Nutricia Advanced Medical Nutrition

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

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INTRODUCTION

Nutricia Advanced Medical Nutrition ('Nutricia'; manufacturer code 'SB') 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.

Nutricia's mission is to lead the use of advanced medical nutrition in disease management. With a broad and unique portfolio of products, we seek to provide solutions and services wherever nutritional intervention can be shown to improve clinical outcomes. In partnership with healthcare professionals and caregivers, we work to make a difference by enhancing recovery and encouraging independence. Our ambition is to deliver only proven benefits through nutrition, as an integral part of disease treatment.

Nutricia is a provider of Food for Special Medical Purposes and Infant Formula for Special Dietary Use in Australia. Food for Special Medical Purposes (FSMPs) and Infant Formula for Special Dietary Uses (IFSDUs) are regulated by the Foods Standards of Australia and New Zealand (FSANZ) – Food Standards Code – *Standard 2.9.5 – Food for Special Medical Purposes*[1] and *Standard 2.9.1 – Division 3 – Infant Formula Products for Special Dietary Use*[2]. We offer a comprehensive product portfolio, a proportion of which is listed on the Pharmaceutical Benefits Schedule as 'nutritional products'.

Nutricia wish to provide comment regarding our products that have been listed for consideration including: Neocate Gold, Neocate LCP, Neocate Advance, Neocate Advance Vanilla, Kindergen, Liquigen, Paediatric Seravit and Locasol.

Nutricia notes that "Authority required" listings are required by the PBS for the following reasons[3]:

"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
09327X **03128P**	Liquigen (triglycerides medium chain oral liquid, 1 x 250 mL bottle) MCT Oil (triglycerides medium chain oil: oral, 500 mL) **Response:** *Nutricia supports an unrestricted listing for Liquigen and MCT Oil.* **Rationale:** 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): • *to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA* Liquigen and MCT Oil are FSMPs and therefore the approval and registration by the TGA is not relevant to this product. The use of Liquigen and MCT Oil is limited to the dietary management of specialised medical conditions requiring high energy where fat absorption is impaired and a high MCT intake is indicated. The labelling, product composition and all other aspects of Liquigen and MCT Oil are compliant with FSANZ standards which make it suitable only for these indications. • *to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons* Liquigen and MCT Oil are nutritionally incomplete, high energy, medium chain triglyceride (MCT) emulsions for the dietary management of extremely rare conditions requiring high energy where fat absorption is impaired i.e. chylous ascites, chylothorax, Fat malabsorption due to liver disease, short gut syndrome, cystic fibrosis and gastrointestinal disorders, Hyperlipoproteinaemia type 1, Intractable childhood epilepsy or cerebrospinal fluid glucose transporter defect, requiring a ketogenic diet, Long chain fatty acid oxidation disorders. Nutricia is not aware of any off label prescribing. All suitable conditions aforementioned are as outlined in Nutricia's PBS submission. Therefore, Nutricia deems it unnecessary to place Liquigen and MCT Oil under 'Authority Required' restrictions as it is only used for the indications listed on the PBS. The PBS usage of Liquigen and MCT Oil is limited to very rare complex conditions, where in practice other healthcare professionals such as dietitians are involved in the dietary management. This multidisciplinary approach also ensures the recommendation of Liquigen and MCT Oil is appropriate for clinical reasons. The rarity of these medical conditions (and hence limited usage of Liquigen/MCT Oil) is

	evidenced by the PBS script data showing a total of 238 scripts dispensed for Liquigen over the financial year of 2013/2014 and 828 scripts of MCT Oil equating to approximately 19 patients and 69 patients respectively. Due to the rarity of these conditions and unsuitability of these products for conditions outside of PBS listed indications, it is unlikely that a patient would be prescribed this product inappropriately. • *to allow the controlled introduction of a medicine in a new therapeutic class* Liquigen is not a new product, it has been PBS listed since 2009. The number of patients is stable between each year, which is demonstrated by script data over the last 4 years where patient numbers vary between 14 – 19 patients each year. MCT Oil is not a new product, it has been PBS listed since 1993. The number of patients has been stabilised in the last 11 years where patient numbers vary between 65 – 84 patients each year. • *to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.* Liquigen and MCT Oil are FSMPs, 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. The potential for inappropriate use/prescription of FSMP 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. **Summary:** As Liquigen and MCT Oil 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 patients from receiving access to the dietary treatment they require.
09328Y	Paediatric Seravit (vitamins, minerals and trace elements with carbohydrate oral liquid: powder for, 200 g) **Response:** *Nutricia supports an unrestricted listing for Paediatric Seravit.* **Rationale:** 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): • *to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA*

	Paediatric Seravit is a FSMP and therefore the approval and registration by the TGA is not relevant to this product. The use of Paediatric Seravit is limited to the dietary management of infants and young children whose vitamin and mineral intake is insufficient due to a highly restrictive therapeutic diet. The labelling, product composition of and all other aspects of Paediatric Seravit are compliant with FSANZ standards which make it only suited to this population group and indications. • *to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons* Paediatric Seravit is a powdered vitamin, mineral and trace element supplement for use from birth for the dietary management of infants and young children whose vitamin and mineral intake is insufficient due to a highly restrictive therapeutic diet. Nutricia is not aware of any off label prescribing. All suitable conditions aforementioned are as outlined in Nutricia's PBS submission. Therefore, Nutricia deems it unnecessary to place Paediatric Seravit under 'Authority Required' restrictions as it can only be used for the indications listed on the PBS. The PBS usage of Paediatric Seravit is limited to very rare complex conditions, where in practice other healthcare professionals such as dietitians and paediatricians are involved in the dietary management. This multidisciplinary approach ensures the recommendation of Paediatric Seravit is appropriate for clinical reasons. The rarity of these medical conditions (and hence limited usage of Paediatric Seravit) is evidenced by the PBS script data showing a total of 280 scripts dispensed over the financial year of 2013/2014 which equates to approximately 24 patients. Due to the rarity of these conditions and unsuitability of this product for conditions outside of PBS listed indications, it would be unlikely that a patient would be prescribed this product inappropriately. • *to allow the controlled introduction of a medicine in a new therapeutic class* Paediatric Seravit is not a new product; it has been listed on the PBS Schedule since 2009. The number of patients is stable between each year, which is demonstrated by script data over the last 4 years where patient numbers vary between 23 – 31 patients each year. • *to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.* Paediatric Seravit is an FSMP, 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. The potential for inappropriate use/prescription of FSMP 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. **Summary:** As Paediatric Seravit 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 patients from receiving access to the dietary treatment they require.
08587Y	Kindergen (whey protein formula supplemented with amino acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose oral liquid: powder) **Response:** *Nutricia supports an unrestricted listing for Kindergen.* **Rationale:** 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): • *to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA* Kindergen is an Infant Formula for Special Dietary Use (IFSDU) and therefore the approval and registration by the TGA is not relevant to this product. The use of Kindergen is limited to the dietary management of infants and young children with chronic renal failure requiring treatment with low protein, low phosphorus and a low potassium diet. The labelling, product composition and all other aspects of Kindergen are compliant with FSANZ standards which make it suitable only for this population group and indication. • *to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons* Kindergen is a low mineral, nutritionally complete formula for the dietary management of infants and children with chronic renal failure and where peritoneal rapid overnight dialysis (PROD) or continuous cycling peritoneal dialysis (CCPD) is required. Nutricia is not aware of any off label prescribing. All suitable conditions mentioned above are as outlined in Nutricia’s PBS submission. Therefore, Nutricia deems it unnecessary to place Kindergen under ‘Authority Required’ restrictions as it can only be used for the indications listed on the PBS.

	The PBS usage of Kindergen is limited to this very rare medical condition, where in practice other healthcare professionals such as dietitians are involved in the dietary management. This multidisciplinary approach ensures the recommendation of Kindergen is appropriate for clinical reasons. The rarity of these medical conditions (and hence limited usage of Kindergen) is evidenced by the PBS script data showing a total of 214 scripts dispensed over the financial year of 2013/2014 which equates to approximately 18 patients. Due to the rarity of these conditions and unsuitability of this product for conditions outside of the above mentioned PBS listed indications, it is unlikely that a patient would be prescribed this product inappropriately. • *to allow the controlled introduction of a medicine in a new therapeutic class* Kindergen is not a new product; it has been listed on the PBS Schedule since 2002. The number of patients is stable between each year and is unlikely to change, which is demonstrated by script data over the last 7 years where patient numbers vary between 14 – 23 patients. • *to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.* Kindergen 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. The potential for inappropriate use/prescription of FSMP 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. **Summary:** As Kindergen 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 very ill young infants/children from receiving access to the dietary treatment they require.
3092R	Locasol (milk powder synthetic low calcium oral liquid: powder for, 400 g) **Rationale:** 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 reasons are outlined in reference to each PBAC criteria for Authority Required listings (in Italics): • *to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA*

	Locasol is an IFSDU and therefore the approval and registration by the TGA is not relevant to this product. The use of Locasol is limited to that of the dietary management of infants and young children where an extreme restriction of calcium and vitamin D is required. The labelling, product composition of and all other aspects of Locasol are compliant with FSANZ standards which make it only suited to this population group and indications. • *to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons* Locasol is a nutritionally complete powdered formula for the dietary management if infants and young children where an extreme restriction of calcium and vitamin D is required (e.g. hypercalcaemia due to Williams Syndrome). Nutricia is not aware of any off label prescribing. All suitable conditions mentioned above are as outlined in Nutricia's PBS submission. Therefore, Nutricia deems it unnecessary to place Locasol under 'Authority Required' restrictions as it can only be used for the indications mentioned above. The PBS usage of Locasol is limited to very rare complex and critical conditions (e.g. Only 1 in 20 000 babies in Australia are born with Williams Syndrome[4]), and due to the nature of the condition, there is no alternative formula these infants/children can use. In practice, other healthcare professionals such as dietitians are involved in the dietary management. This multidisciplinary approach ensures the recommendation of Locasol is appropriate for clinical reasons. The rarity of these medical conditions (and hence limited usage of Locasol) is evidenced by the PBS script data showing a total of 153 scripts dispensed over the financial year of 2013/2014 which equates to approximately 13 patients. 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. • *to allow the controlled introduction of a medicine in a new therapeutic class* Locasol has been listed on the PBS Schedule since 1994. The number of patients is stable between each year, which is demonstrated by script data since its listing where patient numbers vary between 2 – 13 patients. The patient number is small and highly variable between each year. • *to alleviate concerns about adverse reactions, possible misuse, overuse or abuse.* Locasol is an FSMP, 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. The potential for inappropriate use/prescription of FSMP 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. **Summary:** As Locasol 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 very ill young infants/children from receiving access to the dietary treatment which is critically required due to the nature of their medical condition.
1545H **1521C**	Neocate Gold (amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400g) Neocate Advance Vanilla (amino acid synthetic formula oral liquid: powder for, 400g) **Response:** *Nutricia supports an Authority Required (streamlined) for the Neocate Gold and Neocate Advance Vanilla for the indication of Eosinophilic Oesophagitis (EO).* **Rationale:** Nutricia supports an Authority Required (streamlined) for Neocate Gold and Neocate Advance Vanilla as the prescribing for the indication of EO fits the current PBAC selection criteria of products for streamlining[5] which includes (in italics): • *Chronic and stable long-term conditions with stable usage and is* Eosinophilic Oesophagitis (EO) is an extremely rare condition and due to its complexity, is managed by a team of healthcare professionals including specialist allergists, immunologists and dietitians. It is estimated to affect 1 in 10 000 children in Australia[6]. EO meets this PBAC criterion as it is a chronic disease requiring long term treatment[7]. • *Less susceptible to risk of misuse or increased prescribing outside of restrictions.* To receive access to PBS reimbursement of Neocate Gold/Neocate Advance Vanilla, only specialist allergists, gastroenterologists and clinical immunologists are able to prescribe it. These specialists are key healthcare professionals whose involvement is required in the management of EO. Therefore, due to this restriction and as specialists in their field, it is unlikely these healthcare professionals would prescribe inappropriately and hence there is less susceptible risk of misuse. Further, dietary treatment of EO is only one part of the management of the condition. The amount of patients with EO who would require a formula such as Neocate Gold/Neocate Advance Vanilla is extremely small. This is demonstrated by the PBS script data where in the financial year of 2013/2014, there were only 503 scripts of Neocate Gold dispensed and 93 scripts of Neocate Advance Vanilla dispensed. This script number equates to approximately 42 and 8 patients in Australia respectively.

	Hence, due to small number of patients with EO requiring a formula such as Neocate Gold/Neocate Advance Vanilla and a multidisciplinary team approach to the management of patients with EO, the potential risks of misuse is extremely low and unlikely. **Summary:** Therefore given the use of Neocate Gold/Neocate Advance Vanilla meets the criteria, Nutricia supports an Authority Required (streamlined) listing to remove an unnecessary burden for doctors and help to reduce delays for patients to receive access to the dietary treatment they require.
1180D, 1192R 8754R, 8755T	Neocate Advance Vanilla (amino acid synthetic formula oral liquid: powder for, 400g) Neocate Advance (amino acid synthetic formula oral liquid: powder for, 400g) **Response:** *Nutricia supports an Authority Required (streamlined) for the Neocate Advance range: Neocate Advance Vanilla and Neocate Advance.* **Rationale:** Nutricia believes it is appropriate for this listing to be moved to an Authority Required (streamlined) for the following reasons: - Nutricia notes the objective of the review is to improve patient safety and care by reducing red tape and administrative burden of health professionals. In relation to improving patient safety and care, Nutricia wish to make note that the ***risks of potential misuse, abuse or adverse effects with prescribing Neocate Advance range (under this PBS Code) is unlikely.*** The new Amino Acid Formula criteria changes implemented in 2012 added a complexity to the prescribing of Neocate Advance and Neocate Advance Vanilla for infants and young children with cow's milk allergy or severe intestinal malabsorption including short bowel syndrome. Due to the changes, which were aimed to manage potential risks of misuse, the scripts for Neocate Advance range have significantly decreased. The total number of scripts decreased from 6530 in 2012/2013 to 5864 in 2013/2014 which is equivalent to a 10% decrease. This demonstrates that doctors are prescribing in accordance with the new criteria. Therefore, under the new amino acid 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 Amino Acid Formulas. Doctors will still be required to fill in Authority Application forms to name the specialist, clinical justifications and date of birth of the patient included in the application[8]. ***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 amino acid formulas PBS criteria are already time consuming 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. Hence, 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, is unlikely to prescribe inappropriately. **Summary:** Nutricia supports an authority required streamlined approach for Neocate Advance and Neocate Advance Vanilla as patient safety is not an issue and it reduces an unnecessary administrative burden for doctors.
2246F, 2560R **5466Q, 5467R**	amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids oral liquid: powder for, 400 g Neocate LCP amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides oral liquid: powder for, 400 g Neocate Gold **Response:** *Nutricia supports an Authority Required (streamlined) for Neocate LCP/Neocate Gold.* **Rationale:** Nutricia believes it is appropriate for this listing to be moved to an Authority Required (streamlined) for the following reasons: - Nutricia notes the objective of the review is to improve patient safety and care by reducing red tape and administrative burden of health professionals. In relation to improving patient safety and care, Nutricia wish to make note that the ***risks of potential misuse, abuse or adverse effects with prescribing Neocate Advance range (under this PBS Code) is unlikely.*** The Neocate Gold and Neocate LCP are Infant Formulas 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. Neocate Gold/Neocate LCP is amino acid based infant formulas for the dietary management of infants with cow's milk allergy, multiple food protein intolerance and other conditions where an elemental diet is indicated. The new Amino Acid Formula criteria changes introduced in 2012 added a complexity to the prescribing of Neocate Gold/Neocate LCP for infants with cow's milk allergy or severe intestinal malabsorption. Due to the changes which were aimed to manage potential risks of misuse, the scripts for Neocate Gold/Neocate LCP have significantly decreased. The total number of scripts decreased from 20, 032 in 2012/2013 to 16,747 in 2013/2014 which is equivalent to a 16% decrease. This demonstrates that doctors are prescribing in accordance with the new criteria. Therefore, under the new amino acid 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 Amino Acid Formulas. Doctors will still be required to fill in Authority Application forms to name the specialist, clinical justifications and date of birth of the patient included in the application. ***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 amino acid formulas PBS criteria are already time consuming 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, is unlikely to prescribe inappropriately. **Summary:** Nutricia supports an authority required streamlined approach for Neocate Gold and Neocate LCP as patient safety is not an issue and it reduces an unnecessary administrative burden for doctors.

References

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4. Better Health Channel. Williams syndrome. http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Williams_syndrome <accessed 7/10/2014>

5. Pharmaceutical Benefits Scheme. *12 Month Review of the Introduction of Streamlined Authorities*. http://www.pbs.gov.au/reviews/streamlined-authorities/streamlined-authorities-12-month-review-2009.pdf <accessed 7/10/2014>

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7. Straumann, A & Schoepfer, A. (2014). Update on basic and clinical aspects of eosinophilic oesophagitis. *Gut* 63:1355 -1363.

8. 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 <accessed 7/10/2014>