

US Headquarters

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18 September 2019

CHMP Chairman European Medicines Agency Domenico Scartlattilann 6 1083 HS Amsterdam The Netherlands

Subject: Withdrawal of Xyndari™, glutamine, 5 grams, oral powder - EMEA/H/C/004734

Dear CHMP Chairman,

I would like to inform you that, at this point of time, Emmaus Medical Europe Limited (Emmaus) has taken the decision to withdraw the application for Marketing Authorisation of Xyndari[™], glutamine, 5 grams, oral powder, which was intended to be used for the treatment of sickle cell disease.

This withdrawal is based on the change in the Company's marketing strategy.

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

Emmaus will continue to support the ongoing compassionate use program(s) pending further discussion with relevant local competent authorities which have granted approval for compassionate use.

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

Yours sincerely,