European Medicines Agency

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PUBLIC STATEMENT ON
PATREX (sildenafil)

NON-RENEWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 15 September 1998, the European Commission granted a Marketing Authorisation for the whole European Union to Roerig Farmaceutici Italiana S.p.A, for the medicinal product Patrex (sildenafil), indicated for the treatment of erectile dysfunction. The Marketing Authorisation was subsequently transferred to Pfizer Limited on 23 February 2001.

Patrex was never marketed anywhere in the European Union. The Marketing Authorisation Holder did not apply to renew the Marketing Authorisation and consequently on 15 September 2003 the 5-year Marketing Authorisation for Patrex expired. It should be noted that there is still one Community Marketing Authorisation valid throughout the European Union for sildenafil i.e.Viagra.

Pursuant to the expiring of the Community Marketing Authorisation the European Public Assessment Report for Patrex has been removed from the EMEA website.

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