Subject: **Direct Healthcare Professional Communication**

February 26th 2015

IMPORTANT SAFETY UPDATE OF PRESCRIBING INFORMATION FOR EUCARDIC® (CARVEDILOL)

Dear Healthcare Professional,

Roche Products (Ireland) Limited (hereafter referred to as Roche) would like to inform you about important new safety information for Eucardic® (carvedilol) regarding severe cutaneous adverse reactions (SCAR), which has resulted in an update to the local summary of product characteristics (SmPC) for Eucardic. (Section 4.4 Special warnings and precautions for use).

This letter is being sent with the agreement of the Health Products Regulatory Authority.

Summary

- Very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with carvedilol.
- Carvedilol should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to carvedilol.

Further Information

During 24 years of post-marketing surveillance (cumulative exposure over 32 million patients), very rare cases of severe cutaneous adverse reactions have been reported with carvedilol to the company safety database. The analysis of these cases identified one literature case with a fatal event of TEN probably causally related to treatment with carvedilol, and a second case reporting SJS possibly causally related to treatment with carvedilol.

As a consequence, the Warnings and Precautions and the Post Marketing Undesirable Effects section of the Eucardic company core data sheet (CDS) and of the local summary of product characteristics (SmPC) have been updated with this important new safety information.

The following new information has been included in the local SmPC for Eucardic:

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No. 214337

Section 4.4 Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs): Very rare cases of severe cutaneous adverse reactions such as toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS) have been reported during treatment with Eucardic (see section 4.8). Eucardic should be permanently discontinued in patients who experience severe cutaneous adverse reactions possibly attributable to Eucardic.

4.8 Undesirable effects

Severe cutaneous adverse reactions (Toxic epidermal necrolysis, Stevens-Johnson syndrome (see section 4.4).

The revised Eucardic product information will be made available on www.medicines.ie.

If you have any questions or require additional information regarding the use of Eucardic (carvedilol), please contact Roche Medical Information by mail, telephone (01 4690700), fax (01 4690791) or email (ireland.druginfo@roche.com).

Please distribute this communication further within your team.

Reporting Adverse Events

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Adverse events should also be reported to the Drug Surveillance Centre in Roche Products (Ireland) Limited by mail, telephone (01 4690700), fax (01 4690793) or email (ireland.drug_surveillance_centre@roche.com).

Yours sincerely,

Dr. Michal Starnawski
Medical Director