THE PAEDIATRIC SOCIETY OF NEW ZEALAND

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Angela Harwood
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Dear Ms Harwood

Re: Agenda for the 56th meeting of the Medicines Classification Committee to be held at Rydges Wellington, 75 Featherston Street, Pipitea, Wellington - Tuesday 19 July 2016, 9.30 am

I am writing on behalf of the Pharmacists and Therapeutics Special Interest Group of the Paediatric Society. We would like to comment on the proposal to reclassify strengths of various minerals submitted by the Natural Health Products Industry.

http://www.medsafe.govt.nz/profs/class/Agendas/agen56.htm

We are concerned if families have access to purchasing higher strengths of various compounds without any regulation, that the risk of administration of inappropriate doses as well as the potential for overdose is greatly heightened for children.

- We would like to know how regulation would be controlled regarding the manufacture of any product being sold under general sale. In particular if these products have not undergone medicine grade quality assurance, can the concentration stated on the label be assured it is what is in the product?

- Are there any restrictions in place to ensure safety for children handling such products? Will there be safety caps enforced on products containing greater than safe doses for children? There do not appear to be any safety warnings proposed on labels for maximum safe daily doses for children.

We have not looked into every supplement but would like to comment particularly on the proposed increase in potassium-containing products.

6.7 Potassium

12. Proposed warning statements if applicable.

When intended for mineral supplementation: State the equivalent quantity of potassium.

If considered appropriate to allow the increase in maximum daily dose to 3000 mg, it is proposed that any risk could be managed by requiring a warning statement similar to:

Do not use with other potassium-containing supplements or with potassium-containing salt substitutes.

What about potassium –sparing diuretics, and other potassium sparing/enhancing drugs and a diet high in potassium? None of these are mentioned in the warning statement or appear to have been thought about.

On page 4 of the potassium proposal, under **'A statement of the benefits to both the consumer and to the public expected from the proposed change', s**pecific reasons are not provided by applicants for the requests to increase the allowed daily maximum dose of potassium.

Under **6. Interactions with other medicines**, there are spelling mistakes as well as comments regarding supplementation of potassium when taking certain medicines which is not a routine occurrence.

'On the other hand, the use of medicines such as amnioglycosides, amphotericin B, beta-2-agonists, cisplatin, diurectics, fluconazole, glucocorticoids and mineralocorticoids, methylxanthines, penicillins, sodium phosphates and stimulant laxatives lead to moderate depletion of potassium levels, and potassium supplementation is recommended for some patients (NMD 2012)'

We have not had time to thoroughly look at every example but also of concern is the increase in elemental iron, folic acid and boron.

We have the following points to add:

6.1 Boron

'12. Proposed warning statements if applicable.
No warning statements are considered to be necessary.'
The safety of maximum daily recommendations for children should be included and is listed as follows: ' in amounts that do not exceed the UL of 3mg 1-3yr; 6mg 4-8yr, 11mg 9-13yr and 17mg 14years or older[1]. This needs to be considered carefully.

6.2 Folic acid
The proposal is the reclassification to unscheduled below 500mcg daily and pharmacy only above 500mcg of folic acid per daily dose.

Folic acid is possibly unsafe when used orally in large doses, long-term. 'Clinical research shows that taking Folic acid in doses 800-1200mcg for 3-10 years increases risk of developing cancer and adverse cardiovascular effects compared to placebo'[1]. We are concerned that the general sale of a higher folic acid product could lead to children being given much higher doses when included with daily dietary folic acid.

6.4 Iron
It is unclear whether the reference is to elemental iron or the salt in each case. The main concern for children is iron toxicity either through accidental overdose or chronic dosing. Without medical input either through pharmacy or prescriber advice, the risk is greater if supplements with a higher iron content are available via general sale.

We would ask that the Medicines Classification Committee consider carefully the impact of reclassifying amounts of the products for general sale both in the context of safety for children, where decisions to take regular supplements is reliant on adults access to appropriate products, as well as general safety to people purchasing supplements without guidance
We look forward to your response.

Yours sincerely

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Chairperson
Pharmacist and Therapeutics SIG
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This letter is supported by:
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References:
1. Natural Medicines Comprehensive Database, 13th Ed. 2013. Therapeutic Research Faculty, CA.