of the receipt of the PEC submission

The provisions given above are also applicable to responses/additional documents.