Direct Healthcare Professional Communication

Subject: Recommendations to prescribers in view of a potential supply shortage of CINRYZE

Dear Healthcare Professional,

Shire wants in consultation with the Medicines and Healthcare products Regulatory Agency to inform you of the following:

Summary

Due to the increasing number of prescriptions for the product CINRYZE 500 Units powder and solvent for solution for injection, the demand for the product may soon exceed the current production capacities.

In order to manage CINRYZE supply over the next months, Shire is requesting the following:

- Patients with severe and frequent attacks of hereditary angioedema (HAE) who are currently receiving CINRYZE for the routine prevention (i.e. patients who are intolerant to or insufficiently protected by oral prevention treatments, or who are inadequately controlled by appropriate on demand therapy should be maintained on CINRYZE treatment as there is no other approved alternative long-term prevention treatment available,
- Consider not to onboard any new patients for routine prevention treatment
- For the treatment of acute angioedema attacks as well as for pre-procedure prevention, Shire is asking that prescribers consider alternative treatment options to CINRYZE that have been approved for this indication for their patients.

Further information

Patient safety is Shire's first priority and we are committed to making every effort to ensure appropriate and continued supplies going forward.

In the event that CINRYZE becomes temporarily unavailable, Shire will notify you.

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CINRYZE is available in a single strength: 500 Units powder and solvent for solution for injection. The active ingredient is C1 inhibitor produced from plasma of human donors. It is approved in the European Union for the following therapeutic indications:

- Treatment and pre-procedure prevention of angioedema attacks in adults, adolescents and children (2 years old and above) with hereditary angioedema (HAE).
- Routine prevention of angioedema attacks in adults, adolescents and children (6 years old and above) with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment. »

Detailed information on this product is available on the website of the European Medicines Agency

http://www.ema.europa.eu

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form

Any suspected adverse reactions observed during use of Cinryze 500 Units powder and solvent for solution for injection may also be reported to Shire at +44 (o)1256 894000 or faxed on +44 (o)1256 894715 or emailed to: globalpharmacovigilance@shire.com

Should you have any questions or require additional information on the use of Cinryze 500 Units powder and solvent for solution for injection, please contact Medical Information at Tel: 0800 055 6614 or by email at medinfoeuceemea@shire.com

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Sincerely,

Felicia Pinto
UK/IE Regulatory Affairs Lead
Shire