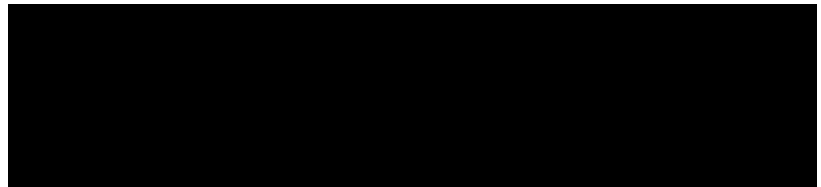


## FSANZ VLED Consultation Response - Application A1230

Response from:



### Introduction

At PharmaCare, we are dedicated to enriching people's lives through health and wellness. We want to inspire Australians to be the best, healthiest and happiest they can be. Whether we're making a vitamin, protein powder, deodorant, skincare moisturiser, or healthy superfood snack, it all comes down to creating the best and most effective products under trusted brands that are household names. We strive to be different, innovative, and surprising – but to always make a positive difference to people's lives, every day.

PharmaCare is 100% Australian and family-owned. And while we have offices globally, and our products are in high demand all around the world, our soul is Australian, our quality is Australian, and our spirit of honesty, hard work and entrepreneurial drive is Australian.

PharmaCare is a leading market supplier of a number of brands of consumer products, foods and therapeutic goods both in the domestic and international markets. These product offerings range across various categories from FMCG, foods, medical devices, cosmetics, Registered medicines, and Listed complementary medicines.

### About the consultation

On the 19<sup>th</sup> November 2021, Food Standards Australia and New Zealand (FSANZ) called for submissions on an application from the company Nestle Australia and New Zealand to consider including very low energy diets (VLED) within standard 2.9.5 Food for special medical purposes (FSMP) of the Food Standards Code (the 'Code'). FSANZ are seeking to adopt Codex STAN 203-1995 nutrient composition for total diet replacement therapy for weight reduction initiated by a health professional.

### Executive Summary

Pharmacare welcomes the opportunity to respond to this consultation.

Pharmacare submits the VLED proposal subject to this consultation goes beyond the purpose of the FSANZ role to protect public health and safety and would create an unnecessarily strict restriction and food standard for certain products used as part of the VLED. While there is merit to the proposal in the use of some food products in VLED for some at risk populations, the majority of the population that would benefit would find relevant and appropriate products inaccessible if this approach was adopted.



Instead, what is defined as a VLED in the proposal is actually more accurately descriptive of a total diet replacement (TDR). We would recommend that the definition is amended to either accurately reflect the type of VLED product (i.e. as a total diet replacement) or a broader definition in line with variability of VLED programs.

Ensuring total diet replacements on the Australian market have specific compositional requirements generated by FSANZ (based on Codex STAN 203-1995) would be useful to ensure safety for patients who are prescribed this diet plan.

However, pigeonholing VLEDs as Total diet replacements only, reduces consumer access for healthy overweight individuals, or other obese individuals without complications that could reasonably benefit from VLEDs, and VLEFs as part of a version of a VLED.

VLEDs on the higher-energy end are low risk and can be/are pursued in the short term by healthy overweight individuals. VLEDs can be followed healthily using formulated meal replacements alongside low calorie meals.

The majority of individuals do not consult a HCP regularly when on VLED programs and therefore access to information on these diets should not be restricted. Australians see prescriptive TDR programs already as restrictive, not realistic for day-to-day life and fear program dependence. Therefore, alternative VLEDs, used for short-term, or VLEFs used in part to adhere to a VLEDs or in conjunction with a normal healthy diet should be available for consumer choice.

#### **FSANZ Intended purpose**

Generally, changes to food standards should be in line with the purpose of FSANZ and the Code. In this respect is the following:

*“FSANZ’s purpose is to contribute to the cooperative food regulatory system by developing science and evidence-based standards, providing evidence-based advice, coordinating regulatory responses and providing information about food standards.*

*The object of the Act is to ensure a high standard of public health protection throughout Australia and New Zealand. FSANZ’s objective is a safe food supply and well-informed consumers.”<sup>(1)</sup>*

Arguably, the proposal goes beyond the purpose of the FSANZ role to protect public health and safety, and would create an unnecessarily strict restriction and food standard for certain products used as part of the VLED, thereby stifling market competition, appropriate and safe use of relevant food products in non-medical diets, and consumer accessibility and choice.



## Proposed Amendments Under Consultation

**Amendment 1: Adding definitions for *very low energy diet (VLED)* and for *very low energy food (VLEF)* to the Australia New Zealand Food Standards Code (the Code).**

### Pharmacare's response:

#### **Definitions proposed are not accurate or appropriate**

Pharmacare does not agree with the definitions provided for VLED and VLEF and their addition to the Code. The definition of VLED provided by FSANZ as *"a range of food for special medical purposes specially formulated for the dietary management of overweight and obesity and which provide the sole source of nutrition when consumed according to the directions for use on the label"* differs to the general meaning to consumers and health professionals. Further, it narrows the generally accepted or understood meaning of VLED.

The Royal Australian College of General Practitioners (RACGP), National Heart, Lung, and Blood Institute (NHLBI) (US) and an expert European panel all define VLEDs as diets based on total energy amount, and an intervention to reduce dietary energy intake. According to these peak bodies and relevant sources, VLEDs typically provide 3300 kJ/800 kcal or less per day<sup>(2,3)</sup>.

Pharmacare is of the view that the definition for VLED as a food for special medical purposes (FSMP) in the proposal better reflects the term **total diet replacement (TDR)**. For example, European Food Safety Authority (EFSA) define TDRs as: *"Specially formulated foods which, when used as instructed by the manufacturer, replace the whole or part of the total daily diet"*. The intended purpose of TDRs are to replace the whole diet and help induce a substantial energy deficit in overweight or obese adults who want to lose weight. This intervention is implemented via prescription from a health professional and may require continued medical and dietetic supervision<sup>(4)</sup>.

Further, using the definition of TDR as provided above allows for the definition VLEF, which is equally problematic and too narrow, to no longer be required.

Therefore, Pharmacare proposes the better definition for this FSMP is **total diet replacement** and not VLED or VLEF.

#### **Using VLEFs as Total Diet Replacements only, reduces appropriate accessibility and consumer access within VLEDs**

VLEDs at 3300kJ/800cal are typically followed by two different types of individuals. There are healthy overweight individuals who take it into their own hands for the short term to achieve weight loss or management goals and at-risk individuals who seek a health practitioner for a TDR program.

Australians see prescriptive VLED programs already as restrictive, not realistic for day-to-day life and fear program dependence<sup>(5)</sup>, many are willing to explore how to execute a diet with the same number of kJ/cal but in different ways.

Some Australians are concerned they will depend on these TDRs to maintain their body weight for the rest of their lives<sup>(5)</sup>. Already, Australians do not meet the recommended minimum number of



serves for any of the five core food groups described in the Australian Dietary Guidelines<sup>(6)</sup>. Increasing the risk of program dependence and without clear guidance on rehabilitation to a normal healthy diet.

Very commonly, Australians find themselves initiating their own versions of VLEDs around 3300kj/800 cal based on resources readily available to them, such as books, blogs<sup>(14a-e)</sup> and foods on the market guiding them to make healthier choices for short term use for weight loss and weight management goals, and education for return to, or combination with, a normal healthy diet.

According to RACGP and NSW Health, TDR interventions should only be for morbidly obese or overweight individuals (BMI >27) with complications, and in preparation of rapid weight loss before surgery which health professionals have protocols for<sup>(7)</sup>.

Our view is that Nestle can continue to formulate their Optifast range to EU CODEX requirements (as TDRs) and in turn, continue to be used by health professionals in Australia<sup>(8)</sup>. However, unnecessarily restricting the use of the VLEFs, and products for use in support of the VLED, in other populations that would benefit from following low energy consumption for the promotion of weight loss (i.e. overweight individuals with no complications) would be detrimental to consumer choice and create inaccessibility which goes against available scientific evidence <sup>(4,9)</sup> of the short term use of VLEDs to meet weight loss and weight management goals

### **Australians consuming VLEDs without medical supervision is generally safe**

Although both defined as VLEDs, EFSA<sup>(4)</sup> have acknowledged that diet plans on the higher end (800 cal) have a better risk profile compared to 450 cal.

In 1970s, one of the first commercially-available VLED brands caused 17 deaths after 8–26 weeks of use which caused concern and resulted in a history of under-prescribing of VLEDs by health professionals<sup>(10)</sup>. The products in question contained low quality protein deficient in essential amino acids, as well as the absence of any fortification with vitamins or minerals and since then, food technology and food standards, including fortification has advanced to peak levels. Since then, European regulators eased their concerns of insufficient and poor quality protein by creating a total meal replacement standard, holding manufacturers accountable<sup>(4)</sup>, and this important change in standards improving quality and safety for formulated meal replacements are currently reflected in the Code.

Formulated meal replacements (FMPs – standard 2.9.3) are safe foods, standardised to 12 g protein (typically containing complete proteins: milk, whey, soy isolate) and are fortified with essential nutrients at 25% RDI<sup>(11)</sup>, making it simple to incorporate FMPs in combination with whole foods to meet appropriate macro and micronutrient levels at VLED requirements. FMPs also have the mandatory statement that they are not a sole source of nutrition, therefore individuals will be aware to also incorporate some “real food” into their meal plans. Though TDRs have been mandated in Europe as a 3-a-day plan and has been useful for many obese individuals, sticking to 800 cal VLED can be done healthily with food alone, or in combination with formulated meal replacements, by healthy overweight or obese individuals (without complications) in the short term (see appendix 1).



### **Individuals typically engage in VLEDs without HCP supervision**

VLED can be used safely and effectively without medical supervision, and Australian's behaviours demonstrate that many pursue a version of VLEDs. Roesler et al 2020's study shows a number of individuals in Australia looking to use VLCD/VLEDs do not consult a health professional and alternatively are more likely to seek support from public forums/social media groups. The European Commission's *Report on foods intended for weight control diets (1990)* also demonstrates that individuals historically have not prioritised HCP involvement as only 24-36% of individuals reported they consulted their HCP before starting the VLED<sup>(12)</sup>.

A possible reason people do not typically engage with an HCP to explore VLEDs is overweight/obese individuals do not have the confidence in HCPs to engage in high level support during one's weight loss journey, or, have already experienced a lack of support<sup>(5)</sup>. As a VLED on the highest end of calories is low risk, giving healthy overweight individuals freedom of choice and the resources to choose is still an important part of the weight loss experience.

### **Australians engage in weight loss programs for various reasons**

As the number of overweight and obese individuals continue to climb in Australia, there are constant changes to government weight loss regimes/guidelines which increase inaccessibility to weight loss options for those who are currently a healthy overweight, looking to lose weight in short term who do not qualify for "medical interventions". Australian adults' experiences with VLEDs differ from those in other countries as there has been no mandated HCP supervision but is clear individuals still participate.

Reviewing the literature through a rapid review conducted on behalf of Pharmacare<sup>(13)</sup>, various motivations for weight loss for individuals at various stages of their weight journey, confirming obese individuals were losing weight for their present and future health. In addition, short term or temporary weight loss goals such as improving physical appearance for weddings, holidays and other events was addressed as the driving factor in healthy overweight individuals. Therefore, HCP supervision may not be necessary for healthy overweight individuals seeking short-term weight loss or to meet certain weight loss, or weight management, goals.

As a VLED on the higher end of the range is low risk and Australians participate in VLED diets safely and within reason, using FMPs in conjunction with other low energy meals without consulting their health professional is acceptable. Thus, there should not be a standard in the Code that means that VLEFs or VLEDs can only be used under medical supervision.

**Amendment 2: Removing the exclusion of foods formulated and represented as being for the dietary management of obesity or overweight from being FSMP**

### **Pharmacare's response:**

Pharmacare supports FSANZ in adding such products as TDRs as FSMPs to the Code, however, the way they are used should be to the discretion of health professionals. Ensuring a standard of compositional requirements and appropriate labelling of TDRs are in line with FSANZ's intended purpose "*to contribute to the cooperative food regulatory system*".



**Amendment 3 & 4: Setting requirement to ensure VLED are consumed within the recommended daily quantity when used as the sole source of nutrition AND including a new division to set compositional requirements for very low energy diets**

**Pharmacare's response:**

Pharmacare does not agree that setting requirements for VLEDs as part of a standard is necessary. However, ensuring TDRs on the Australian market have specific compositional requirements as per a FSMP standard (i.e. based on EU codex) could be useful to ensure safety for patients who are prescribed this type of diet plan, and help HCPs navigate products in the existing Australian market.

There is a question that a change of this nature (as currently proposed) limits the autonomy of the healthcare professional and appropriate market viability. Healthcare professionals need to have adequate training and education on how to safely and confidently use TDRs, and if the requirements were extended to also capture any VLED or VLEF it would be too prescriptive, and not within the current model of HCP delivery. As aforementioned, research suggests that TDRs are already seen as under-prescribed<sup>(10)</sup> and individuals do not feel supported properly by their health professionals in their weight loss journey<sup>(5)</sup>. Therefore, there is a cause for concern whether the impact be a positive one for HCPs and overweight/obese Australians.

Furthermore, in the consultation proposal FSANZ says:

*Nearly all FSMP are imported from the EU or US, with the majority from EU. In order to limit the impost on manufacturers and therefore ensure continued supply of these products to Australia and New Zealand, the existing compositional and labelling requirements in*

*Standard 2.9.5 harmonise where possible with overseas regulations.*

It is unlikely Australians will cease importing VLED products or use them without practitioner supervision if such a narrow and prescriptive approach is taken to essentially remove VLED products and/or VLEFs from the market. Instead, they are likely to access through personal importation products of questionable standard, and/or safety from foreign jurisdictions.

**Amendment 5: Including a provision stating that Standard 2.9.6 will cease to apply to VLED two years after commencement of the draft variation.**

**Pharmacare's response:**

Pharmacare agrees introducing TDRs (as defined above) but not VLED or VLEFs as a FSMP with a transition of two years is reasonable.



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## Appendix 1

Criteria	Proposed AU/Current EU	Proposed EU	Comments
Protein	50 g	75 g	FMPs are standardized to contain >12 of protein. 2 shakes at the minimum level of protein, and main meal can reach >54 g Protein <sup>(a)</sup> .
CHO	50 g	30 g	30 g is based on how much glucose is needed for the brain. 50-100 g of glucose is needed to prevent ketosis. A typical FMP on the market has a range of 17-35 g of total CHO (including milk). 2 shakes + a low carb meal would still result in an intake of >100 g CHO
LA	3 g	11 g	Most meats contain a concentration of 70 and 85% PUFAS, 15 g of pecans or brazil nuts meet the standard <sup>(b)</sup> .
ALA	0.5 g	1.4 g	Can be achieved with a handful of walnuts, flaxseeds or a piece of fish for dinner. 2 serves of red oily fish per week meets adequate intake requirements and has shown to reduce risk of chronic disease <sup>(b)</sup> .
Energy	450-799 cal	Min 600 cal	FMPs require >203 cal/>850 kj as per the standard and most FMPs on the market try to meet the

			minimum requirement (not including specialty FMPs like Keto etc). A VLED 800 cal diet can be met with 2 shakes and one reasonably-sized low fat main meal or a snack and small main meal.
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