Pursuant to Article 10 of the Ordinance on Clinical Trials on Medicinal Products and Good Clinical Practice (Official Gazette No. 25/15 and 124/15), the Central Ethics Committee at its 235th session on 31 January 2019 adopts the following

RULES OF PROCEDURE ON THE AMENDMENTS

TO THE CEC RULES OF PROCEDURE

Article 1

Article 18, paragraph 2 of the CEC Rules of Procedure of 14 September 2016 is amended as follows:

> "Pursuant to Article 27 of the Ordinance, the Agency for Medicinal Products and Medical Devices shall maintain a record on Development Safety Update Reports (DSUR), Suspected Unexpected Serious Adverse Reactions (SUSAR) that have occurred in clinical trials in the Republic of Croatia, and other safety issues, and notify CEC and the Ministry of Health accordingly. An employee of the Agency for Medicinal Products and Medical Devices participates in the sessions and reports, in a written and oral manner, on the information collected in the period between two sessions."

Article 2

These Rules of Procedure on the Amendments to the Rules of Procedure of the Central Ethics Committee shall enter into force on the day of their adoption.

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The President of the Central Ethics Committee

Prof. Iveta Merćep, M.D., Ph.D.