

« Brexit »
Notice to Marketing Authorization Holders
For Human medicinal products registered via Mutual recognition, decentralized or
purely national procedures

The United Kingdom (UK) formally left the European Union (EU) on 31 January 2020 and became a third country. A transition period began on 1 February 2020, during which EU pharmaceutical law remains applicable to the UK. **This is due to end on 31 December 2020.**

Since the legislation imposes that some activities related to medicinal products should be performed only in Member States of the European Union, the ANSM reminds the Marketing Authorization Holders (MAHs) about their responsibility in making the necessary changes in their marketing authorization dossiers, before 31 December 2020.

This should be in place in order to ensure that medicines can continue to be supplied in the Member States of the EU after the transition period.

Thus, as of 1 January 2021, the MAH, the so called “exploitant” (responsible for placing the product on French market), the batch testing and/or batch release site(s), the EU qualified person responsible for Pharmacovigilance (EUQPPV) and the Pharmacovigilance Master file (PSMF) should be located in the European Union.

In case the MAH would not be able to proceed with the above-mentioned changes in the dedicated timeline, and only in this case, he should inform the ANSM as soon as he is aware and at the latest on 15 November 2020. The ANSM should be informed by e-mail only via the following dedicated e-mail box:

brexit@ansm.sante.fr

The following informations should be precised: name of the product, CIS code, procedure, marketing status in France and the non-compliance should be clearly identified.

The ANSM reminds the MAHs that a medicinal product which marketing authorization’s dossier is not compliant with the above-mentioned requirements could not be placed anymore on the market after 1 January 2021.