## <u>GLP-1 Receptor Agonists Supply Shortage Information -</u> <u>Trulicity® (dulaglutide) and Ozempic® (semaglutide)</u>

Trulicity® (s/c dulaglutide) and Ozempic® (s/c semaglutide) are parenteral GLP-1 receptor agonists licensed for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (either as monotherapy as an adjunct to diet and exercise, when metformin is considered inappropriate, or as add-on therapy).

Due to the high unprecedented demand for GLP-1 receptor agonists globally, we have been informed by Eli Lilly and Company Ltd, the manufacturers of Trulicity®, and Novo Nordisk Ltd, the manufacturers of Ozempic®, that there are stock shortages in the UK. This is related to increased global use, not related to safety or quality related concerns or regulatory action. Manufacturers are working to meet this increase in demand while also implementing actions to manage increased use and minimise patient impact.

The situation is rapidly changing. Currently, the shortage of Trulicity® (dulaglutide) is of all strengths of solution for injection devices (0.75mg, 1.5mg, 3mg and 4.5mg), and the shortage of Ozempic® (semaglutide) is of the 1mg solution for injection device.

The Department of Health and Social Care (DHSC) issued medicine supply notifications (MSNs) for Trulicity® (MSN/2022/079) and Ozempic® (MSN/2022/080). Information from the DHSC and NHSEI Medicines Supply Teams, and the Specialist Pharmacy Service's (SPS) Medicine Information department, (including anticipated resupply dates, actions, alternatives, considerations and background) can be accessed on the SPS Medicines Supply Tool below (registration required):

- <u>Shortage of Dulaglutide (Trulicity) 0.75mg, 1.5mg, 3mg and 4.5mg solution for injection</u> <u>devices – SPS - Specialist Pharmacy Service – The first stop for professional medicines</u> <u>advice</u>
- Shortage of Semaglutide (Ozempic) 1mg/0.74ml solution for injection 3ml pre-filled disposable device – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

The Primary Care Diabetes Society (PCDS) has also issued the following consensus statement, which contains further information for primary care and a GLP-1 receptor agonist comparison table for alternatives:

• <u>PCDS consensus statement: A strategy for managing the supply shortage of the GLP-1</u> <u>RAs Ozempic and Trulicity - DiabetesontheNet</u>

## Key Actions for Clinicians:

- Patients should be assessed on an individual basis and notified that there is a shortage
- Ensure that Trulicity® or Ozempic® are being used for licensed indications only
- New patients should **not** be initiated on Trulicity® or Ozempic® until the supply issues have resolved. This is to help maintain supply/continued product availability for existing Trulicity® and Ozempic® patients
- Currently, the supply issue with Trulicity® (dulaglutide) is anticipated to continue until the end of January 2023. No new patients are to be initiated on Trulicity® (dulaglutide) at any dose until the supply issues have resolved. Stock should be reserved for existing patients already on Trulicity® (dulaglutide)
- Currently, the supply issue with Ozempic® (semaglutide) 1mg strength is anticipated to continue until mid-October 2022. Existing patients already on Ozempic® (semaglutide) should continue if they have sufficient supply to last until the resupply date, or switched to an alternative until then if they have not got sufficient supply (see further actions below). Thereafter, it is only available for existing patients until January 2023 when full supplies are



expected to become available. New patients should not be initiated on Ozempic® (semaglutide) at any dose until supply issues have fully resolved

- Consider initiating patients on alternative clinically appropriate GLP-1 receptor agonists until the shortages have resolved. Alternative GLP-1 receptor agonists licensed for the treatment of type 2 diabetes mellitus include:
  - S/c injections: liraglutide (Victoza®) which is on formulary, and exenatide (Bydureon® and Byetta®) which is an option during the shortage even though it is non-formulary
  - Oral tablets: Rybelsus (oral semaglutide) which is on formulary
  - Currently these can support an uplift in demand
- Different GLP-1 receptor agonists differ in dose, dosing schedule and tolerability, as well as evidence base for effectiveness and clinical outcomes. Please use the guidance from the SPS and PCDS (see links above) for available preparations, indications, doses, dose titration etc.
- If patients are switched to an alternative GLP-1 receptor agonist, they should be counselled on the change in medication, the dosing schedule, and how to operate the new device (if different to the original preparation)
- Kent and Medway ICB addition: GLP-1 mimetics can be initiated locally in primary care as well, by those clinicians who have received appropriate training (e.g. PITstop)
- Specialist advice should be sought if there is uncertainty about the most appropriate management option as per the above

## Further Actions for Ozempic® (semaglutide) only:

- Establish whether patients have sufficient supply to last until the resupply date (mid-October). If they do not, consider:
  - Initiating an alternative GLP-1 receptor agonist (as above)
  - Prescribing Rybelsus instead (a once daily semaglutide tablet)
  - For patients already on Ozempic® (semaglutide) 1mg once a week, consider extending the dosing interval (e.g., to every 10 days), or consider the appropriateness of decreasing the dose to 0.5mg once a week, until the issue is resolved. Do **not** supply/administer 2x0.5mg injections once a week (to make a 1mg total dose once a week) to avoid exacerbating supply issues (also off-license use)
  - For patients already on 0.5mg once a week, do **not** increase the dose
  - Consider, for patients who are also on insulin therapy, increasing the dose of insulin to cover the period without Ozempic® treatment (without needing to switch to an alternative GLP-1 receptor agonist)
- For full guidance and more information, please see the guidance from the SPS and PCDS (see links above)
- **Caution:** Abrupt improvement in glycaemic control has been associated with temporary worsening of retinopathy, especially when semaglutide is added to insulin therapy. Avoid adding in semaglutide to patients with active proliferative or pre-proliferative diabetic retinopathy, and/or active maculopathy or macular oedema
- In addition: It is important to state that one Ozempic® (semaglutide) pen is enough for 4 weeks supply. Prescribing in primary care must be reviewed to ensure that excess pens are not being prescribed (e.g., more than one). It is even more important to ensure that the correct quantity of pens are prescribed during the shortage to maintain supply

## For Further Information:

- The Lilly Medical Information Team can be emailed at <u>UKMedInfo@Lilly.com</u> or contacted by telephone on 01256 315000 in the UK. For healthcare professionals, their website can be visited for FAQs or to chat online <u>Contact | Lilly UK</u>
- The Novo Nordisk Medical Information and Customer Care Centre can be contacted by telephone on 0800 023 2573 or their website can be visited for their chat service or to submit a healthcare professional, or patients and members of the public, Information Request Form <u>Contact us (novonordisk.co.uk)</u>