

Special Foods Subcommittee of PTAC

Meeting held 22 July 2015

(minutes for web publishing)

Special Foods Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008*.

Note that this document is not necessarily a complete record of the Special Foods Subcommittee meeting; only the relevant portions of the minutes relating to Special Foods Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Special Foods Subcommittee may:

- a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
- b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
- c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes have been ratified by PTAC at its meeting on 5 & 6 November 2015.

**Record of the Special Foods Subcommittee of PTAC meeting
held at PHARMAC on 22 July 2015**

1 Therapeutic group review

1.1 The Subcommittee noted that PHARMAC had received correspondence regarding the wording of both the 'fat' and 'carbohydrate' nutrient modules Special Authority criteria, specifically questioning whether the "and/or" before the last criterion. The comment had been made that using the word "or" in the criteria widens the access beyond what was intended and that the word "and" would work in most cases. Due to the differing circumstances in the hospital and the community, the Subcommittee considered the appropriateness of wording the Special Authority and restrictions, differently for each listing.

1.2 The Subcommittee **recommended** that the Special Authority separator prior to the last criterion ("for use as a component in a modular formula") for nutrient modules be changed to "and" in the community listing in the Pharmaceutical Schedule and remain as "or" in the hospital medicines list (changes marked in bold and strikethrough):

Carbohydrate

SA 1522 Special Authority for Subsidy

Initial application — (Indications other than cystic fibrosis or renal failure) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 cancer in children; or
- 2 cancers affecting alimentary tract where there are malabsorption problems in patients over the age of 20 years; or
- 3 faltering growth in an infant/child; or
- 4 bronchopulmonary dysplasia; or
- 5 premature and post premature infant; or
- 6 inborn errors of metabolism; ~~or~~ **and**
- 7 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Fat

SA 1523 Special Authority for Subsidy

Initial application — (Inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 3 years where the patient has inborn errors of metabolism.

Initial application — (Indications other than inborn errors of metabolism) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Any of the following:

- 1 faltering growth in an infant/child; or
- 2 bronchopulmonary dysplasia; or
- 3 fat malabsorption; or
- 4 lymphangiectasia; or
- 5 short bowel syndrome; or
- 6 infants with necrotising enterocolitis; or
- 7 biliary atresia; or
- 8 for use in a ketogenic diet; or
- 9 chyle leak; or

- 10 ascites; ~~or~~ **and**
- 11 for use as a component in a modular formula made from at least one nutrient module and at least one further product listed in Section D of the Pharmaceutical Schedule or breast milk.

Food Thickeners

- 1.3 The Subcommittee reviewed the evidence since its previous recommendation that food thickeners and pre-thickened fluids should not be listed in Section D of the Pharmaceutical Schedule. The Subcommittee considered that there was still a difference of opinion between many practitioners in this area, including speech and language therapists.
- 1.4 The Subcommittee noted that an international standard had been generally adopted relating to the degree of thickness of food thickeners/thickened liquids. The Subcommittee **recommended** using the international terminology of labelling the degree of thickness of food thickeners/thickened liquids as follows; Thin fluid (level 80), stage 1 (level 150), stage 2 (level 400) and stage 3 (level 900).

Inborn Errors of Metabolism / Metabolic Products

- 1.5 The Subcommittee noted that the evidence for adult patients being better off on the Phenylketonuria (PKU) diet is more anecdotal.
- 1.6 PHARMAC staff requested information on the level of compliance with the PKU diet in order to define the upper limits for PKU product usage. The Subcommittee considered patient receiving a PKU diet to be mostly fully compliant and that there is very little partial compliance. The Subcommittee considered that measuring compliance is not possible and that patient feedback indicated that if there was a product they could comply with, then they would.
- 1.7 The Subcommittee noted that of the 150 – 160 patients with PKU in New Zealand, there are 93 on a full PKU diet.
- 1.8 The Subcommittee noted that the tetrahydrobiopterin (BH4) or sapropterin was available overseas for the management of PKU that was resultant from a specific enzyme deficiency. The Subcommittee considered that this is an expensive product and the size of the patient group is small (approximately 5 patients).
- 1.9 The Subcommittee noted that certain products that are marketed for a “PKU diet” or “PKU friendly” available overseas have a relatively high amount of protein which impacts on patient choice through additional limitations in their regular diet.

Oral Supplements / Complete Diet – Standard Supplements

- 1.10 The Subcommittee noted that during its 2010 consideration of the listing of oral feed powder and the recommendation to reference ready-to-drink formulations to oral feed powder, the recommendation was based on nutritional information only. The Subcommittee noted that, now that the product has been funded for several years, it is aware of additional factors such as texture and thickness that affect compliance. The Subcommittee considered that, internationally, liquid Oral Nutritional Supplements (ONS) appear to be the standard.
- 1.11 The Subcommittee noted correspondence from Dietitians NZ requesting full funding for liquid ONS for all patients. In addition, Dietitians NZ identified three smaller priority

groups: exclusive enteral nutrition (EEN) in children with Crohn's disease, cystic fibrosis and head and neck cancers. The Subcommittee considered that the overall evidence for widening access to full funding of liquid ONS for all patients was weak.

- 1.12 The Subcommittee noted that liquid ONS incurred a handling fee that the patient is expected to pay. The Subcommittee considered that in some instances, this fee could be considerable. The Subcommittee noted that this fee was imposed even when the ONS was partially subsidised.
- 1.13 The Subcommittee noted that EEN for children with Crohn's disease has been ranked against other funding options PHARMAC has. The Subcommittee considered that EEN reduces the need for the progression to treatment with biologics. The Subcommittee **recommended** that biologic treatment be used as the appropriate comparator.
- 1.14 The Subcommittee **recommended** that powdered ONS was acceptable as a supplement for children in most instances. However, the Subcommittee expressed concern when powdered ONS constituted more than 50% of a child's daily calorie intake as there is a risk that excessive consumption of vitamin A and the need for close monitoring to avoid toxicity. In these situations liquid ONS would be appropriate. The Subcommittee noted that this would be relevant to both EEN and cystic fibrosis.
- 1.15 The Subcommittee noted most that patients did not solely use powdered ONS and chose to pay for additional liquid ONS, to use in conjunction with the powder. The Subcommittee discussed the practical and social difficulties associated with only using powder, such as children and teenagers requiring ONS at school.
- 1.16 The Subcommittee **recommended** full funding of liquid ONS for cystic fibrosis patients with a medium priority.
- 1.17 The Subcommittee noted that cancer patients with mouth or throat ulceration from radiology treatments did not like the powder due to discomfort and irritation. Other reasons for patients preferring ONS to powder supplements included the time required to mix the formula, taste fatigue, and the additional cost of milk to mix with the powder.
- 1.18 The Subcommittee **recommended** full funding of liquid ONS for patients with head and neck cancer with a medium priority.
- 1.19 The Subcommittee **recommended** removing the word "infant" from Special Authority criteria and the HML restriction for High Calorie Products (2kcal/ml). These products are not suitable for infants due to their high osmolality, protein content per litre and micronutrient composition. Caution should be used for children under 8 years of age. The Subcommittee recommended the following change to the Special Authority in the Pharmaceutical Schedule and the HML restriction (changes marked in strikethrough):

Section D of the Pharmaceutical Schedule
SA1195

Initial application – (Indications other than cystic fibrosis) only from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals valid for 1 year for applications meeting the following criteria:

All of the following:.

1. Any of the following:
 - 1.1 any condition causing malabsorption; or
 - 1.2 faltering growth in an infant/child; or
 - 1.3 increased nutritional requirements; or
 - 1.4 fluid restricted; and
2. other lower calorie products have been tried; and
3. patient has substantially increased metabolic requirements or is fluid restricted.

Section H for Hospital Pharmaceuticals (HML)

Restricted

Any of the following:

1 Patient is fluid volume or rate restricted; or

2 Patient requires low electrolyte; or

3 Both:

3.1 Any of the following:

3.1.1 Cystic fibrosis; or

3.1.2 Any condition causing malabsorption; or

3.1.3 Faltering growth in an infant/child; or

3.1.4 Increased nutritional requirements; and

3.2 Patient has substantially increased metabolic requirements.

Ketogenic Diet

- 1.20 The Subcommittee noted the data presented to it by PHARMAC staff regarding the use of the ketogenic diet feeds since it became listed in 2011. The Subcommittee noted that the patient group size and expenditure figures indicated an average of two tins per patient per week which was lower than expected if used as a complete diet.
- 1.21 The Subcommittee noted that ketogenic diet feeds have become popularised with multiple cookbooks now available based on modified Atkin's and ketogenic diets. The Subcommittee considered that this may have an impact on patients requesting the products for cooking purposes. The Subcommittee noted that the appropriate prescriber base for ketogenic diet products is very small in New Zealand. The Subcommittee noted that it will be possible for PHARMAC to write to them and individually and address this possibility.

Infant Formula

- 1.22 The Subcommittee noted that the use of amino acid formula (AAF) was still far in excess of what was expected and having a significant proportion of overall expenditure on Special Foods. The Subcommittee expressed concern that this represented misuse of this pharmaceutical. The Subcommittee noted that the prescribing ratio of these products should be expected to be at least 3:1 in favour of EHF. It was expected that AAF use in children over the age of 12 months would only be for a small number of infants with multiple severe food intolerances. Subcommittee members indicated that it would be estimated that up to 50 children would fall into this category. PHARMAC staff presented data demonstrating that 1311 of the 2,541 total Special Authority applications and renewals (52%) are for infants over 12 months of age in both of the last two financial years. The Subcommittee

considered that AAF and EHF infant formula is having a significant impact on the Combined Pharmaceutical Budget and considered the options available to improve prescribing practice.

- 1.23 The Subcommittee considered that further restricting the Special Authority criteria for EHF and AAF, such as limiting prescribers to smaller groups, for example by restricting to paediatrician prescribing only, may improve some prescribing practice but may also induce inequities in access to treatments in remote areas.
- 1.24 The Subcommittee considered an approach to improve education amongst prescribers would have minimal impact if employed in isolation to other measures. In relation to this point the Subcommittee noted the data presented by PHARMAC staff regarding Special Authority audits on prescribers of EHF and AAF completed by Audit and Compliance, Ministry of Health, on behalf of PHARMAC between 1 June 2012 and 31 May 2013. This audit focused on the prescribing practices of extreme prescribers. This audit revealed high levels of prescribing where PHARMAC Special Authority criteria had not been met. Follow up letters were issued by PHARMAC to inform the prescribers of the audit findings. PHARMAC staff have since performed a review of Special Authority numbers for the period 12 months after the letters were issued. This review found a considerable decrease in numbers of initial Special Authority applications for AAF, approximately 30%, for the prescribers. However, PHARMAC staff noted that the overall reduction was less than expected and furthermore the methodology of the audit does not allow measurement of factors such as transferrals in prescribing duties.
- 1.25 The Subcommittee considered the possibility of imposing a part-charge for infant formula to bring the cost to patients down to that of regular formula; ie PHARMAC will fund the clinical aspect of the formula, but not the food component. However, PHARMAC staff indicated that part-charges are put in place when clinical equivalents are available at the subsidised price and noted the issues regarding inequity for patients. It was suggested that, only those who could afford to pay the part charge would be able to access appropriate treatment.
- 1.26 The Subcommittee considered an approach whereby approvals would be restricted to patients under 12 months of age and any applications for children above 12 months of age would be considered via the Named Patient Pharmaceutical Assessment (NPPA) policy. However it was considered that the patient group would be too big for this to be appropriate with up to 50 applications/renewals expected per year.
- 1.27 The Subcommittee **recommended** that PHARMAC put together a clinical panel to look at infant formula initial applications for children over 12 months of age and renewals for all children over 12 months of age. The Subcommittee noted that while there would be initial set-up costs related to a panel; overall this approach is likely to be very cost effective.
- 1.28 The Subcommittee **recommended** PHARMAC provide educational support regarding EHF and AAF formulas for prescribers in primary and secondary care to improve prescribing practice.
- 1.29 The Subcommittee **recommended** re-auditing high use prescribers after first communicating an appropriate penalty for non-compliance. In addition, correspondence to other clinicians such as general practitioners and community

dietitian prescribers should be included within the scope of the audit to determine whether responsibilities are being transferred onto other prescribers.

- 1.30 The Subcommittee **recommended** amending the SA1380 criteria for initial applications for EHF to include an additional criterion of 'Step down from funded amino acid formula' to ensure the pathway was in place to allow children receiving AAF to be transferred to EHF.

Gluten Free Foods

- 1.31 The Subcommittee reviewed the data on gluten free foods provided by PHARMAC staff and noted that whilst 1% of the New Zealand population has been identified as having coeliac disease, there were only approximately 4000 prescriptions used in 2014.
- 1.32 The Subcommittee noted that 95% of coeliac patients in New Zealand do not receive prescribed gluten free foods on prescription. The Subcommittee attributed the low number of prescriptions to the greater availability of gluten free foods in supermarkets and the mark ups applied to partly subsidised gluten free foods.
- 1.33 The Subcommittee considered that the low numbers of patients accessing gluten free products via prescriptions and the widespread availability of gluten free foods, even in remote areas, has removed the clinical need for these products to remain listed in the Pharmaceutical Schedule.
- 1.34 The Subcommittee **recommended** delisting gluten free foods from the Pharmaceutical Schedule.

Matters relating to Products Listed in Other Therapeutic Groups

- 1.35 The Subcommittee noted an article by Nutricia on a treatment for small intestine bacterial overgrowth (SIBO) in which elemental products are used as a partial diet supplement. The Subcommittee considered this would be an expensive treatment that has only weak evidence for efficacy and **recommended** PHARMAC monitor its use.

2 Nutrison 800 Complete Multi Fibre Enteral Feed

Application

- 2.1 The Subcommittee reviewed an application from Nutricia Ltd for the listing of enteral feed with fibre 0.8 kcal / ml in Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for the dietary management of patients with low energy and/or low fluid requirements.

Recommendation

- 2.2 The Subcommittee **recommended** that enteral feed with fibre 0.8 kcal / ml be listed in Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule with medium priority.
- 2.3 The Decision Criteria particularly relevant to these recommendations are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things, (iv) The clinical benefits and risks of pharmaceuticals, (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Discussion

- 2.4 The Subcommittee noted that the energy requirements of low mobility/immobile, long-term tube fed patients, including elderly people in rest homes is low and that funded products can lead to weight gain with people on long term tube feeds and once gained it was extremely difficult to reverse this. The Subcommittee considered that, should a low energy product be listed, that there may be an initial rise in its use, but considered generally that the patient group would be small.
- 2.5 The Subcommittee considered the alternative to a low energy feed would be a standard 1kcal product, and that this would require reduced volumes, quarterly blood tests and regular weighing. The Subcommittee considered the issues associated with having to manipulate feeds to achieve lower calorie levels and the wastage that currently occurs following dilution of funded products.
- 2.6 The Subcommittee considered that community patients would not require more than 1000ml of low energy feed per day.
- 2.7 The Subcommittee discussed Special Authority restrictions to access and noted that usually patients would be initiated on a standard 1 kcal / ml enteral feed and only switched to a low energy feed if weight gain was unacceptable. The Subcommittee considered that this would become the new standard of care in obese tube fed patients and those with low energy requirements.
- 2.8 The Subcommittee considered that it would be appropriate for low energy feed to be initiated in community patients who were obese, gaining inappropriate weight or had been initiated in hospital (eg obese patient post cardiovascular accident). The Subcommittee considered that should a low energy feed be funded, then its use should be reviewed in community 6 months after initiation.

3 Nutrison Protein Plus Multi Fibre

Application

- 3.1. The Subcommittee reviewed an application from Nutricia Ltd for the listing of high protein enteral feed with fibre 1.28kcal/ml in Part II of Section H of the Pharmaceutical Schedule and in Section D of the Pharmaceutical Schedule for the dietary management of disease related malnutrition in patients with increased protein requirements.

Recommendation

- 3.2. The Subcommittee **recommended** that high protein enteral feed with fibre 1.28kcal/ml for listing in Section D of the Pharmaceutical Schedule for patients in the community be declined.

Discussion

- 3.3. The Subcommittee considered that Nutrison Protein Plus Multi Fibre enteral feed is already included as an example brand in High Protein products in the HML and accounts for a high proportion of tube feeds used in hospitals.
- 3.4. The Subcommittee noted papers provided by the applicant. The Subcommittee considered the strength of the evidence (eg Hoffer and Bistran, 2012; and Hoffer and Bistran, 2013) is focussed around the need for short term increased protein energy requirements in an acute setting (e.g. ICU). However, it considered that it is lacking with relevance to benefit for long-term use in the community setting. The Subcommittee noted a systematic review by Hoffer and Bistran (2012) review of 13 studies identified via MEDLINE, all of which used surrogate end points, rather than clinical end points, and none of which were randomised. The Subcommittee noted that the main outcome was an improvement in nitrogen balance with increased protein. However it noted that the conclusion was that there was a need for randomised clinical trials in this area. The Subcommittee noted that there are no studies which show clinically definitive results.
- 3.5. The Subcommittee noted that high protein enteral feed with fibre 1.28kcal/ml was for a very small number of tube fed patients in the community setting.
- 3.6. The Subcommittee considered that high protein enteral feed with fibre 1.28kcal/ml should be cost neutral with enteral feed 1.5 kcal / ml and enteral feed with fibre 1.5 kcal / ml.
- 3.7. The Subcommittee considered that there is no unmet need in the community setting, as increased protein requirements could be met by the addition of protein modules or other funded products.
- 3.8. The Subcommittee considered that tube fed renal patients have feeds available that are tailored to their requirements.

4 Fortisip Compact and Fortisip Compact Protein

Application

- 4.1 The Subcommittee reviewed a reapplication from Nutricia Ltd for Fortisip Compact and Fortisip Compact Protein; original application viewed by this subcommittee in August 2012, recommendation as per below:

Recommendation

The Subcommittee **recommended** that Fortisip Compact only be listed on the Pharmaceutical Schedule if cost-neutral to the Pharmaceutical Schedule.

The Decision Criteria particularly relevant to this recommendation are: *(iii) The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (v) The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services, (vi) The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Pharmaceutical Schedule.*

Recommendations

- 4.2 The Subcommittee **recommended** no change to the 2012 recommendation and that both Fortisip Compact and Fortisip Compact Protein only be listed if cost-neutral to oral feed (powder).

Discussion

- 4.3 The Subcommittee reviewed the new evidence provided by Nutricia Ltd in relation to Fortisip Compact and Fortisip Compact Protein. The Subcommittee considered that the quality of the evidence was poor and that there was no new evidence in the application that challenged the previous recommendation that it should be cost neutral to oral feed (powder).
- 4.4 The Subcommittee considered that listing Fortisip Compact or Fortisip Compact Protein would lead to increased usage of oral feeds and increase the cost per kcal over currently funded oral feed powder.

5 Product Changes – Nutricia, Abbott and Nestlé Health Science

General

- 5.1. PHARMAC staff receive frequent notifications of minor product changes in the Special Foods therapeutic group and sought advice on how best to determine if there was a way to filter out which changes require Subcommittee review and which ones don't. The Subcommittee discussed the most efficient and clinically sound way of reviewing product changes.
- 5.2. The Subcommittee noted that minor products changes must continue to be reviewed by the Subcommittee in order to identify potential issues such as allergens and that comparison tables provide the optimal way for comparisons to be made.

- 5.3. The Subcommittee **recommended** that PHARMAC require suppliers to inform PHARMAC, with any proposed changes made to listed products, concurrently when informing the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia for any products funded in both countries.
- 5.4. The Subcommittee **recommended** that PHARMAC communicate with suppliers to request literature be provided with a product when potential allergens have been added.

PKU Anamix Junior (Nutricia)

- 5.5. The Subcommittee noted the change in pack size and protein content of PKU Anamix Junior (Nutricia) from a 29g pack containing 8.4g protein to a 36g pack containing 10g of protein.
- 5.6. The Subcommittee **recommended** accepting the PKU Anamix Junior pack size change to a 36g pack containing 10g of protein.

TYR Anamix Junior (Nutricia)

- 5.7. The Subcommittee noted the change in pack size and protein content of TYR Anamix Junior (Nutricia) from a 29g pack containing 8.4g protein to a 36g pack containing 10g of protein and the niacin level had also been altered to match the PKU Anamix range.
- 5.8. The Subcommittee **recommended** accepting TYR Anamix Junior pack size change to a 36g pack containing 10g of protein.

Elemental and semi-elemental products – Vital HN 1.5kcal/ml 1000ml bottle

- 5.9. The Subcommittee noted that Abbott Nutrition informed PHARMAC of their intention to discontinue the peptide based oral feeds, Vital HN and Alitraq, in mid-2016. The Subcommittee noted that the supplier provided a proposal to instead list Vital HN 1.5kcal/ml 1000ml bottle (vanilla flavoured) as a direct replacement for those products.
- 5.10. The Subcommittee noted these products are extensively hydrolysed rather than elemental products and need to be described correctly in the Pharmaceutical Schedule.
- 5.11. The Subcommittee **recommended** accepting the listing of Vital HN 1.5kcal/ml 1000ml bottle (vanilla flavoured) as a direct replacement for Vital HN and Alitraq.

Pediasure Plus RTH 1.5kcal/ml 500ml bottle listing

- 5.12. The Subcommittee noted that Abbott Nutrition have requested that Pediasure Plus RTH 1.5kcal/ml 500ml be listed with the same Special Authority criteria and restrictions as Nutrini Energy RTH in Section D of the Pharmaceutical Schedule and as an example brand in Part II of Section H of the Pharmaceutical Schedule.
- 5.13. The Subcommittee **recommended** the listing of Pediasure Plus RTH 1.5 kcal / ml 500ml bottle as a Paediatric Enteral Feed 1.5 kcal / ml.

Sustagen Hospital Formula change (Nestlé Health Science)

- 5.14. The Subcommittee noted that Nestle had informed PHARMAC staff that there will be changes to Sustagen Hospital Formula tin size, from 900g to 840g, as manufacturing has been moved to Europe. The Subcommittee noted that currently the 900g powder is listed in Section D of the Pharmaceutical Schedule and in Part II of Section H of the Pharmaceutical Schedule.
- 5.15. The Subcommittee **recommended** the change in pack size to Sustagen Hospital Formula from 900g to 840g be accepted in the schedule if the price per kcal remained the same.

Monogen (Nutricia)

- 5.16. The Subcommittee **noted** an email from Nutricia Ltd regarding Monogen and outlining a change to be made in the formulation that included an increase in folate, vitamins C and E, DHA, and MCT.
- 5.17. The Subcommittee **noted** that the price and pack size are to remain the same.
- 5.18. The Subcommittee **noted** that the addition of fish oil (DHA) was unlikely to affect allergies in patients and as this is a prescribed product, patients will be monitored by their prescriber for changes.
- 5.19. The Subcommittee **recommended** the changes in the Monogen formulation, that included an increase in folate, vitamins C and E, DHA and MCT, be accepted.