



THE PAEDIATRIC SOCIETY OF NEW ZEALAND

Secretariat: Denise Tringham
PO Box 22 234
Wellington 6441
Tel: (04) 938 4827
Fax: (04) 976 4827
Email: denise@paediatrics.org.nz
Website: www.paediatrics.org.nz

18 September 2013

Mr Anthony Hill
Health and Disability Commissioner
PO Box 1791
Auckland 1140

E-mail: hdc@hdc.org.nz

Dear Mr Hill

Re Decision 11HDC01072, 9 July 2013

Following the report cited above, the recommendation has been given for 'all other district health boards' to 'ensure they have in place appropriate policies on off-label prescribing' and 'policies and protocols that set out what is required of staff members in relation to..clinical activities.. and provide copies of the above policies to the National Health Board by 30 September 2013'. (I understand that this date has now been extended).

The document relating to this recommendation has been discussed at the Pharmacist and Therapeutics Special Interest Group of the Paediatric Society via video-conference on 11th Sept 2013.

Feedback from this group is as follows:

We are concerned about the impact that this recommendation will have on the use of medicines in our paediatric population which includes a wide range of ages from premature neonates to teenagers. Many medicines we use on a daily basis in paediatrics are used 'off-label' due to the age of our population and lack of robust clinical trials in this age group. As standard practice we utilise medication and clinical protocols, and text books specifically designed for this age group that commonly recommend doses of medicines 'off-label' eg. omeprazole for infants less than one year for GORD. In the majority of cases, the use of medicines is not categorised as clinical research or experimental.

We are also concerned that the quality and content of medication data sheets available to prescribers is not comprehensive or consistent enough to reliably inform them as to whether the medication and dose they are prescribing are licensed for use in paediatrics. For example, the data sheet for oral methotrexate doesn't mention its use in rheumatological conditions only injectable methotrexate is listed for this use.

At our video-conference, we discussed the need for clarification around the document in relation to prescribing medicines for children.

- We would like clarification regarding 'common off-label' use in relation to the paediatric population. What policies and protocols, if any, are required for this common use? (Currently the 'off-label' use of medicines in children is so common that obtaining consent is not usually considered necessary.)
- We would also like to discuss a national document that we could use when prescribing medicines in this population rather than individual policies at each hospital and medical centre. This will take time to develop.
- We expect that the New Zealand Formulary for Children which is due to be available from late November this year will have information available on whether the medicine is unapproved and whether the indication or the dose is unapproved. We would like to use this information to guide a national document which all paediatric prescribers could use to inform them of unapproved medicine use. However we anticipate that the formulary may not initially be sufficiently comprehensive to cover all prescribing for children, and that there will still be frequent off label use of medicines in this age group.

Could you please respond with clarification in regard to off-label prescribing in the paediatric population? This affects all prescribers in hospital as well as the community.

Yours sincerely,

Louise McDermott
Chair, Pharmacist and Therapeutics SIG
The Paediatric Society of New Zealand