Unicorn Foundation
Seeking the cure for Neuroendocrine Cancers

4 October 2021

To: Sarah Fitt
Chief Executive
PHARMAC

Di Safarti
Chief Executive
Te Aho o Te Kahu

Tēnā korua Sarah & Di,

PHARMAC brand switch to generic Octreotide

Unicorn Foundation NZ is concerned at potential impacts of the change in octreotide brand for our patients. From 1 September, Novartis' Sandostatin LAR will be phased out so that by 1 March 2022 95% of neuroendocrine cancer patients will be receiving Teva's generic octreotide.

We have two key concerns about the brand switch that we are monitoring closely:

1. Side effects for patients resulting from the brand switch
2. Impacts on the nurse workforce resulting from the brand switch

This letter details the rationale behind our concerns and outlines the action we are taking to monitor the situation and gather data. I plan to provide regular updates to you both to highlight findings and flag concerns as the brand switch is implemented over the coming months.

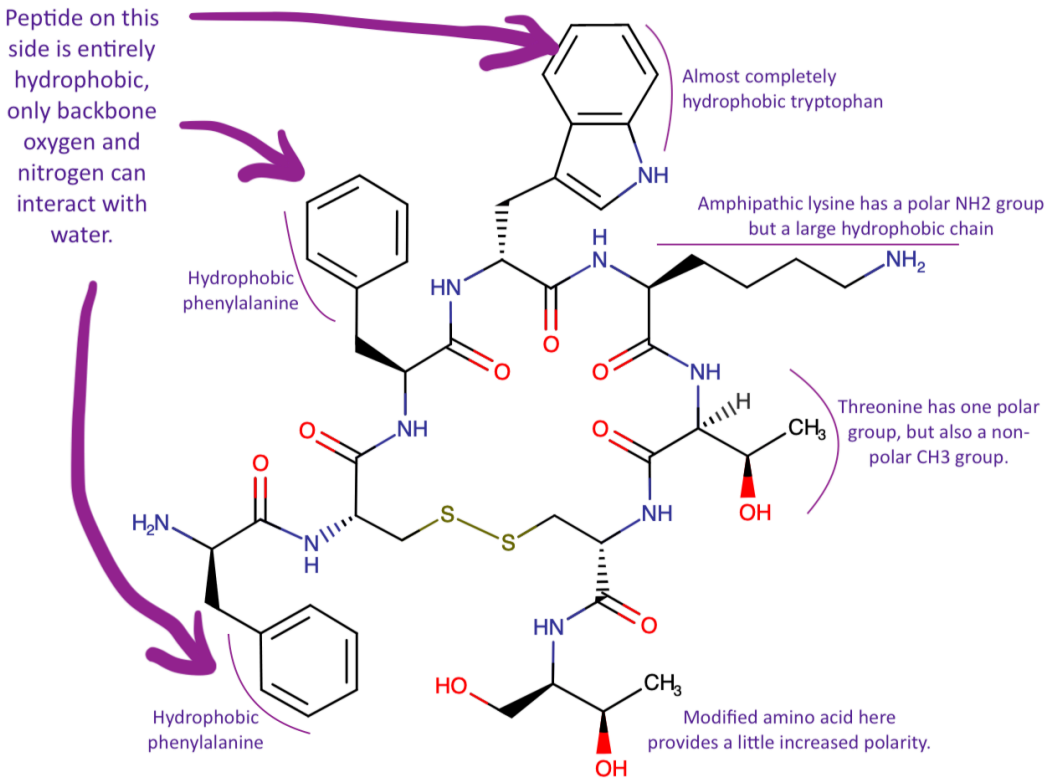
Side effects for patients resulting from the brand switch

Octreotide is a peptide drug with particular structural features that make us concerned about the brand switch. A simple analysis of the biochemical structure of the peptide drug (figure 1, below) shows that it is extremely hydrophobic. The lack of polar groups means that the peptide is extremely difficult to solubilize, as I have annotated on the figure. This is borne out in the instructions that accompany the Novartis Sandostatin LAR™ product – extremely precise mixing instructions, very large needle size, provision of technical support and product replacement guarantees.

Our concern with an octreotide generic is that **the solubility problem means that the excipients are crucial**. The excipients and formulation chemistry of octreotide solubility are not included in the patent. However, they are crucial to achieving and maintaining solubility – and bioavailability - of this peptide. If the bioavailability is diminished, the efficacy of the drug will be affected. Equally, if a patient reacts to the change in excipients, their ability to tolerate octreotide will be affected. As such, we will be gathering data on the side effects experienced by patients as a result of the brand switch through an ongoing survey of health professionals over the next six months.

We hope that our survey does not identify tolerability issues with the generic product. However, if we do see issues of concern we will engage with PHARMAC to explore the next steps. Our goal is to ensure that the neuroendocrine cancer sector (health professionals and patients) is confident and comfortable with the quality and efficacy of available treatments.

Figure 1: *Structure of octreotide highlighting hydrophobicity of the peptide*



Impacts on the nurse workforce resulting from the brand switch

Unicorn Foundation NZ works extensively with nurses and health professionals to provide education around treatment and support of neuroendocrine cancer patients. We have also worked with Novartis who provide training for nurses who administer Sandostatin LAR™.

We understand that a clinical evaluation by PHARMAC of the Teva product indicated that it is substantially equivalent to the Sandostatin LAR™ product, and concluded that it will be no different for nurses to administer. This misses the point that nurses are deeply uncomfortable administering such a challenging injection without additional training and support. Equally, patients are alarmed when an untrained nurse arrives to give the injection, and they will ask for an experienced nurse instead.

We are alarmed at the lack of provision in the generic supply arrangements for ongoing nurse education and support to ensure this crucial medicine is administered as effectively as possible. Our concern has led to us launching a nurse survey to collect information about the brand switch and any issues that are encountered in administration of the generic product. The survey will go out to all nurses on our database, and the purpose of the survey is to record:

- Any issues experienced with administering the new (generic) product.
- Patient issues (e.g. side effects) that nurses are seeing since switching products.
- Maintain a log of queries/support requests relating to the Teva product.

This survey will remain open for the full period of the transition, so we can document issues as they arise. We will maintain a rolling log to capture issues as they are encountered and communicate our findings to you on a regular basis.

On the broader issue of somatastatin analogues, we also note that the Lanreotide tender is unresolved. Given the pressure on the health system, we cannot understand the rationale for PHARMAC's delay on resolving this tender. Many of our patients receive their octreotide injections as outpatients at hospital. We request that you urgently prioritise access to Lanreotide, as medications that enable self-administration will support neuroendocrine cancer patients to remain safe from exposure to COVID-19.

Ngā mihi nui

Michelle Sullivan
Chief Executive Officer
Unicorn Foundation NZ