EN
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Answer given by Mr Andriukaitis
on behalf of the European Commission
(28.2.2019)

The Commission would like to inform the Honourable Member that there is a pending assessment of a marketing authorisation application via the EU centralised procedure for a medicinal product containing an active substance lifitegrast for use in ophthalmology[1].

The assessment by the European Medicines Agency's (EMA) scientific Committee for Medicinal Products for Human Use (CHMP) is expected to be finalised in 2019. In case of a positive CHMP opinion the next standard step is a decision-making process at the Commission level, with involvement of the Member States, potentially leading to a marketing authorisation valid across the whole EU. As the procedure is in its early stage, more precise estimation of timelines of the process in question cannot be provided.

[1] https://www.ema.europa.eu/en/medicines/medicines-under-evaluation