Private Supply Notice: TOUJEO® (insulin glargine 300 units/mL) Available in Australia on Private Prescription effective from 1 December 2016

22 November 2016

Dear Health Care Professional,

Sanofi is pleased to advise you that, as of 1 December 2016, TOUJEO® (300 units/mL) will be available in Australia as a private prescription for the treatment of diabetes mellitus in adults.

Toujeo® SoloStar® is a prefilled pen that contains a longer-acting[1] formulation of insulin glargine (300 units/mL) compared with Lantus® (insulin glargine 100 units/mL). Toujeo is designed for once-daily subcutaneous administration.

Toujeo is not currently available on the Pharmaceutical Benefits Scheme (PBS) and will not be available at a PBS-subsidised price, so patients will incur out of pocket costs. As an indication, Sanofi's price to wholesalers for a pack of 5 pens will be $119.05 (incl. GST). Patients should allow for wholesaler and pharmacy fees which may vary from pharmacy to pharmacy. We recommend advising patients to check with their pharmacist to determine the cost of having their Toujeo prescription dispensed.

Toujeo (300 units/mL) will appear in commonly used script writing software.

It is important to note that this strength of insulin glargine (300 units/mL [Toujeo]) is not bioequivalent and therefore not automatically interchangeable to other basal insulins and will require dose adjustment.

Some guidance material on how to initiate a patient on Toujeo is attached with this correspondence. An educational leaflet for patients is also attached for distribution to patients treated with Toujeo.

To find out more about Toujeo go to www.toujeo.com.au
If you have any questions and/or require any further copies of these educational materials, please contact Sanofi Medical Information on 1800 818 806 or email medinfo.australia@sanofi.com.

Please review the Product Information before prescribing.

Yours sincerely,

Dr Marie Hartley
Medical Leader Diabetes and Cardiovascular

sanofi-aventis australia pty ltd trading as Sanofi ABN 31 008 558 807
Talavera Corporate Centre, Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113 -
Tel: +61 (0) 2 8666 2000 – Fax: +61 (0) 2 8666 3000 - www.sanofi-aventis.com.au

PBS Information: Toujeo is not listed on the PBS

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING TOUJEO.
FULL PRODUCT INFORMATION IS AVAILABLE FROM SANOFI-AVENTIS AUSTRALIA PTY LTD AT
HTTP://PRODUCTS.SANOFI.COM.AU/AUS_PI_TOUJEO.PDF OR BY CALLING 1800 818 806.

Toujeo (insulin glargine) **Indications:** Treatment of diabetes mellitus in adults **Contraindications:** Hypersensitivity to insulin glargine or any of the excipients. **Precautions:** Not recommended for treatment of diabetic ketoacidosis; hypoglycaemia; switching between insulin glargine 100 U/mL and Toujeo; switching between other insulins and Toujeo; intercurrent illness; insulin antibodies; insulin label must always be checked before each injection to avoid medication errors between Toujeo and other insulins; pregnancy category B3; lactation; careful glucose monitoring and dose adjustments may be necessary in elderly patients; not studied in children; renal and hepatic impairment. **Interactions:** Oral antidiabetic medicinal products; cardiovascular, analgaesic, anti-inflammatory, neurological, antipsychotic agents (see full PI); antibiotics; corticosteroids, other hormonal therapies (see full PI); diuretics; protease inhibitors; sympathomimetic agents; lithium; alcohol; sympatholytics including β-blockers; others, see full PI. **Adverse Effects:** Hypoglycaemia; visual impairment; injection site reactions; others, see full PI. **Dosage and Administration:** Subcutaneous, once daily. Not for intravenous use. Dose adjustment may be required e.g. if patient's weight or life-style changes or change in timing of insulin dose. The desired blood glucose levels as well as doses and timing of anti-diabetic medication must be determined and adjusted individually. Instruct patients to never re-use a needle. Toujeo must not be drawn from the cartridge of the pre-filled pen into a syringe. Insulin glargine 100 U/mL and Toujeo are not bioequivalent and are not directly interchangeable. Toujeo must not be diluted or mixed with any other insulin products. When switching from insulin glargine 100 U/mL or other basal insulin products to Toujeo, dose may need to be adjusted. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. ≥18 years. Reference Document: PI, 30 June 2015 Date reviewed: 1 July 2015

PBS Information: Lantus SoloStar and Lantus cartridges are listed on the PBS as a long-acting insulin analogue for the treatment of type 1 and type 2 diabetes.

PLEASE REVIEW PRODUCT INFORMATION BEFORE PRESCRIBING LANTUS.
FULL PRODUCT INFORMATION IS AVAILABLE FROM SANOFI-AVENTIS AUSTRALIA PTY LTD AT
HTTP://PRODUCTS.SANOFI.COM.AU/AUS_PI_LANTUS.PDF OR BY CALLING 1800 818 806.

Lantus® (insulin glargine). **Indications:** Once-daily subcutaneous administration for type 1 diabetes mellitus patients (adults and children) and type 2 diabetes mellitus patients (adults) who require insulin for control of hyperglycaemia. **Contraindications:** Hypersensitivity to insulin glargine or any excipient. **Precautions:** Hypoglycaemia; hepatic, renal and visual impairment; lipodystrophy and other injection site reactions; antibody production; intercurrent conditions; not studied in children <2 years, pregnancy category B3, lactation; not intended for i.v. use; not recommended for treatment of diabetic ketoacidosis; LANTUS® MUST NOT BE DILUTED OR MIXED WITH ANY OTHER INSULIN OR SOLUTION. Instruct patient to check insulin label before each injection to avoid accidental mix-ups between insulins. **Interactions:** Oral antidiabetic agents; cardiovascular, analgaesic, anti-inflammatory, neurological, antipsychotic agents (see full PI); antibiotics; corticosteroids, other hormonal therapies (see full PI); diuretics; protease inhibitors; sympathomimetic agents; lithium; alcohol; sympatholytics including ß-blockers; others, see full PI. **Side effects:** Hypoglycaemia; injection site reactions; visual disturbances; others, see full PI. **Dosage and Administration:** ≥6 years. Subcutaneous, once daily. Lantus® is equipotent to human insulin. Initial dose determined depending on desired blood glucose levels and doses and timing of any antidiabetic medication. For changeover from once daily NPH or ultralente, initial dose usually not changed; for changeover from twice-daily NPH to once-daily Lantus, initial dose usually reduced by approximately 20% compared to total daily NPH dose; for initiation of type 2 patients, initial dose usually approximately 10IU. For changeover from once daily insulin glargine 300 units/mL to once daily Lantus®, recommended initial dose is approximately 80% of insulin glargine 300 units/mL that is being discontinued. Date reviewed: 16 February 2016. Reference Document: PI, 06 November 2015.

Ref: 1. Toujeo Product Information

sanofi-aventis australia pty ltd trading as Sanofi, ABN 31 008 558 807
Talavera Corporate Centre Building D, 12-24 Talavera Road, Macquarie Park, NSW, 2113
Date of preparation: September 2016 SAANZ.TJO.16.09.0327