

26th January 2012

Direct Healthcare Professional Communication: Update on temporary supply shortage of Apidra (insulin glulisine) [rDNA origin] cartridges for injection affecting: Apidra 3ml Cartridges, Apidra SoloStar and Apidra OptiSet in Ireland

Dear Healthcare Professional,

Further to our communication on 10th November 2011, Sanofi would like to update you on the supply shortage of Apidra 3mL cartridges and Apidra SoloStar.

The shortage was due to a technical incident at a manufacturing site which led to a temporary interruption in production. A number of actions have been taken by Sanofi to address this manufacturing issue and to accelerate the process of returning to normal supply which is expected as follows:

Update on the current situation in Ireland

As previously advised Apidra presentations currently on the market are safe to use. None of the other Sanofi insulin products (Lantus, Insuman) have been affected.

A new supply for Apidra SoloStar and Apidra 3mL cartridges for use with Sanofi reusable pens will become available during the first week in February 2012 with a return to full supply capacity expected in early April 2012.

As per our communication on 9th October 2011, all OptiSet presentations are to be discontinued from 31st March 2012. Apidra OptiSet has been out of stock since September 2011. No further supply of Apidra OptiSet will be made available.

This information has been approved for distribution by the EMA (European Medicines Agency), the CHMP (Committee for Medicinal Products for Human use) and the Marketing Authorisation Holder.

Call for Reporting

Healthcare professionals should report any serious adverse events suspected to be associated with the use of Apidra to The Irish Medicines Board using the on-line reporting function on the IMB website (www.imb.ie) or alternatively by contacting the IMB at 01 6764971.

In addition, this information may be reported to Sanofi Ireland Ltd., please phone 01-4035600.

Further information

Further Information

• Should you require further information, please contact your local Sanofi diabetes account manager or Sanofi Medical Information at 01 403 5600, or email IEMedinfo@sanofi.com

Sincerely,

Dr Velichka Valcheva Medical Director, Sanofi Ireland