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 (Ministry of Health), Bryan Simpson (New Zealand Formulary), Janet Mackay (PHARMAC), Joanne Beachman (New Zealand Private Surgical Hospitals Association), Michael Tatley (New Zealand Pharmacovigilance Centre), 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

The meeting commenced at 9.35 am.

Introduction and matters arising from previous meeting

1 Welcome, apologies

Sandra opened the meeting with a karakia. Apologies were noted. Sandra welcomed Margaret Hand, Māori nurse practitioner who is joining the EAG and Dr Brendan Ng who is attending as a guest and may join as clinical lead. For the benefit of new members, the group introduced themselves.

Charlie Charters has left his role at the Ministry of Health. Rommel Anthony is his replacement and will be approached and invited to the next meeting.

2 Declarations of interest

The group were reminded to raise any conflicts during today's meeting or let Billy or Sandra know of any new relevant conflicts of interest to be recorded.

3 Minutes from previous meeting May 2019

The minutes were confirmed as an accurate record.

4 Review of actions list

190501 Anticoagulants

See item 14. Peter noted that ACC would like to be involved in the working group.

190502 Health and Disability Commissioner (HDC) report on medication errors – summary of key messages
Complete.

190503 National Medication Chart review
See item 10.

190504 Data and digital updates
Complete. Shayne Hunter, Ministry of Health, has been invited to the EAG meeting on 26 February 2020. For information, Billy tabled the formal response from Shayne regarding SNOMED CT and READ code decommissioning. The date by which this to be completed is unknown. There were no further comments or discussion.

190506 National medical warnings
This has been discussed with the Ministry's identity and eligibility, national digital services team. Survey questions have been drafted and will be distributed via an electronic platform through district health board (DHB) quality and risk managers.

190507 and 190508 Patient transfers to aged residential care facilities
In progress. A questionnaire has been drafted to survey DHBs to ascertain current practice, challenges, and examples of solutions for medication management when patient care is transferred.

190201 Medicine alert groupings
Chris James will be asked to provide an update by email, or at the next meeting.

190206 Application to PHARMAC for a range of funded oral syringes for administration of oral liquid medicines
See item 17.

180501 Alert 17 Alteplase and Tenecteplase
One DHB hospital has not sent their completed action plan. It was agreed to remove the item as this is not going to progress.

5 Review of terms of reference (paper)

Sandra tabled the draft terms of reference (ToR) which incorporates feedback from the last EAG meeting and from internal review at the Commission. Sandra presented a summary of the purpose and intent of the ToR:

- key role of shining the light on medication safety issues as they emerge and responding to trends and challenges relating to medication safety and health equity
- work across the sector at both a strategic and operational level
- be available, responsible and accountable to the sector and the Commission

- collaborate as a group and establish links across networks with an interest in medication safety.

Sandra asked the EAG whether the ToR accurately conveyed their understanding of the purpose, focus, scope and authority, noting in particular the invitation for the ex-officio representatives to be full members of the EAG.

The ToR explicitly requests the demonstration of network links by the consumer and Māori representative members, and by inference does not expect the same of all members. The EAG agreed that it should be expected of all members to demonstrate their network links, be proactive in engaging with these networks, and demonstrate their commitment to consumers and equity for Māori.

The EAG discussed the status and responsibilities of being an ex-officio or full member and their ability to contribute to discussions and decision-making. Most of the ex-officio representatives and a number of the members, felt it was essential to retain the ex-officio status. This enables them to maintain independence and the ability to represent the stance of a stakeholder agency while still participating actively at all levels in the EAG.

An online definition of 'ex-officio members' specifies that the term denotes only how one becomes a member of a body (by virtue of holding another office). Unless specifically stated in regulations or bylaws, the rights of an ex-officio member are the same as other members. It was suggested that it could be thus defined in the ToR and ex-officio representatives given the same rights as other members without losing their independence or the status of representing an organisation.

Sandra thanked everyone for the feedback and the EAG asked the medication safety team to further refine the ToR to:

- clearly include all members' roles in the membership list
- strengthen the focus on equity
- include engagement with consumer and Māori representatives in working groups
- define the process of decision making / voting and related membership distinction
- define the membership rights as being for both members and ex-officio members.

Action: The Commission medication safety team to revise and circulate the ToR.

6 HDC decision in case 17HDC00191

In this decision, the HDC recommends 'that PHARMAC, Medsafe and the Health Quality & Safety Commission incorporate adequate education to the sector with the launch of new drugs that have both the potential for significant hazard and the potential for very widespread use by non-specialists'. Billy asked for comment on whether this was the responsibility of the EAG and, if so, what the approach should be.

The EAG discussed whether potential harm can be anticipated, depending on the completeness and availability of information for a new medicine. Potentially, there is some

ability for the agencies referred to in the HDC recommendation to provide guidance that focuses on the safe introduction and use of new medicines, in the form of:

- clinical stewardship and / or a latent risk assessment tool to be utilised by PHARMAC (or other relevant committees) in the decision-making process.
  - ACC would be keen to be involved.
  - the EAG could ask PHARMAC to work on their behalf to provide a tool for stewardship.
  - the tool would not stop decisions from being made, but would identify potential risks in terms of the decision and the required risk mitigation strategies.

The role or potential role of a committee to review new medicines and decide which might need further information or risk assessment. However, on discussion it was identified that there are too many new medicines to review and consider in a timely way and a medicine funding application to PHARMAC does not provide clarity on if, or when, a medicine may be funded. It was agreed that the role and responsibilities for medicines regulation and funding are already defined elsewhere and the EAG does not have the mandate to get involved.

Clarification was sought on the current process to reduce potential harm when introducing a new medication. Janet summarised the activities PHARMAC often undertakes to support the funding of a new medicine and reflected on the circumstances of the funding of dabigatran (which was the subject of the HDC case). She noted that PHARMAC have decided not to respond to the HDC but agreed they would be willing to discuss incorporating a tool that could provide risk assessment when there are sentinel medicines being considered for funding.

In terms of incorporating ‘adequate education to the sector’ it was felt that education alone is inadequate, or not particularly effective in mitigating risk or changing behaviour when there is a new high alert medicine. Information is available, but accessibility, dissemination and uptake are ongoing issues.

NZ Formulary is available as a repository of information and Bryan commented that they see significant increases in website traffic when a new medicine is released. They liaise with PHARMAC, Medsafe and the Medicines Adverse Reactions Committee (MARC) to ensure they have the best knowledge and safety information available to the sector. A mechanism to alert prescribers and administrators, for example electronically, would be preferable; however, a large amount of prescribing is still manual; this is part of the wider issue of limited use of and investment in electronic prescribing.

The EAG agreed the agencies specified will meet with ACC and the Ministry to clarify the current process for implementation of new medicines and to define responsibilities, relationships between the agencies, and potential risk identification and mitigation.

Action: The Commission medication safety team to coordinate a meeting between agencies to discuss further.

7 Gabapentinoids (pregabalin and gabapentin)

Billy tabled an email forwarded to him by the Medsafe pharmacovigilance team in relation to concerns with the risks of gabapentinoids and their increased use. These concerns have led to them being reclassified as controlled drugs in the United Kingdom and there is growing evidence in New Zealand of patient harm, misuse and interactions with other medicines. The email asks that the safety and effectiveness of these medicines be reviewed, discussed by MARC and a Medsafe alert applied. The EAG was asked for comment.

There is awareness of these issues relating to the use of pregabalin and gabapentin. The EAG discussed:

- re-classification as controlled drugs
- processes and costs of putting them into DHB's monitored medicines category
- difficulties in oversight, particularly in the private sector
- variations in guidelines and prescribing practices
- effectiveness as pain relief
- management by, and access to, acute and chronic pain services
- other education and resources for consumers
- an 'analgesic' stewardship programme, which could encompass gabapentinoids as well as opioids.

The EAG noted that further consideration is needed following investigation of the response or actions by Medsafe and MARC.

Action: Billy to contact Medsafe and MARC and investigate their response.

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 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 inform consumers and consider 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 of New Zealand or the Pharmaceutical Society of New Zealand
- 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 included:

- 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 across the 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 foetal anticonvulsant syndrome being classified as an ordinary consequence of treatment. Peter thanked Billy for his work on the paper and asked if he can share it with FACSNZ.

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. FACSNZ 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 FACSNZ to present to the EAG.

9 National Medication Chart review

Billy presented a mock-up of the chart with the proposed changes. The most significant change is the placement of the allergies section inside the chart rather than on the front cover. This is so it is visible to prescribers, administrators and pharmacists when prescribing, administering or reviewing prescribed medicines.

The movement of the allergies section was considered useful. The title of the section was debated and it was decided it would remain as is; the term ‘allergies’ can mean both medication and food-related allergies and it is important to have both. The size of the section has decreased and the EAG suggested the size be increased and the section split into two columns. This could be achieved by moving the non-administration codes or recommended administration times to the front page.

The EAG agreed that the change was not significant enough to require a pilot of the revised chart. DHBs will receive feedback with a summary of the suggested changes, including those that have been incorporated into the revised chart and those that weren’t and the reasoning for the decisions.

10 Terlipressin salt vs base strength description

Rob had been contacted by David Mitchell, NZULM, with a concern that a new supplier has applied to register and market a terlipressin product described as 0.85 mg strength (base) which is identical to the current version on the market that is described as 1 mg strength (acetate).

Prescribing and dosing issues occurred in 2014 when a terlipressin product had a packaging change that described it as 0.85 mg strength (base). There was push back from the medication safety community who worked with the local sponsor and Medsafe to have the packaging returned to the 1 mg strength description.

It was discussed whether consistency with the international market or standards should dictate the New Zealand market. Consistency is important but this is less of an issue with new products. The concern is when a supplier is retrospectively applying a variant strength description to a well-established and known medicine.

Rob presented this item for noting only, to make the EAG aware that issues with this type of product could potentially recur. The current steps for application and supply of a new product include NZULM and NZ Formulary so there are opportunities to identify similar issues but there are some gaps in the process.

Rob has contacted Medsafe and will contact them again as no response or decision has been received regarding this new terlipressin product.

Action: Rob to contact Medsafe for an update or response to the terlipressin concerns.

11 NZePS update (paper)

In the absence of a representative from the Ministry's medicines management digital services team, Billy tabled a paper providing an update on New Zealand ePrescription Service (NZePS) use in general practice and community pharmacy. The paper was for information and discussion.

Overall, rollout and usage of the NZePS is slow and is slowing progress of other medication safety initiatives. Funding for systems updates to integrate with NZePS is still a barrier for most providers. Orion has been approached and they indicated that it is a big piece of work that is planned but is not a high priority. Orion would like providers to transition to their new product; however, there hasn't been any assurance that NZePS has been considered as part of this transition.

The EAG discussed formally providing recommendations to the Ministry of the value of NZePS, particularly in terms of patient safety. The EAG could ask the Ministry to use their influence to find out why this isn't a priority, guide vendors via their contracting processes and set standards and expectations.

<u>New universal frontline mental health service</u>

Taimi informed the EAG that a new universal frontline mental health service is being established, which is expected to help 325,000 people with mild to moderate mental health and addiction needs by 2023/24. A request for proposal (RFP) is being developed. Taimi suggested that the RFP process could be used to make medication safety a priority, by including reference in the demonstration of requirements for the provision of services.

The EAG thought that was a good idea. The medication safety team will send a letter to the Ministry to ask that RFPs include a commitment to the appropriate and safe use of medicines, and tenders for the provision of services demonstrate this commitment.

RFP documentation is already underway, so communication to the Ministry needs to be prompt. Andi asked the EAG to send the letter to her and she would disseminate promptly as appropriate.

Action: Billy to draft a letter to the Ministry regarding their RFP documentation.
Action: Andi to disseminate the letter regarding RFP documentation.

12 Tall Man lettering list review

Billy tabled the draft ToR for a working group for the review of Tall Man lettering. He asked for the EAG to indicate interest in remaining on, or joining, the working group. Billy also sought recommendations of members:

- Lucy (in her absence) as a nurse representative could replace Sandra
- Rob agreed to remain on the working group
- Bryan expressed interest if needed.

Action: Billy to contact the other former working group members to confirm their involvement.

13 Anticoagulants

Billy tabled the proposed draft ToR for the anticoagulants working group for discussion, and a driver diagram for reference and illustration. Billy asked the EAG to comment on the proposed inclusion of antiplatelets: it was agreed that they should be included. The EAG suggested representation of the following on the working group:

- quality and risk manager (existing member)
- clinical pharmacologist
- primary, secondary and tertiary hospital pharmacists
- a general practitioner, to cover the hospital-to-home transition and ongoing care
- ACC
- a haematologist with a specialist interest / nomination from the Haematology Society of Australia and New Zealand or Australasian Society of Thrombosis and Haemostasis
- VTE or haemostasis specialist nurse.

14 Opioid stewardship

The literature review paper by Doris Chan (pharmacy undergraduate) was tabled alongside the proposed ToR and driver diagram for the opioid stewardship working group. Billy noted this work will not start immediately given the current workload but invited comment on the proposed papers and the membership list. The EAG suggested representation of the following on the working group:

- prescribers from public and private sector including junior doctors and anaesthetists or surgeons who undertake prescribing in private hospitals
- anaesthetics or pain specialist
- general physician
- addiction specialist
- consumer representative from the addiction sector
- Andi (Ministry of Health) indicated interest
- representation from the New Zealand Orthopaedic Association as orthopaedic services are regular prescribers of opioids
- general practitioner or psychiatrist/general practitioner
- pain service (either acute or chronic) nurse specialist
- pharmacists.

There was discussion about whether gabapentin, pregabalin, or any medicine with abuse/addiction potential, should be included in this work. No conclusion was reached.

Action: Matt to send the name of a recommended physician to Billy.

15 Transdermal patch alert update

For information only, Billy tabled two alerts: individual and organisational. This is an update to the Commission's existing alerts, to include placing the patch on an inaccessible area of the body for cognitively impaired patients, to prevent inappropriate removal of the patch by the patient. The update is in response to an event where a patient removed and ingested their fentanyl patch.

The NZ Formulary now include this information and the My Medicines team are considering adding a similar statement to their patient medicines information leaflets.

Billy also tabled an updated list of medicines available as patches in New Zealand. The EAG agreed this was useful and thanked Billy.

16 Oral syringes funding application

A letter to the general managers planning and funding (P&F) has been finalised and will be sent to Caroline Gullery (general manager P&F, Canterbury DHB) for critique and peer review. The letter asks if the managers agree, in principle, that oral syringes should be funded and then ways to work up a model for purchase and distribution. It was suggested that funding should be based on a clinical decision; Billy noted the application refers to anyone that needs an oral syringe.

17 Compounding working group

The compounding working group published 32 new and updated standard New Zealand formulations for compounding by pharmacists. This update is to inform the EAG that the working group will be re-activated in the coming weeks to look at other medicines suggested by the sector.

18 Meeting dates for 2020

26 February
27 May
26 August
25 November

Dates taken as read. No discussion held.

Meeting closed at 2:20pm with a karakia from Margaret.