

Guidance on submission of Marketing Authorization/Extension, MA Variation and Renewal applications, 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 <u>guidance published the 7th May 2019</u>, the Marketing Authorizations Department will accept:

- 1. the submission of MA variation and renewal applications/noifications through the relevant portals; the submission of what required in the above mentioned guidance can be postponed
- 2. the submission through CESP of MA/extension applications (N,MR,DC); the submission of what required in the above mentioned guidance can be postponed

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