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Pharmaceutical Benefits Advisory Committee

Ms Sue Swensson

PBAC Secretary

Principal Pharmacist / Director

PBAC Secretariat

GPO Box 9848

Canberra ACT 2601

Dear Ms Swensson,

I write in response to your letter of 16 May 2012 regarding changes to the Pharmaceutical Benefits Scheme (BPS) listings of protein hydrolysate and synthetic amino acid infant formulae.

Firstly, thank you for your prompt response. It enabled our organisation to clearly and authoritatively pass-on the requirements and practicalities of the new listing arrangements to numerous paediatricians and general practitioners and allayed quite a bit of angst to parents who were otherwise going to be denied these formulae in their particular circumstances. We are fielding inquiries and concerns daily and directing parents to your correspondence.

I would advise that there remains quite a bit of confusion in the general practice and paediatric medical community about the new listing. Many who meet the criteria for the new listing are being denied access to these formulae by general practitioners and paediatricians who do not realise they are still able to prescribe under set conditions.

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

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 protein hydrolysate formula is only intended for children who have failed to respond to a strict cows'-milk-protein-free diet **using soy formula** and that consequently, amino acid formula is only intended for those children who have failed both protein hydrolysate and 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.** You also recommend at that time that even over the age of 6 months, in CMA babies, tolerance to soy formula should be established by clinical challenge (ie rather than soy formula trial.) What happened to that recommendation? Is it still current? if so, surely that impacts on that new listing? If not, how have things so substantially changed that you would require children to fail soy formula when you know that the incidence of soy intolerance among CMA children is so high? Surely these babies have been through enough by this stage.
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 reconsider the change.

Kind regards,

Joanne Matthews
President
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