

European Medicines Agency

Eudra CT

EudraCT number: 2012-005097-66

Sponsor code: NCAG2512

Title: Effect of two homeopathic preparations on blood pressure in comparison to metoprolol (trade name Beloc-Zok® mite 47,5 mg) in 90 patients suffering from mild hypertonia. A prospective, confirmatory, open, randomized controlled, 3-armed, repetitive study over 6 weeks in parallel design.

Dear Ladies and Gentlemen,

Referring to your reminder email dated September 7th, we would like to inform you that the clinical trial, EudraCT number: 2012-005097-66, was prematurely terminated. On December 7th, 2016, Homviora Arzneimittel Dr. Hagedorn GmbH Co.KG submitted the signed Substantial Amendment Notification Form (Annex 2) with the "temporary halt of trial" and the immediate termination of the clinical study. As far as the reason concerned, a justification statement by Prof. Dr. Sibbing was enclosed.

Due to the trend of increasing of the systolic and diastolic blood pressure the plus values in the Beloc-Zok control arm." It was therefore not reasonable to resume the study in this way.

Attached please find a copy of Annex 2, submitted to Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) in 2016. The clinical trial was discontinued.

Should you have any further questions, please do not hesitate to contact us at any time.

Kind regards



Dr. Violetta Horn

CEO

Homviora Arzneimittel Dr. Hagedorn GmbH & Co.KG

Attachment:

Copy „ Substantial Amendement Notification Form (Annex 2)“