Safety Notice 004/20

Lantus discontinuation and introduction of new insulin glargine products

11 June 2020

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Diabetes Clinics
- Endocrinologists
- Diabetes Educators
- Directors of Medical / Clinical Services
- Directors of Nursing
- Directors of Pharmacy
- Emergency Departments
- Preadmission Clinics
- Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 9269 5599

Email:
CEC-MedicationSafety@health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

June 2021

Due to the recent Lantus® patent expiry there are an increasing number of insulin glargine products becoming available. Clinicians who prescribe, dispense and administer insulins may be unfamiliar with the various products, leading to potential confusion, unintended duplication and medication-related harm.

Background

Second brand and biosimilar insulins are entering the Australian market. Insulin glargine is the first insulin formulation to be affected. The original brand of insulin glargine, Lantus® is being discontinued and from 31 July 2020 will no longer be available. Optisulin® is a second brand of insulin glargine made by the same manufacturer as Lantus®. Semglee® is a biosimilar insulin glargine made by a different manufacturer. Lantus®, Optisulin® and Semglee® products all contain 100 units/mL of insulin glargine.

Second brand and biosimilar insulin glargine products available

The brands of insulin glargine 100 units/mL listed in Australia on the Pharmaceutical Benefits Scheme (PBS) as at 1 June 2020 include:

Type	Brand name and strength	Device
Original brand (Sanofi)	Lantus® 100 units/mL (discontinued July 2020) 	Cartridge Solostar prefilled pen
Second brand (Sanofi)	Optisulin® 100 units/mL 	Cartridge Solostar prefilled pen
Biosimilar (Alphapharm)	Semglee® 100 units/mL 	Prefilled injector pen

Over time there are likely to be more products containing insulin glargine available, including combination products.

There is a high concentration insulin glargine available, Toujeo®. This **high concentration insulin is not interchangeable** with 100 units/mL insulin glargine products. For more information on high concentration insulins see Safety Notice 007/19 High Concentration Insulin Products.

Changing between brands of insulin glargine

All patients using Lantus® will need to change to a second brand or biosimilar insulin glargine 100 units/mL product after 31 July 2020. The choice of which product to use should be made by the prescriber in consultation with the patient. While the PBS lists all the brands as 'equivalent' and therefore suitable for substitution by a pharmacist, to minimise potential problems arising from switching, the products should only be substituted when discussed with the prescriber or by approved protocol from the local Drug and Therapeutics Committee (DTC).

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Suggested actions by Local Health Districts / Speciality Health Networks

1. Distribute this notice to all relevant staff and clinical departments.
2. Ensure that:
   - DTCs consider which insulin glargine product(s) are available on the hospital formulary.
   - If possible, patients are maintained on their usual brand of insulin glargine. On admission the brand of insulin glargine the patient was using at home is documented.
   - Where substitution of insulin glargine products is required it occurs in consultation with the prescriber and the patient.
   - Prescribers are aware that:
     - the full brand/trade name plus active ingredient name and strength should be included in the order
     - the same brand should be prescribed throughout the patient's hospital stay and provided to the patient on discharge
     - if changing brands of insulin glargine no dose adjustments are required. Patients should have their dose administered at the same time as their previous brand was administered each day.
   - That staff administering insulin glargine are aware that:
     - they must contact the prescriber for clarification before administering if they are concerned that the order is incorrect, inappropriate or incomplete
     - patients changing brands of insulin glargine may experience changes in blood sugar level (BSL) responses. Staff are to follow usual monitoring and escalation of high or low BSLs.
   - All relevant medical, nursing and midwifery staff receive appropriate education so that they are aware of the various brands of insulin glargine, what is available on the hospital formulary, the differences and how they should be prescribed and documented.
   - Patients are advised of any changes made to their insulin therapy, including substitutions. Written information should be provided, such as the Consumer Medicines Information (CMI) and any other available information relating to brand changes.
   - At transfers and on discharge:
     - the brand/trade name of insulin glargine is communicated, including on medication lists and discharge summaries
     - patients are provided with education on discharge regarding what insulin glargine product they are being supplied and how this may differ to insulin they may have at home – and that they should NOT USE BOTH.
3. Consider employing electronic clinical decision support within electronic medication management/dispensing systems to reduce potential selection and prescribing errors.
4. Monitor, document and report adverse outcomes associated with the use of insulin glargine products.
5. Ensure a system is in place to document and review actions taken.

References

- Australian Government Department of Health. Biosimilar Awareness Initiative. Updated March 2020.
- Council of Australian Therapeutic Advisory Groups. Overseeing biosimilar use. Guiding principles for the governance of biological and biosimilar medicines in Australian hospitals. CATAG, 2016.
- NSW Health Policy Directive PD2016_033 Approval Process of Medicines for Use in NSW Hospitals.
- NSW Health Policy Directive PD2013_043 Medication Handling in NSW Public Health Facilities.