

Minutes of the meeting of
Medication Safety Expert Advisory Group (EAG)
4 September 2019

Location	Eagle Room, Miramar Links Conference Centre, Wellington
EAG Members	Sandra Fielding (Acting Chair), John Barnard, Margaret Hand, Matt Doogue, Rob Ticehurst, Sharon Kletchko, Taimi Allan
Ex officio	Andi Shirtcliffe (MoH), Bryan Simpson (NZF), Janet Mackay (PHARMAC), Joanne Beachman (NZPSHA), Michael Tatley (NZPhvC), Peter Jansen (ACC)
Commission staff in attendance	Billy Allan, Caroline Tilah, Susan Melvin, Jane Lester (minutes)
Apologies	Gareth Frew, Beryl Wilkinson, Bev Nicolls, Chris James (Medsafe), Lucy McLaren, Sunita Goyal (ACC)
Guests	Brendan Ng

Agenda item 8 - Sodium valproate in people of child bearing potential (paper)

Billy tabled a report on the dispensing volumes of sodium valproate in women from 2009 to 2018. There is a risk of foetal anticonvulsant syndrome from sodium valproate. The data indicate there is still quite high usage in people of child bearing potential and disproportionately high usage in the Māori population. Currently risk mitigation includes:

- resources for consumers and health professionals that are being reviewed by the ACC-led foetal anticonvulsant syndrome group (FACSNZ)
- petitions to the health select committee to request an inquiry and a registry of use
- highlighting the need for prescribers and dispensers to be informing consumers and considering risk mitigation strategies around contraception or pregnancy decision making
- discussions within FACSNZ about having balanced conversations regarding the 'greater risk' versus treatment benefit
- use of the Conporto event detection and mitigation programme to alert and provide guidance to prescribers and pharmacists on advising two forms of contraception to people of child bearing potential prescribed sodium valproate.

Potential further risk mitigation could include:

- an electronic alert or mandate or expectation that the risk is discussed between pharmacist and consumer (the 'contraceptive conversation')
- consumer consultation about what constitutes a real and appropriate conversation and what might work in terms of a contract or agreement as part of that conversation
- warning labels on the medication pharmacy label – vendors can do this if directed and are usually directed in this way by the Medical Council or the Pharmaceutical Society

- linking the prescribing and dispensing of sodium valproate with access to and consultation about contraception
- enforcing documentation that must be completed to show that the conversation about risk has occurred
- prescribing or competency assessments; a common curriculum by the responsible authorities
- investigation into what is happening between primary care and mental health in managing co-prescribing and consumer information.

Issues discussed:

- an electronic alert or warning label could cause pharmacy or the consumer to stop medication inappropriately
- conversations at general practice level about contraception are known to be poor; adding this into the conversation adds further complications
- limited access to information at the point of prescribing; prescribers are unaware of co-prescribing or risks unless they are referring to NZ Formulary or other sources of information
- prescriber's preparation and education
- knowledge gaps and lack of connection between areas of health care delivery eg, mental health and general practice.

Peter noted that ACC want to work cross sector on this. They have accepted a number of claims, which indicates that these conversations are not happening reliably. Claims relating to the use of sodium valproate are expected to increase following the high court decision which threw out the exclusion of fetal anticonvulsant syndrome being classified as an ordinary consequence of treatment. Peter also thanked Billy for the work on this paper and asked if he can share it with the ACC group.

The EAG agreed that a cautionary advisory label from NZ Formulary was a valid option if it is carefully worded. Andi and Bryan will discuss this further.

The EAG agreed that current actions are not enough and further analysis of the data and understanding of the issues should be pursued. FACS NZ will be invited to a future EAG meeting to discuss how the EAG can support or endorse their work.

Action: Billy will send Peter a copy of the sodium valproate use in people of child bearing potential paper.

Action: Bryan and Andi to discuss wording options for a cautionary label.

Action: Billy to invite FACS NZ to present to the EAG.