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

In response to the Honourable Member, we can confirm that the European Medicines Agency (EMA) is currently evaluating an extension of indication for Lynparza in the first-line maintenance treatment of BRCA-mutated advanced ovarian cancer[1].

This procedure (for a variation of the marketing authorisation of Lynparza) is expected to be finalised later this year. In view of the pending scientific assessment, a more precise timing is not possible.

EMA's Business Continuity Plan has been put in place to ensure that any activities directly related to authorisation, maintenance and supervision of medicines are not affected by EMA's relocation to the Netherlands[2]. As a result of this policy, this authorisation procedure is following the foreseen timetable and there have been no unexpected delays.

[1] https://www.ema.europa.eu/documents/minutes/minutes-chmp-meeting-17-20-september-2018_en.pdf
[2] https://www.ema.europa.eu/documents/other/european-medicines-agency-brexit-preparedness-business-continuity-plan_en.pdf