Agence nationale de sécurité du médicament et des produits de santé

« Brexit »
Notice to clinical trials sponsors

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 clinical trials should be performed only in Member States of the EU, the ANSM reminds the clinical trials sponsors about their responsibility in making the necessary changes in clinical trials applications, before December 31st, 2020.

Thus, **as of 1 January 2021, the sponsor or its legal representative and the qualified person to release batches of the investigational medicinal product(s) into the EU (manufacturer or importer) should be located in the EU.**

In case the sponsor 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: the EudraCT number of the trial and the non-compliance clearly identified.

The ANSM remind the sponsors that a clinical trial whose application does not comply with the above-mentioned requirements may no longer be conducted on France after 1 January 2021.

ANSM – October 2020