Minutes of the meeting of the Medication Safety Expert Advisory Group (EAG) held on 30 August 2017, at PHARMAC Office, Wellington

Present:	Alan Davis (Chair), Matt Doogue, John Barnard (via teleconference), Avril Lee, Lucy McLaren, Nelson Aguirre, Rob Ticehurst, Bev Nicolls, Gareth Frew.
Invited ex officio:	Andi Shirtcliffe (MoH) until 12p.m, Desiree Kunac (NZPhVC), Chris James (Medsafe), Janet Mackay (PHARMAC)
In attendance:	Carmela Petagna, Billy Allan, Charmaine Pene (minutes)
Guests:	Maria Vidovich (HQSC), Sarah Upston, (HQSC), Phyllida Duncan (Medicines NZ), Greg Williams (PHARMAC), Te Rina Ruru (observer)
Apologies:	David Woods, Sandra Fielding, Charlie Charters, Beryl Wilkinson

The meeting commenced at 9.36 am.

1. Welcome, apologies and declaration of interest

Alan Davis welcomed everyone to the meeting and thanked PHARMAC for hosting the day's meeting. Apologies were noted.

There were no changes to the members' declarations of interest.

2. Acknowledgements

The chair, Alan Davis welcomed Te Rina Ruru who is attending as an observer.

Te Rina gave a mihi and shared her story as a sibling with a brother who suffered a severe brain injury when she was a teenager and how she took on the role of full-time carer at the age of 14yrs. She later went on to complete two degrees as well as establishing the NZ Brain Injury Support network. Having experienced herself the effect of a sibling with a brain injury, her current focus is helping young people who have a whānau member suffering a brain injury, and the impact it has on their own wellbeing.
Around the table introductions were carried out.

3. Patient Story

Alan provided the consumer story relating to an elderly man admitted to hospital with a bronchial infection and was not responding to antibiotics - doxycycline. The patient was then prescribed ciprofloxacin. After a severe adverse reaction (toxic epidermal necrolysis, TEN), it was found that the patient had a documented allergy to ciprofloxacin.

When investigated, the hospital found it had a number of interventions in place e.g. medicine reconciliation on admission that highlighted allergies, the patient's health record was up to date, the allergy was documented on the medication chart, the patient had MedicAlert bracelet, and policies were up to date.

The investigation identified that

- The prescriber was a junior doctor acting on the instructions of a more senior doctor.

- There was a culture that the 'senior knows best', with a lack of critical thinking. It was acknowledged that the system does not always accept challenges.
- There was a generally a poor understanding of the risk (the previous allergic reaction was also TEN).
- There was an assumption that the prescription was correct and multiple policies/procedures were not followed. For example, laboratory form did not include the allergy and microbiology approval to use ciprofloxacin was not sought.
- The prescriber received oral directions (telephone) from a consultant and as a result the consultant did not see the medication chart nor asked for an allergy status.
- The event occurred during the first day of the doctors strike and the junior doctor had no prior experience / history with the patient and did not read the notes.
- Nursing staff administered the medicine without questioning the allergy status shown on the notes and chart.

It was acknowledged that
- Electronic prescribing is not the full answer, as alerts can be over ridden.
- There is a relaxed attitude to allergy information as it is often not valid or reliable.
- People who raise concerns need to be supported, perhaps with a named 'trusted' senior person to go to.

Recommendations from case included;
- To undertake an allergies campaign to promote awareness
- Staff directly involved received education / training
- The Patient story to be shared

4. Minutes of 08 March 2016 meeting.

The minutes were confirmed as a true and accurate record.

Moved: Bev Nicholls Seconded: Lucy McLaren

There was a query relating to para 20, on if the document 'Recommendations for the safe administration of intrathecal chemotherapy and intravenous vinca alkaloids in NZ' has been distributed within the sector?

Andi and Billy explained that:
- The document 'Evaluation of Current Practice for the Administration of Intrathecal Chemotherapy & Intravenous Vinca Alkaloids' was developed by the New Zealand Hospital Pharmacists' Association (NZHPA) and published by Quality and Safe Use of Medicines (SQM) in 2007.
- The NZHPA is currently updating the guidance – it is still in early draft.
- The review to date has been confined to pharmacists at the major cancer centres.
- There are some aspects that the review group require wider input on - there are quite varying opinions on some of these.
- There is acknowledgement that there needs to be engagement with the broader 'oncology' community in the guidance review.
- NZHPA is engaging with the cancer team at the MoH to see how best to take this forward, and where this might sit within the Ministry's priorities to inform where we go next with the guidance review.
- Final sign off will be through the NZHPA Executive and the Commission (MSEAG).

5. Action list update (see also Appendix 1; separate document)

6. Serious Adverse Events – policy update (Sarah Upston, Specialist, Adverse Events Learning Programme, HQSC)

Sarah noted it was the first catch up since the policy has been published. She noted that she had spoken to the members in November 2016 when the policy was draft and invited the member's feedback. The key changes to the policies were;

- Increase in consumer focus
- Stronger emphasis on governance
- Flexibility in review methods
- Introduction of 'Always report and review' list

The policy should be read in conjunction with the guidance document and resources. The policy and resources will be reviewed periodically and updated. The members were invited to consider what medicine harm they want to include on the always report and review list.

Action: To support the members in this, Billy is to circulate the always report medicine event lists from other jurisdictions.

Action: To be discussed at the November EAG meeting.

Discussion noted the potential duplication in reporting between the Commission's serious adverse events, CARM and MERP. This had been acknowledged by the programme team and Billy advised that he and Sarah share information between them on medications adverse events.

It was also noted that while an event is notified in Part A (within 15 working days from the event date), there is not always the closing of the loop with the completion of Part B (which is the summary findings and should be submitted within 70 working days of an event) should the event be subsequently withdrawn or downgraded from a SAC 1 or 2 event. Also the severity code in Part A may change upon further analysis in Part B.

In addition, it was noted that definition of a 'near miss' in the policy was inconsistent with the international definition applied to medicine events. This feedback had also been provided during the Serious Adverse Events policy review.

Action: Rob Ticehurst to send to Sarah, via Billy, further feedback on the definition of a 'near miss' for consideration at the next policy review.

7. MERP (Desiree Kunac)

The MERP report for quarter 2 (1 April to 30 June), 2017 had been circulated with the agenda. MSEAG discussed several events.

The members discussed a potential for harm event due to two different strengths of levothyroxine oral suspension being in use (NZ standardised formulation 25microgram/mL and 15microgram/mL). EAG agreed that this issue should be signalled wider within the sector. The Compounding Advisory Group are aware of the issue and are working to resolve it.

It was noted that if the NZePS was fully functional that this would then support the ability for the sector to extract and analyse community dispensing data (to ascertain what strength of levothyroxine suspension are being prescribed and dispensed). The group agreed that the requirement for the NZePS data to be available for analysis, and the need for clear governance and leadership be raised at the senior executive level within the MoH. The members therefore, agreed that a letter on behalf of the EAG be sent to Director General, Chai Chua, highlighting the requirement for NZePS data to be made available.

Postscript Carmela subsequently spoke with Medicines Management Digital Services national product manager, Charlie Charters, who advised that this is being considered as part of the broader approach being taken on the eMedicines programme, the risks / lost opportunities, and NZePS is a crucial part of this approach. Charlie advised that MSEAG should not take any action at this time, pending updates on issues from MoH.

An event of serious harm with co-prescribing of warfarin and aspirin in a high risk patient. It was noted that this medicine combination is highlighted in the Commission's Atlas of Healthcare Variation polypharmacy domain, with a four-fold variation in prescribing across New Zealand. The Atlas is being updated. It was agreed that the Commission (health intelligence) be invited to the next EAG to provide an update on the Atlas polypharmacy domain update.

Action: The Secretariat to send an invitation to the health intelligence hub to attend the next EAG to provide an update on the Atlas polypharmacy domain.

Another potential for harm event was discussed, where look-alike sound-alike name confusion contributed to ciclosporin being dispensed when cyclophosphamide was prescribed. It was noted that MERP had received 5 other similar reports, and that the Pharmacy Council has been advised.

The MERP report highlighted a cluster of events with Vitadol C. These related to the dose being delivered as 'drops' rather than 'mL'. Vitadol C is supplied with a dropper, not an oral syringe, and oral syringes are not funded. The chair suggested that a working group be established, or support be provided to an existing organisation, to review the delivery devices available for liquid paediatric does administration. Item to be discussed at next EAG (under working groups).

Action: To discuss the need for a liquid medicine delivery device working group at the next EAG.

In the meantime, MERP to write to Karicare (the manufacturer of Vitadol C) to see if they can change to a more appropriate dosing device such as an oral syringe, or add a dose mark to the dropper.

Action: MERP – Desiree Kunac, agreed to write to Karicare on the error.

The chair acknowledged the receipt of a letter of response from Novo Nordisk dated 28 August 2017 and their comprehensive reply to the issues raised with them on safety concerns regarding NovoRapid FlexPen and NovoMix-30 FlexPen. Four of the five changes proposed by MERP and PDA (Pharmacy Defence Association) had been accepted by Novo Nordisk. However, Novo Nordisk are not considering a name change for their insulins.

The HDC has made adverse comment on dispensing errors resulting from confusion over look-alike sound-alike insulin names. It was agreed that the Secretariat, with MERP and the PDA (should they wish to participate), should write to the HDC explaining the favourable results of this systems approach to reducing dispensing errors and patient harm.

Action: MERP and the PDA (should they wish to participate), to write to the HDC.

8. Medicines New Zealand (Phyllida Duncan – Technical Advisor)

Phyllida Duncan addressed the EAG on behalf of Medicines NZ CEO – Graeme Jarvis. Phyllida provided an overview of the organisation. The voluntary organisation represents an industry of private companies who are engaged in research, development, manufacture and

marketing of prescription medicines. Their aim is to demonstrate the value of medicines in the healthcare system and ensure optimal access to innovative medicines with a focus on pharmaceuticals innovation. The organisation position's itself as a partner in the health sector in maintaining good health of all New Zealanders.

The members discussed the issue of labelling and getting standardisation on certain products. Phyllida, advised that the majority of their member companies are international and therefore New Zealand is a small part of a global supply chain and where any change New Zealand may require has to fit with the company's overall market stakeholders. This also means that decision-making can take time as any labelling recommendations from New Zealand have to be escalated from the local office to the international headquarters. The member companies follow international best practice guidelines, such as those of the Medicines and Healthcare Products Regulatory Agency (MHRA; UK) and Therapeutic Goods Administration (TGA, Australia). The companies individually report any adverse events through CARM.

Phyllida observed the plethora of online pharmacies and counterfeit medicines on the global market. Phyllida noted the WHO estimates 50% of medicines for sale online are fake with an annual death toll of one million.

Medicines NZ have undertaken collaborative information-sharing workshops with key stakeholders such as MoH, PHARMAC, and Medsafe. Phyllida advised that if there are any product specific issues to talk directly with the company concerned (and Medsafe).

Medicines NZ gave an open invite to contribute to their newsletter. The Secretariat to contact Medicines NZ on potential newsletter topics.

Action: The Secretariat to forward information on Patient Safety Week and the Dr. Mike Hamilton workshop series for possible inclusion in a Medicines NZ newsletter.

The chair thanked Phyllida for coming to speak to the group.

9. PHARMAC (Greg Williams, Manager Procurement and Contracts and Janet Mackay, Manager Implementation Programme)**.**

PHARMAC discussed their annual tendering process to supply products. They advised that suppliers must be registered in New Zealand. They confirmed that there is a transition process when moving from one like product to another.

New listings come from funding proposals from a variety of sources e.g. suppliers, clinicians, clinical groups and patient groups.

Requests for proposals (RFPs) are conducted for potential products.

Greg invited the EAG to inform PHARMAC of products that do cause issues, so they can note it particularly when they undertake the tendering process. Safety issues are also considered by one of PHARMAC's subcommittees (Tender Medical Evaluation Subcommittee).

The Chair thanked Janet and Greg for their presentation to the EAG.

10. Patient Safety Week (PSW) Update: November 5-11 November 2017 (Marija Vidovich, Communications team, HQSC)

The theme of patient safety week 2017 is 'Let's Talk Medicines'. The members were given a presentation showing the resources for Patient Safety Week which are available online for ordering. The resources are free (funded by ACC and the Commission). Marija noted that

the resources had been consulted on. The target audiences included Māori, Pasifika, and Chinese population groups. There is also 'branded' paper bags for pharmacies to put a consumer's medicines into.
The members provided positive feedback and hoped the representational cartoon figures showing female/male, young adult/adult versions of a clinician and consumer would continue to be used in the long-term.
Marija advised that emails had gone out to the sector and on the website about the resources as well as via stakeholder networks e.g. Pharmacy Guild, Practice Managers Network.
The Chair thanked Marija for their speaking to the EAG

11. International Speaker – Michael Hamilton (Billy Allan, Medication Safety Specialist)
Billy provided an update on the regional workshops to be held in Auckland, Hamilton, Wellington and Dunedin over the period 30 October – 03 November 2017. Registrations are now live on the Commission's website and emails sent to key stakeholder groups.

It was noted that the workshops linked into the WHO Global Challenge and are titled 'Medication without harm - how will New Zealand rise to the challenge?'

It was noted that the WHO Geneva Office had only one dedicated staff working on the global challenge and despite enquiries there doesn't seem to be a designated member in New Zealand spearheading the challenge here. Alan noted the key themes for the global challenge being; transitions of care, polypharmacy and high harm medicines which fits with the medication safety programme of the Commission.

12. Safe use of opioids update (Avril Lee, Clinical Lead)
Avril, advised of a recent internal team workshop held in August which was attended by Mary Seddon for expert advice. Mary was a co-author of a recent high harm medicines paper published in the NZMJ that reviewed DHBs data collected using the adverse drug reactions (ADE) trigger tool. The findings supported that opioids remains one of the highest area of harm in hospitals.

Avril, noted that the workshop, was a discussion on taking the information we have from the collaborative and from the recently released paper and going back to the drawing board on what is the most appropriate measure to use in hospitals to reduce opioid related harm. A toolkit (change package) is being worked up by the medication safety specialist advisor which will be consulted on within the sector.

There has been proactive engagement with a number of DHBs to encourage using the bundles from the How-to Guide. With the change package being developed incorporating, the OIC and OIVI bundles and aspects of the adverse drug event (ADE) trigger tool it is intended that this change package be piloted with willing DHBs.

A second workshop will be held (the next day) in August to progress the discussion on a potential quality safety marker (QSM).

And finally, Avril said that the programme is also interested in engaging with DHBs who are looking at opioids prescribed on discharge.

13. Programme update

13.1 **ACC update** – Carmela Petagna. The programme team has had a meeting with Peter Jansen and Dee Young from ACC on their medication harm numbers and have since been provided a treatment injury report. ACC noted that medicines related

events are small compared with overall harm claims. Carmela said that there is an opportunity to work with ACC on providing education to health professional on submitting claims as it was noted by ACC that approximately half the claims submitted are declined. There is also potential to work with ACC on allergies and drug reactions and the programme is keen to continue to talk and engage with ACC on these matters. She noted that ACC were sponsors of Patient Safety Week and have a speaker session on the four regional workshops featuring Michael Hamilton.

13.2 **eMR definitions workshop** – Billy Allan. The workshop was held 21 July 2017 and focussed on refining the definitions. Discussion was also held on possibly introducing manual as well as electronic markers. Gareth expressed interest in this tool being transferable to a new software – MedMan. However, eMR is not available in its current form and discussion is occurring with Orion (vendor). It was also noted that MedMan is not suitable in its current form for hospital use.

13.3 **Medication safety regional workshops** – Allan Davis. The workshops were a series of discussion with those working on the coalface on the issues around medication safety practice and systems. Alan noted that there is strong feedback that the sector would like these workshops to continue. He also noted that the sector wanted a Quality Safety Marker for opioids. The workshops also identified leadership potential for future engagement and capacity building.

The Northern regional medication safety working group has been reinstated and have a meeting scheduled 5 September 2017 which Alan would be attending as the Northland DHB representative. He also noted that there is representation from both secondary and primary organisations.

13.4 **Aged Residential Care** – Billy Allan. Phase two testing of the hybrid chart is now complete. The recommendations from this testing are being progressed in discussion with Toniq. Once finalised the chart with a training guide is to be distributed to the aged care sector supported by HealthCERT, MoH. While it is noted that a significant number of residential facilities are moving to an electronic chart there is still value in releasing the resource for those small facilities that chose to continue to use a manual charting system.

14. Northern Region Adverse Drug Reactions and allergies (Rob Ticehurst).

Rob Ticehurst chair's the group and he provided an update to the EAG. ADR and allergies is a longstanding problem across the country and where there is minimal sharing and no standardised reporting system. The region has been waiting on an update to the national medical warning system (NMWS) but this has not eventuated. However, there remains a desire by the Northern Region to continue with a regional effort to standardise ADR and allergy early warning reporting. Their work may provide the proof of concept for the rest of the country. Rob showed an example electronic reporting form. Concerto upgrade will facilitate sharing and this is an opportunity. Overarching principles include:

- standards based e.g. NZULM, SNOMED CT
- HL7/FHIR for data messaging
- keep it simple
- single national repository.

Next steps, the development of a Concerto reporting form - finalise October 2017 and discussions with MoH and vendors.

A question was asked if it was the role of the EAG to advise on the content of what an ADR warning system should have? Chris James said it needs to be clear that it is an adverse drug reaction warning system as there were other systems in the sector for reporting.

Carmela suggested an EAG working group to support and inform this work, including advising on the content of the reporting form. It was agreed that an EAG working group on ADR and allergies be formed with Rob Ticehurst as lead.

Action: Rob Ticehurst to advise on working group members; to establish the working group.

Desiree Kunac left the meeting 3pm

15. Working Groups update (Carmela Petagna)

Carmela confirmed that the changes from the last EAG have been incorporated into the document. She noted that groups maybe inactive until such time as an associated action occur e.g. the national medication chart review, the working group will be activated when the review is to take place.

It was noted that a Compounding Advisory Group (CAG) session was held 11 August 2017, which was led by Dave Woods and facilitated by the Commission. There was a question as to who is on this group as no other EAG members attended.

Action: Secretariat to follow up with Dave Wood.

It was suggested that a working group for the ULM be established to advise on NZULM technical operational issues (such as displaying 'form' descriptors in more appropriate English). It was agreed that the group would consist of Matt Doogue and Rob Ticehurst from EAG, with Billy Allan, and David Mitchell (NZULM).

Action: Carmela Petagna to update the working groups list.

16. HDC and Coroner's Adverse Events Reports (Billy Allan)

It was agreed by the members that these reports be circulated for information only (as many received these reports through their networks or workplace) and therefore did not need to be an agenda item in future.

The members did not consider any further action was required.

17. Other business: The November EAG location is confirmed as Auckland.

Next meeting: 29 November 2017, Novotel Auckland Airport, Auckland.

The meeting closed at 3.35 pm.