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The Hon Tanya Plibersek MP
Minister for Health and Ageing
PO Box 6022
House of Representatives
Canberra ACT 2600

Dear Minister,

I write in regard to changes to the Pharmaceutical Benefits Scheme (PBS) listings of protein hydrolysate and synthetic amino acid infant formulae. We have previously corresponded with the PBAC regarding this matter and remain concerned with the changes to the listing.

The purpose of this letter is to respectfully object to the decision and provide you with a copy of an online petition we recently co-ordinated asking that you require the PBAC to review this decision. It contains 442 signatures along with 111 comments from those signatories. A further petition in similar terms has been signed by 649 people along with 131 comments and been forwarded to the PBAC directly along with our attached correspondence.

Given the number of affected families with distressed infants, we feel it is only a matter of time before it is drawn to your attention in rather more adverse terms and thought it best to provide the information and concerns to yourself directly.

We understand the governance arrangements between the PBAC and your office and only request that you require the PBAC to review the decision.

Our concerns are specifically for children under the age of 24 months. With regard to children over the age of 24 months, we agree with the PBAC's position.

The PBAC's new listing regarding these specialized infant formulae has tightened prescribing regulations such that general practitioners and paediatricians are now only allowed to prescribe these products if the child has an appointment to see a paediatric gastroenterologist or allergist. Given that both groups of specialists are difficult to access in even the most populated parts of the country and the prevalence of severe and combined intolerances causing a need for these formulae is more common than you might expect, this is not going to be a sustainable position.

So, our reasons for pursuing this are as follows:

1. We agree that children who persist with various severe intolerances beyond the age of 12-15 months, with no sign of abatement should be reviewed by the paediatric specialists mentioned by the PBAC.

However, the prevalence of CMPI and soy protein intolerance for children under 12 months currently runs at about 1% of the population. (2% for CMPI, half of whom will be soy intolerant). While not all of these will require the specialized formulae above, many will. We would respectfully suggest that these combined intolerances are not difficult to diagnose and that many general practitioners and paediatricians are more than appropriately versed in diagnosing and treating these conditions. Many children, in fact most, grow out of these intolerances by 12 to 15 months of age and would not otherwise require the involvement of specialists.

2. The number of specialists available to review these cases is tiny compared to the number of children requiring review. In some parts of the country they simply don't exist. Currently the only paediatric hospital in WA has two paediatric gastroenterologists and the waiting list to see them is over 2 years. This cohort of medical professional is difficult to access. To further crowd their appointment schedules with children who can, in most cases, be more than adequately managed by paediatricians is at best, inefficient. At worst, it is crowding out very serious cases that require far more urgent treatment than can be made available.
3. We are also concerned by changes to the listings to the effect that these formulae are only to be prescribed for children who have failed soy formula. Yet, according to the PBAC position statement from 2008, **soy formula is not recommended for babies under the age of 6 months because few babies had been studied, and the reported rate of adverse reactions to soy protein was higher in that age group.** The PBAC also recommend that even over the age of 6 months, in cows milk intolerant babies, tolerance to soy formula should be established by clinical challenge (ie small amount included in the diet rather than a full soy formula trial.) It seems that the new listing contradicts the PBACs own published findings.
4. An unintended consequence but definite affect of the listing change is delaying the introduction of amino acid based formulas to children. These formulae can so alter a child's pain levels and attitude to food that to delay their introduction is intrinsically counter-productive because:-
 - a. These formulae taste awful and are harder to introduce to children the older they get – babies over 6 months often refuse them.
 - b. During the time that these formulae are withheld from these children, they are establishing behaviours toward food that can take years to undo. A child learns very early that eating hurts and will only eat instinctively in the first 3 to 4 weeks of life. After that, pain outweighs any instinct to eat and these children, depending on the length of time these formulae are withheld, often require years of paediatric speech therapy and dietetic attention to re-establish their feeding skills. The cost to the system is far greater not to mention the cost to the family and the child.
5. We are aware that the level of knowledge about gastrointestinal/ allergy issues amongst some general practitioners and paediatricians is currently inadequate, however RISA maintains that this is a very sweeping way to deal with this concern. There are many competent GP's and paediatricians who already deal with this medical condition competently on a daily basis and to take away this option adds to pressure mounting on paediatric gastroenterologists (and allergists) who are already overworked with very long waiting lists where they even exist in Australia. Children who really need to get access to these specialists (not just with combined intolerances) will have an even harder time getting access. GPs and paediatricians should be able to diagnose cow's milk protein intolerance and allergy and treat

it appropriately (given how common it is) saving referral to a paediatric gastroenterologist or allergist for those children who fail to respond to appropriate first line therapy. In WA at the moment there are only two full time paediatric gastroenterologists for the entire state. Children who fail nasogastric tube feeding and are enterally fed, who are officially under the GI team, don't always get to see them. RISA is aware of many parents from WA who are flying their children, at their own expense, to eastern states just to get access to an appropriate specialist. This is a failure of our otherwise excellent health system that is not intended. Our health system aims to catch and protect children in these circumstances but there is currently a yawning gap. These changes have the potential to increase the gap in the system.

6. Our members are the patients of affected paediatric allergists, gastroenterologists, paediatricians and general practitioners across the country. In quite a few instances our members and our medical advisory board **are** general practitioners and paediatric gastroenterologists. **We haven't yet come across a single one who supports these changes.**

We would contend that this decision is not only a terrible impost on affected families but also on the medical community who serve these families. The pages that follow contain comments from affected families who are well aware of the impracticalities imposed by this change to the listing and we strongly urge you to require the PBAC to review their decision.

Kind regards,

Joanne Matthews
President
Reflux Infants Support Association Inc