21 April 2017
EMEA/H/C/002800

Public statement

Unituxin

Withdrawal of the marketing authorisation in the European Union

On 20 March 2017, the European Commission withdrew the marketing authorisation for Unituxin (dinutuximab) in the European Union (EU). The withdrawal was initiated by the marketing authorisation holder (MAH), United Therapeutics Europe Ltd, which had requested the European Commission to withdraw the marketing authorisation due to short- and intermediate- term inability to supply Unituxin in sufficient quantities for meeting current global demands. The MAH has confirmed that it has no future plans to commercialise Unituxin in the EU until the supply issues have been resolved.

Unituxin was granted marketing authorisation in the EU on 14 August 2015 for the treatment of high-risk neuroblastoma. The marketing authorisation was initially valid for a 5-year period.

The MAH has confirmed that any neuroblastoma patients who are currently receiving Unituxin treatment will have the possibility to receive the full treatment until completion of the 5 courses. No new patients with high risk neuroblastoma will be started on Unituxin therapy due to the lack of drug supply.

The European Public Assessment Report (EPAR) for Unituxin will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact