**SciPharm Société à responsabilité limitée**
7, Fausermillen
L-6689 Mertert
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Dr. Tomas Salmonson
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Reference: Treprostinil SciPharm Sàrl (EMEA/H/C/004847)

Mertert, September 5th, 2018.

Subject: Withdrawal of Treprostinil SciPharm Sàrl solution for infusion, 1.0 mg/ml, 2.5 mg/ml, 5.0 mg/ml and 10.0 mg/ml.

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, SciPharm Sàrl has taken the decision to withdraw the application for Marketing Authorisation of Treprostinil SciPharm Sàrl solution for infusion 1.0 mg/ml, 2.5 mg/ml, 5.0 mg/ml and 10.0 mg/ml, which was intended to be used for the treatment of adult patients with severe, non-operable or with recurrent or persistent chronic thromboembolic pulmonary hypertension (CTREPH) to improve exercise capacity and symptoms of the disease.

The withdrawal is based on the request for non-clinical data, which we are not able to provide for this type of application within the timeframe allowed in the Centralised Procedure.
The future development and the re-submission strategy is under evaluation.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

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

Please do not hesitate to contact us in case of questions.