

Date: 5th April 2019

Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Ambrisentan Zentiva, Ambrisentan, strength(s) 5 and 10mg, film-coated tablets, EMEA/H/C/0004955

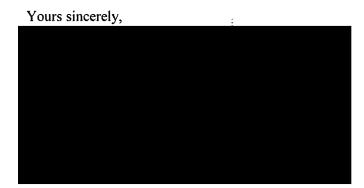
Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, Zentiva k.s. has taken the decision to withdraw the application for Marketing Authorisation of Ambrisentan Zentiva, (Ambrisentan), strength(s) 5 and 10 mg, film-coated tablets, which was intended to be used for pulmonary arterial hypertension.

This withdrawal is based on the following reasons - Company's decision.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.





Registered in the commercial register maintained by the Municipal Court in Prague - Section A - Entry 64046