22 May 2014
EMA/308394/2014
Press Office

Start of community reviews

CHMP meeting of 19-22 May 2014

Table 1. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Oxynal 10 mg/5 mg, 20 mg/10mg prolonged-release tablets Targin 10 mg/5 mg, 20 mg/10mg, 40 mg/20 mg, 5 mg/2.5 mg prolonged-release tablets	Oxycodone hydrochloride, Naloxone hydrochloride	Article 13 of Commission Regulation (EC) No 1234/2008	The procedure was triggered by Germany due to disagreements between member states regarding the extension of indication (Type II variation) of Oxynal and Targin prolonged-release tablets and associated names to “Second line symptomatic treatment of patients with severe to very severe idiopathic restless legs syndrome after failure of dopaminergic therapy”.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu