p h a r m ACE u t i c a l s

Dr. T. Salmonson, CHMP-Chairman
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Zeewolde, May 29th 2017

Ref.: APREG 013.17/RV

Concerns: Withdrawal of ELMISOL EMEA/H/C/004330/0000

Dear Dr. Salmonson

We would like to inform you that, at this point of time, ACE Pharmaceuticals BV has taken the decision to withdraw the applications for Marketing Authorisation of ELMISOL 5, ELMISOL 10, ELMISOL 25 and ELMISOL 50 (Levamisole hydrochloride 5, 10, 25 or 50 mg tablets) which were intended to be used for the "treatment of steroid sensitive nephrotic syndrome in children from 2-18 years of age".

This decision was made with the main consideration that the submitted pivotal Investigator Initiated trial (The Levamisole Trial) did not qualify sufficiently for ICH-GCP compliance. The data from this study could therefore not be used for the assessment of the Benefit-Risk balance.

ACE Pharmaceuticals still believes that ELMISOL has a significant value in the treatment of the SSNS-children. New GCP-compliant studies have been started.

ACE Pharmaceuticals BV reserves the right to make further submissions at a future date for this (or other) therapeutic indication(s).

ACE Pharmaceuticals BV agrees for this letter to be published on the EMA website.

Sincerely yours,
ACE Pharmaceuticals BV

[redacted]