

Nutricia Early Life Nutrition

**Submission to: Public Consultation on  
Authority Required Medicines for the Post-  
market Review of Authority Required PBS  
Listings**

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## INTRODUCTION

Danone Nutricia Early Life Nutrition ('Nutricia'; manufacturer code 'NU') as part of Nutricia Australia Pty Ltd welcomes the opportunity to provide comment on the Public Consultation on Authority Required Medicines for the Post-market Review of Authority Required PBS Listings.

Danone Nutricia Early Life Nutrition recognizes that the nutrition received from preconception through to toddlerhood can profoundly impacts long term health. Our mission is to stand by Mums, Dads and Carers to nurture new lives, we do this through research into Early Life Nutrition and the provision of high quality services and products.

Part of our product portfolio includes Infant Formula in Australia which is regulated by the Food Standards of Australia and New Zealand<sup>1</sup>. Some of these products are for infants with special feeding requirements such as mild to moderate cows' milk protein allergy and lactose intolerance, products which are currently listed on the PBS.

Nutricia wish to provide comment regarding our products listed for consideration including: Karicare Aptamil Pepti-Junior Gold and Karicare Aptamil Gold De-Lact.

Nutricia notes that "Authority required" listings are required by the PBS for the following reasons<sup>2</sup>:

*"A medicine or medicinal form is considered for restricted benefit or authority required listing for the following reasons:*

- to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA*
- to allow the controlled introduction of a medicine in a new therapeutic class*
- to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons*
- to alleviate concerns about adverse reactions, possible misuse, overuse or abuse."*

Nutricia is supportive of a move from the current Authority required listings to an Unrestricted listing or an authority required (streamlined) listing for reasons consistent with the aim of this review: *to improve patient safety and care by reducing red tape and administrative burden for health professionals.*

PBS Code	Response for relevant product
<p><b>02975N, 02989H</b></p>	<p>Karicare Aptamil Gold De-Lact (milk powder lactose free formula predigested)</p> <p><b>Response:</b> <i>Nutricia supports an unrestricted listing for Karicare Aptamil Gold De-Lact</i></p> <p><b>Rationale:</b> Nutricia believes it is appropriate for this listing to be unrestricted as it does not meet the PBAC criteria for restricted benefit or authority required listing. The rationale for how it does not meet the criteria is outlined in reference to each Authority Required PBAC criteria (in Italics):</p> <ul style="list-style-type: none"> <li>• <i>to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA</i></li> </ul> <p>Karicare Aptamil Gold De-Lact are Infant Formula for Special Dietary Use (IFSDUs) regulated by FSANZ and therefore the approval and registration by the TGA is not relevant to this product</p> <p>The use of Karicare Aptamil Gold De-Lact is limited to the dietary management of young infants with lactose intolerance. The labelling, product composition and all other aspects of Karicare Aptamil Gold De-Lact are compliant with FSANZ standards which make it suitable only for these indications.</p> <ul style="list-style-type: none"> <li>• <i>to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons</i></li> </ul> <p>Karicare Aptamil Gold De-Lact is a lactose free infant formula for the dietary management of infants with lactose intolerance. Nutricia is not aware of any off label prescribing; it is only suitable for infants with lactose intolerance which is confirmed with testing as outlined within the PBS criteria.</p> <p>The use of Karicare Aptamil Gold De-Lact is small as evidenced by the PBS script data showing a total of 6084 scripts dispensed for Karicare Aptamil Gold De-Lact (these statistics are inclusive of the old formulation under PBS Code 2349P, 2350Q) over the financial year of 2013/2014 equating to approximately 507 patients.</p> <p>Due to the rarity of these conditions and unsuitability of this product for conditions outside of the PBS listed indications, it is unlikely that a patient would be prescribed this product inappropriately.</p> <ul style="list-style-type: none"> <li>• <i>to allow the controlled introduction of a medicine in a new therapeutic class</i></li> </ul> <p>Karicare Aptamil Gold De-Lact is not a new product and has been listed on the PBS since 1995 (older formulation were under previous PBS codes 2349P, 2350Q). Nutritional products are not regarded as a 'new therapeutic class' as they are not</p>

	<p>‘therapeutic goods’. Further, the class of ‘nutritional products’ are not “new” on the PBS as there is a long history of product reimbursement within this class.</p> <ul style="list-style-type: none"> <li>• <i>to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.</i></li> </ul> <p>Karicare Aptamil Gold De-Lact is an IFSDU as regulated by FSANZ. These products are not classed as a therapeutic good but rather as a “food” which are inherently safer than therapeutic products and adverse reactions are rare. Therefore, the potential for inappropriate use/prescription of this product is extremely unlikely due to the nature of the products and their lack of known potential for misuse, overuse or abuse. It is unlikely that FSMPs would be used by individuals for whom it is not intended.</p> <p><b>Summary:</b> As Karicare Aptamil Gold De-Lact does not meet the PBAC criteria for Authority Required listings, Nutricia believes it appropriate for this listing to be unrestricted to remove an unnecessary burden for healthcare professionals and prevent delays to young infants from receiving access to the dietary treatment they require.</p>
<p><b>08259Q</b></p>	<p>Karicare Aptamil Pepti-Junior Gold (Protein hydrolysate formula with medium chain triglycerides)</p> <p><b>Response:</b> <i>Nutricia supports an Authority Required (streamlined) for Karicare Aptamil Pepti-Junior Gold</i></p> <p><b>Rationale:</b> Nutricia believes it is appropriate for this listing to be moved to an Authority Required (streamlined) for the following reasons:</p> <p>Nutricia notes the objective of the review is to improve patient safety and care by reducing red tape and administrative burden of health professionals.</p> <p>In relation to improving patient safety and care, Nutricia wish to make note that the <b><i>risks of potential misuse, abuse or adverse effects with prescribing Karicare Aptamil Pepti-Junior Gold (under this PBS Code) is unlikely.</i></b></p> <p>Karicare Aptamil Pepti-Junior Gold is an Infant Formula for Special Dietary Use (IFSDU) as regulated by FSANZ. It is classed as a ‘food’ and is not a therapeutic good. As an IFSDU, the potential for misuse or adverse effects is unlikely and extremely low as IFSDUs are used to address nutritional requirements of an infant in the dietary management of their medical condition.</p> <p>Karicare Aptamil Pepti-Junior Gold is an extensively hydrolysed infant formula for the dietary management of infants with cow’s milk allergy and soy protein allergy or malabsorption.</p>

The new extensively hydrolysed formula criteria changes introduced in 2012 added a complexity to the prescribing of Karicare Aptamil Pepti-Junior Gold for infants with cow's milk allergy.

Due to the changes which were aimed to manage potential risks of misuse, the scripts for Karicare Aptamil Pepti-Junior Gold have significantly decreased. The total number of scripts decreased from 13 539 in 2012/2013 to 12 941 in 2013/2014 which is equivalent to a 4% decrease. This demonstrates that doctors are prescribing in accordance with the new criteria.

Therefore, under the new extensively hydrolysed formula criteria, it is unlikely that changing from an Authority Required to an Authority Required (streamlined) will cause any increase in potential risks of misuse or overuse of Karicare Aptamil Pepti-Junior Gold. Doctors will still be required to fill in Authority Application forms to name the specialist, specify clinical justifications and date of birth of the patient included in the application<sup>3</sup>.

***In relation to reducing red tape and administrative burden, Nutricia supports a move to streamline as the current Authority Required approval adds an unnecessary step to an already time consuming criteria.***

The extensively hydrolysed formula PBS criteria for infants with cow's milk allergy are an already time consuming criteria for doctors. As part of the criteria, GPs are required to spend time to consult with the specialist and then after consultation with the specialist, to then call DHS and wait in phone queues to seek Authority Required approval.

Consulting with specialists is a time consuming task in itself for GPs. It would be unlikely during the consultation with a patient; the GP would be able to speak to a specialist therefore requiring additional time outside of their consultation with a patient to follow up.

Therefore, adding an extra step for doctors after consultation with a specialist to call DHS for authority approval over the phone will take more time away from doctors; is unnecessary and will further delay the child from receiving access to the dietary treatment they require.

Where the indication requires the specialist to treat the patient, the specialist also has to call DHS and wait in phone queues to seek Authority Required approval. This seems unnecessary and a similarly time consuming task as specialists are experts in their field and therefore, would be unlikely to prescribe inappropriately.

**Summary:** Nutricia supports an authority required streamlined approach for Karicare Aptamil Pepti-Junior Gold as patient safety is not an issue and it reduces an unnecessary administrative burden for doctors.

## References

1. Food Standards of Australia and New Zealand. Food Standards Code – Standard 2.9.1 – Division 3 – Infant Formulas for Special Dietary Use. <http://www.comlaw.gov.au/Series/F2008B00658> <accessed 7/10/2014>
2. PBAC Guidelines. *General guidelines followed by the PBAC.* <http://www.pbac.pbs.gov.au/information/role-of-pbac.html> <Accessed on 7/10/2014>
3. Pharmaceutical Benefits Scheme. *2. Prescribing Medicines – Information for PBS Prescribers - Authority PBS Prescriptions.* [http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section\\_1\\_2\\_Explanatory\\_Notes](http://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section_1_2_Explanatory_Notes) <accessed 7/10/2014>

