Regulatory update - EMA encourages companies to submit type I variations for 2019 by end of November 2019

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The European Medicines Agency (EMA) is advising [marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) to submit type IA and type IAIN [variations](https://www.ema.europa.eu/en/glossary/variation) for 2019 no later than Friday 29 November 2019. This will enable EMA to acknowledge the validity of the submissions before the Agency's closure between 23 December 2019 and 6 January 2020 and within the 30-day timeframe set out in Article 14 of [Commission Regulation (EC) No 1234/2008](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:334:0007:0024:en:PDF).

[Marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) planning to report Brexit-related Type IA/IAIN [variations](https://www.ema.europa.eu/en/glossary/variation) in December 2019 will receive the acknowledgment of the validity of the submissions within 30 days as per the usual procedure.

[Marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) are advised to submit any [type IB variations](https://www.ema.europa.eu/en/glossary/type-ib-variation) or [groupings](https://www.ema.europa.eu/en/glossary/grouping) of type IBs and type IAs by 6 December 2019 for a start of procedure in 2019. For submissions received on or after 9 December 2019, the procedure may not start until January 2020.

For procedural or regulatory queries related to these procedures for human medicines, [marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) can send an email to: [iaquery@ema.europa.eu](mailto:iaquery@ema.europa.eu) or [ibquery@ema.europa.eu](mailto:ibquery@ema.europa.eu).   
For veterinary medicines, [marketing authorisation holders](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) are advised to contact the vet applications team in advance of an upcoming submission at the following e-mail address: [vet.applications@ema.europa.eu](mailto:vet.applications@ema.europa.eu).

Type I [variations](https://www.ema.europa.eu/en/glossary/variation) are minor changes to the [marketing authorisation](https://www.ema.europa.eu/en/glossary/marketing-authorisation) of a medicine.

Type IAIN and IA [variations](https://www.ema.europa.eu/en/glossary/variation) have no impact on the quality, safety or [efficacy](https://www.ema.europa.eu/en/glossary/efficacy) of the medicine. Type IAIN [variations](https://www.ema.europa.eu/en/glossary/variation) must be notified to the [national competent authority](https://www.ema.europa.eu/en/glossary/national-competent-authority) or EMA immediately following implementation in order to ensure the continuous supervision of the medicine. [Type IA variations](https://www.ema.europa.eu/en/glossary/type-ia-variation) do not require immediate notification and should be notified to the [national competent authority](https://www.ema.europa.eu/en/glossary/national-competent-authority) or EMA within 12 months of implementation, or earlier in certain cases.

[Type IB variations](https://www.ema.europa.eu/en/glossary/type-ib-variation) must be notified to the [national competent authority](https://www.ema.europa.eu/en/glossary/national-competent-authority) or EMA before implementation, but do not require a formal approval. Upon acknowledgement of receipt of a valid notification, the [marketing authorisation holder](https://www.ema.europa.eu/en/glossary/marketing-authorisation-holder) must wait for a period of 30 days to ensure that the notification is deemed acceptable by the [national competent authority](https://www.ema.europa.eu/en/glossary/national-competent-authority) or EMA before implementing the change.