



Napp Pharmaceuticals Limited – Important Information Regarding DepoCyte Supply

Unfortunately, we are experiencing a temporary supply issue from the manufacturer of DepoCyte. The attached letter from the EMA provides further information, however, until this matter is resolved, we will be unable to fulfil any further orders from February 2017 onwards. We apologise for the inconvenience that this may cause you and would like to assure you that we are striving to resolve this as quickly as possible.

Should you have any questions, please don't hesitate to contact me.

Kind regards

Helen Coombs
Supply Chain Planner – Bard Pharmaceuticals
01223 424444

Dear Sir/Madam

Pacira Pharmaceuticals, Inc. the sole finished product manufacturer for DepoCyte[®], have recently advised Napp Pharmaceuticals Limited of a manufacturing issue with the supply of the DepoCyte[®] drug product and that they will be unable to deliver new supplies of DepoCyte[®] as planned in the near future. As a consequence, availability of DepoCyte[®] may become restricted until this problem can be addressed. Pacira Pharmaceuticals, Inc. is currently working on rectifying the issue.

Consequently, in the meantime, Napp Pharmaceuticals Limited will be striving to manage the current stock of Depocyte[®] to the best advantage for everyone. However, it is acknowledged that stock will run out in some EU countries. Napp Pharmaceuticals Limited would like to ensure that patients currently undergoing treatment with DepoCyte[®] can continue their treatment as deemed appropriate by their treating physicians. We would appreciate your cooperation in managing this temporary situation by ordering DepoCyte[®] on a case by case basis with a maximum of 2 vials per patient per order until stock levels revert back to normal. In particular, it should be made clear if an order is for a new patient, to determine if there will be sufficient medication to complete treatment.

Please note that the manufacturing issue only affects new batches of DepoCyte[®] not yet released to market. There is no concern with regard to quality, and therefore patient safety, with existing batches already released to the distribution chain.

Napp Pharmaceuticals Limited and Pacira are working closely with the National Competent Authorities and the European Medicines Agency to keep them informed of the product supply situation.