Dr .Tomas Salmonsson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of EMEA/H/C/002737/0011

11 August, 2016

[redacted]

Product Name:	Adempas®
Strength:	0.5, 1, 1.5, 2, 2.5 mg
Dosage form:	film-coated tablet
INN:	riociguat

Dear Dr Salmonsson,

For the Type II variation/ Annex I (Regulation 1234/2008) application linked to an extension of indication for a medicinal product already authorized, we would like to inform you that, at this point of time, Bayer Pharma AG (MAH) [redacted] have taken the decision to withdraw the application to extend the approved indication PAH with the sub-population Congenital Heart Disease.

www.bayer.com

[redacted]

This withdrawal is based on the revised product development strategy for the product.

This withdrawal has no impact on patients participating in on-going clinical trials or compassionate use programmes with riociguat (Adempas).

There is no consequence on the use of Adempas in its authorised indications.

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.

Yours sincerely,

[redacted]