Minutes of the meeting of
Medication Safety Expert Advisory Group
(MSEAG) on 30 May 2018

Location	Novotel AUCKLAND
EAG Members	Alan Davis (Chair), Sandra Fielding (Deputy chair), Bev Nicholls, Beryl Wilkinson, Dave Woods, Gareth Frew, Lucy McLaren, Matt Doogue, Rob Ticehurst
Ex officio	Andi Shirtcliffe Ministry of Health, Bryan Simpson NZF, Chris James Medsafe, Desiree Kunac MERP NZPhVC, Janet Mackay PHARMAC, Peter Jansen ACC
Commission staff in attendance	Carmela Petagna, Charlie Charters, Billy Allan, Dee Alexander
Apologies	Avril Lee, Nicolette McDonald, Shelley Pakoti, Te Rina Ruru

Meeting commenced 9.32 am

1 Welcome, apologies and declarations of interest

Alan welcomed everyone to the day and Bryan to his first meeting as ex-officio member.

It was noted this will be Carmela's final meeting following an internal restructure at the Commission and establishment of a new Patient Safety Team. Carmela is now Senior Portfolio Manager for the Community Improvement Team. Carmela's leadership of the medication safety programme has shaped the programme, built strong networks and enabled many successful achievements over the past seven years.

It was noted the recent MERP project to secure sustainable funding and governance has not at this stage identified funding beyond 30 June 2018 therefore this may be the last meeting MERP exists. The huge contribution MERP has made to the MSEAG was acknowledged and Des was thanked for her valuable input.

Apologies and declarations of interest were noted.

2 Minutes from previous meeting 28 February 2018

Minutes were confirmed as an accurate record.
Moved by Gareth Frew and seconded by Lucy McLaren.

3 Actions review from previous meeting 28 February 2018

<u>180205 Alert17 Alteplase and tenecteplase.</u>

There are still seven DHBs to confirm completion of the Alert action plan. It is a patient safety matter to ensure mitigation actions from the action plan are implemented across the sector.

Action 180501 Follow up stroke network

<u>180204 Always report and review (ARR) events.</u>

The new adverse events policy includes several always report and review events as a subset of preventable serious adverse events. Previous discussions have explored the possibility of a medication safety event. Should the event be a cross sector event and include events in primary

care rather than focused on secondary care events? There must be an infrastructure in place, an ARR event should never happen.

Potential events were discussed. One suggestion is the administration of a drug to a patient with a known allergy, however there are no forcing mechanisms in place to prevent this happening. Another suggestion is a dispensing error (for example wrong patient), however there is not a consistent system in place to prevent this either. Dosing errors with Methotrexate are still occurring so another possibility is to focus on high alert medicines (eg methotrexate, potassium). Agreement was not reached on a specific ARR event.

The group agreed discussions would continue, and a meeting will be arranged with ACC to explore events involving errors leading to claims and high risk medicines.

Action 180502 Medication safety specialist to arrange a meeting with ACC

<u>180203 Medicines alert groupings</u>

MSEAG requested feedback from a recent NZF meeting regarding the future governance of the alert groupings work. The MSEAG was advised funding is an issue and a business case is in process with a proposal being developed by bpacNZ. It will need close alignment with NZULM, and there are many technical aspects including HISO standards.

Action 180503 MSEAG chair to write to Stewart Jessamine, Director Protection, Regulation and Assurance, Ministry of Health and ask for an update

<u>171102 Liquid medicine dose measuring devices</u>

The application has been submitted to PHARMAC. It doesn't fit into any clear therapeutic group but may link to negotiations around medical devices and is currently being followed up. This is linked to action 170807 the communication with Karicare re medication error relating to Vitadol C.

<u>161123 REX inhalers</u>

The MERP and MSEAG wrote to REX Medical expressing safety concerns over the presentation and confusing similarity of the REX family of inhalers. REX have responded and have changed the label. This is now going through the Medsafe approval process.

It would not be possible to achieve standardisation of all reliever inhalers to the colour blue, because of the combined reliever/preventer preparations now available. Patient education needs to emphasise the type of inhaler rather than the colour. Different colour caps are an issue because caps become lost and can be interchanged between different inhalers. Cap design is more important than cap colour. It is also difficult to change products once in the market.

The group discussed whether there needs to be anything extra in the PHARMAC labelling preferences in relation to inhalers. PHARMAC's labelling preferences relate to products being considered for funding as part of the Annual Tender, but there are wider issues influenced by legislation (all products must meet the legislative requirements). The New Zealand legislation is under review and there will be an opportunity for the MSEAG to provide feedback to the consultation on the Exposure Draft of the Therapeutic Products Bill (anticipated in August).

The US Food and Drug Administration and the International Medication Safety Network are meeting in the near future to inform labelling guidelines and this information could be useful to inform New Zealand discussions.

Action 180504 MSEAG to provide feedback on the Exposure Draft of the Therapeutic Products Bill once released

Action 180505 PHARMAC labelling preferences to be circulated for information

4 WHO global patient safety challenge

The circulated matrix was discussed. The matrix summarised the main activities of the agencies with responsibility for medicines in New Zealand – Ministry of Health, Medsafe, PHARMAC, ACC and the Commission. There are four domains with broad range of activities identified cross agency. Nothing new is being planned at this stage, activities largely represent business as usual.

In order to document a fifty percent reduction in preventable harm from medicines in New Zealand there will need to be a baseline, but there is no mechanism for measuring or establishing a baseline at present. There is a risk of New Zealand not being able to respond to the WHO global patient safety challenge if MERP ceases to exist and there are no national consistent data collected on medication error.

The WHO global challenge is an opportunity to raise the profile of medication safety in New Zealand. There is now a representative on the WHO global health network and there needs to be ongoing discussion of contributions and actions from New Zealand.

5 National project mapping repository

The proposal to set up a national project mapping repository was discussed. This would be a great opportunity to share knowledge around who is working on what, provide a central database of medication safety initiatives, and potentially become a place to find knowledge and quality improvement tools.

A role of the Commission is to add value by facilitating the sharing of initiatives, and connecting interested parties together across medication safety networks. The repository would be a central place to share activities, knowledge, research and projects occurring across New Zealand in the area of medication safety. It could be helpful for the network to have a repository to pool resources, share expertise and work on projects together where possible to increase research numbers. It would provide visibility of individual projects to see current work in medication safety, and increase possibilities for collaboration.

A similar repository is in use in Australia, the quality use of medicines mapping project. This has been useful when initiating projects to see if another group is working on the same or similar topic and to inform project design and collaboration.

If a national repository is not progressed what would the alternative be for New Zealand medication safety networks, and how would different centres or groups learn what is happening or what work has been completed? Greater sharing of projects and initiatives between twenty DHB there could bring immediate value, however many projects and ideas have an even wider value, extending broadly across sector groups. Options include either an informal exchange of information or a more formal database produced in a sharable format.

The NZPhvC operates a NZ Medication Safety email network that links medication safety champions from across primary and secondary care enabling an informal exchange of medication safety issues and information.

There was general agreement there is value in sharing this kind of information, especially between professional groups without natural links. The MSEAG has a role to become aware of work taking place in medication safety and to share this with the health sector.

Action 180506 Med safety team to meet to discuss feasibility

6 Specify brand criteria

Discussion was initiated at the February MSEAG to clarify the current list, process, and how information about medicines to be considered for 'specify-brand' can be shared with HCPs. There is no brand warning in many electronic systems. The 'specify brand' document and process is currently being reviewed into a format suitable for circulating to the sector.

Action 180507 Medication safety specialist to amend document and put forward for publication

7 NZF information to stakeholders

Bryan Simpson provided an explanation of the New Zealand Formulary's (NZF) process for informing stakeholders of changes to the NZF content. This was in response to MSEAG concerns about recent significant changes to the NZFC paracetamol dosing monograph which did not appear to have been widely communicated ie. ideal body weight dosing changed to dosing on actual body weight and a 5g max daily dose, which has since been changed back to 4g.

The NZF has a website list, and an email programme for users. Around ten thousand users per day access NZF and six thousand are signed up to receive email updates. Although an up-to-date list is maintained, there is no current method to identify changes. Risks are involved when old data (which may be used in error) are displayed. A programme is being developed to enable users to look up old versions however the risks need to be identified and managed before this becomes more widely available.

NZF attends stakeholder meetings, publishes articles, builds education into CME for health practitioners, and links with professional bodies and networks. There are technical aspects as well as educational aspects of the information communicated, and NZF would welcome suggestions to further increase visibility and improve processes to inform and update stakeholders.

Providing information to undergraduate and new graduate programmes, and increasing the level of active teaching about NZF to these groups, is an opportunity to improve medication safety education to emerging practitioners. This will be further explored.

8 Funding/availability change of gabapentinoids and safety risks

Pregabalin has recently been funded, and restrictions for gabapentin freed-up. International experience has shown there is significant potential for the misuse of the gabapentinoids. There is a concern similar misuse may occur in New Zealand, with potential safety risks around increased availability. All networks are responsible for raising awareness and informing prescribers of potential risks.

Pegasus Health PHO has recently sent a message to their GPs to increase awareness and ensure monitoring. It was discussed that sharing this message more widely to all PHOs could be useful. PHARMAC will be monitoring the uptake of these products over the next year (at least).

Action 180508 Discuss with health quality intelligence team whether to include the prescribing of the gabapentinoids in the Atlas

Action 180509 Medication safety specialist to distribute the Pegasus message (with their permission) to all PHOs for dissemination to prescribers and pharmacists

9 Widen access to rivaroxaban

From August 2018 the funding restriction will be removed from rivaroxaban. The group noted this is unlikely to cause significant safety issues as the sector now has a greater understanding of the use of novel anticoagulants with the previous funding of dabigatran. Prescribers will need access to accurate prescribing data, including information and alerts on co-prescription with other medicines, and notification these are high risk medicines. A reversal agent is likely to be needed. BpacNZ are planning an article on the clinical use of rivaroxaban.

10 Patient story of informed consent for administering medicines

Sandra Fielding presented "Tell me what this is for" and discussed using motivational interviewing techniques to support medication knowledge. Evidence suggests many patients do not understand their medications. Sandra emphasised the importance of understanding from each patient's perspective what their level of knowledge is, and using OARS (open ended questions, affirmation, reflective listening and summary statements). Providing medication information is a highly collaborative consent process and an interdisciplinary responsibility.

11 Conference update

Sandra Fielding presented highlights from the recent International Forum on Quality and Safety in Healthcare in Amsterdam, and her study tour to the Netherlands. These included advanced bedside technology to improve safety of medicines management, and a keynote from Don Berwick, Institute for Healthcare Improvement discussing the problems still existing in healthcare today despite major efforts in quality improvement over the past decade. How do we focus on the challenges ahead in resourcing the system, developing health services and improving world population health? One of the most important things to remember is - the individual taking responsibility for their own health.

Action 180510 Circulate publications to MSEAG when available

12 Conporto

A pilot programme has been developed by Patients First to look across various electronic health systems including GP, hospital and community pharmacy. If a risk indicator is activated the GP is alerted prior to the appointment. Green Cross Health has been trialling the system and the Commission has been involved in evaluation discussions.

13 Medication error reporting and learning in NZ

The action group for the future of the Medication Error Reporting Programme (MERP) held a final meeting in April 2018.

This time limited action group (which was formed to explore sustainable governance and funding arrangements) has completed the agreed activities. At this stage no sustainable funding solution has been identified for the MERP from 1 July 2018. Affected individual stakeholders and groups may decide to continue discussions or design new projects to address identified gaps, and work may continue on the business case.

The need for and value of an integrated shared no-blame cross-sector system, with standardised national error reporting for the purposes of learning was confirmed. Broad cross sector interest was identified but no single agency was identified willing to take up a funding/governance role.

The risks of the current MERP programme ceasing activities include a continuity risk if the standardised infrastructure to report medication error disappears; a national system risk if the system to detect early warning smoke signals or patterns of error is lost; and a financial risk if the

costs of errors increase or new systems need to be designed. There is also the risk of New Zealand not being able to respond to the WHO global patient safety challenge.

Should funding not be secured by 1 July 2018, and the MERP ceases functioning, transition and closure arrangements will be managed by the NZ Pharmacovigilance Centre, Dunedin.

Future options include further developing the business case, modifying existing reporting systems to include standardised classification based on international WHO classifications (to provide national reporting and learning), designing new systems with international interoperability, and exploring central funding.

There are many benefits of the current MERP system. It has shown significant benefits recognised by healthcare providers, regulators and manufacturers, and has resulted in specific changes to reduce the risk of medication harm for patients. The NZPhVC hosts and maintains the database of events, reviews and analyses reports with findings presented to the Commissions MSEAG for consideration.

Without the MERP there will be a gap for reporting and learning from medication error in New Zealand using internationally standardised classification. This is a national system issue. The opportunity to develop, scale and embed the existing MERP system will be lost, and there will be a system level risk until a new national system is developed.

14 MERP quarterly update

Desiree presented the MERP report for the period 01 October 2017 to 18 May 2018. There were 512 reports received with 157 reports reviewed and logged to the MERP database. Due to limited resource 355 low priority reports are still to be reviewed. Seven high priority reports were highlighted for MSEAG consideration. Those generating discussion included:

<u>Methotrexate and blister packs</u>
Daily dosing of methotrexate instead of weekly due to patient inadvertently taking wrong sequence of tablets from blister pack. It was noted:

- no standardisation for blister packs
- awareness around blister packs needs to be raised
- opportunities for education exist when packs sold to pharmacists and to patients
- patients newly introduced to blister packaging need monitoring and follow up
- special emphasis whenever the pack contains a high alert medicine

The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee is investigating why oral methotrexate dosing errors continue to occur and how to implement preventive measures. New Zealand has contributed to the International Medication Safety Network's (IMSN) submission to this EMA's investigation.

<u>Ambiguous labelling of ciclosporin injection</u>
Ambiguous labelling of ciclosporin injection where ampoule does not state total amount contained in ampoule leading to dosing errors. The MERP has advised Medsafe and PHARMAC of these errors and to seek an update. The label meets the requirements of the existing legislation which is under review.

The MERP has collated responses from the NZ Medication Safety email network on key labelling and packaging issues and submitted these for consideration in the agenda of the FDA/IMSN Global Summit on Packaging and Labelling to be held June 2018.

Errors with tramadol liquid

Further wrong dose and wrong strength errors with liquid tramadol occurred this quarter. The MERP has followed up with Medsafe regarding confusion between similar product packaging of commercial 100mg/mL drops and pump spray. The sponsor of the drops and spray is voluntarily withdrawing both products until the safety issues can be resolved. The possibility of a funded commercially produced extemporaneously compounded tramadol 10mg/mL oral liquid is being pursued. The Pharmacy Defence Association and Pharmacy Council have communicated safety advice to pharmacists.

Action 180511 Medication safety specialist to follow up on commercially produced 10mg/mL extemporaneously compounded formulation

Atropine 0.01% eye drops safety concerns

This weaker strength is increasingly being prescribed by optometrists for children with myopia. Unfamiliarity with this use and strength, and no commercially available product are possible contributors to wrong strength errors. The Health and Disability Commissioner has published a case recently where the commercially available atropine 1% eye drops were dispensed when 0.01% prescribed. The MERP has received similar reports which highlights this is a wider systems issue.

The Pharmacy Defence Association and Pharmacy Council have communicated safety advice to pharmacists. The 0.01% strength must be sterile and sourced from a specialised compounding pharmacy. NZFC provides a caution in the atropine monograph. Other actions facilitated by the MERP include atropine 0.01% eye drops now listed in NZULM, warning now included in TONIQ dispensing system.

Alan and the group thanked Desiree again for the commitment and knowledge contributed to the MERP over many years, and for bringing these valuable reports to MSEAG. The reports have highlighted many serious medication safety issues and near misses across New Zealand, including patterns and smoke signals. Actions from this information have resulted in tangible system changes and improved medication safety nationally.

15 Medicines management digital services sector oversight group

A number of key health agency stakeholders have a joint interest in improving the way medicines are managed across the system. A group has formed to provide strategic advice, leadership and oversight of medicines management digital services in New Zealand. The group includes representatives from DHBs, Ministry of Health, and other government agencies, professional colleges and organisations. The clinical lead for the medication safety programme has recently been appointed to join this group as a clinical medication safety and MSEAG representative.

Initial meetings focused on resolving contractual and communication issues with existing vendors across the system where there is disparity as a result of different vendors with different roles.

Four initial priorities for this group are: the national roll out of NZePS; exploring what can be done to enable system architecture (a key enabler that needs to be driven from central leadership); looking at hospital medicines systems; and opening access to data with interoperability as a high priority.

Success will see medicines information safely and securely following a patient through the health system with communication between providers, and consumers able to direct how their medicines information is provided.

Action 180512 Add as a regular agenda item for future MSEAG meetings

16 eMedicines programme update

There is currently the highest interest to date among clinical staff for NZePS, however barriers exist to progressing and implementing within DHBs at top leadership and funding levels. Over the past year the number of prescriptions being scanned has more than doubled, with a queue of GP practices waiting for the exemption for a triplicate controlled drug prescription. The Midland region is currently testing the use of the NZePS dispensing data for Medicines Reconciliation, and work continues with DHBs including Capital Coast DHB around integration of NZePS in addiction services.

The conversation needs to be changed away from individual systems and towards achieving the flow of medicines information. Systems are fragmented, and nowhere does the whole end to end process exist. The main barriers appear to be lack of capacity, funding and leadership.

17 Learning and improvement group refresh

Karen Orsborn, Director, Health Quality Improvement and Deputy Chief Executive, provided an update on recent changes to the Commission's Learning and Improvement group. Over the past seven years the medication safety programme has come a long way including the successful roll out of a national medication chart, initiation of a system for paper based medicines reconciliation and many other achievements.

The Commission has two core functions of monitoring data and helping providers make improvements. The strategic direction for the next few years involves the four strategic priorities of improving consumer and whānau experience, improving health equity, reducing harm and mortality, and reducing unwarranted variation in patterns of care.

There is a move away from topic based programmes, to sector based groups of patient safety (includes medication safety), hospital improvement, community improvement, and a DHB funded mental health and addictions group. There have also been financial pressures with no increased funding over the life of the Commission and a reduced budget for the improvement arm.

There has been a focus on around thirteen specific topics with small teams and a reduction of harm in these areas. Other issues such as leadership, culture, information technology, Safety one Safety two, and consumer engagement are now more of a focus along with an increased focus on community including aged residential care.

The future of the MERP was discussed and the question asked what should the MSEAG be doing as a group. The Commission's role as custodian of funds is coming to an end with no sustainable governance or funding identified from 1 July 2018. The information provided from MERP to the MSEAG has been extremely valuable resulting in safety actions taken at multiple levels to prevent similar errors and the closure of this programme will create a vacuum in this reporting and learning. It is important that medication errors continue to be reported at a national level with a way of learning from these events.

Alan acknowledged and thanked Carmela on behalf of the group for her passionate and strategic leadership in medication safety, and her skills and influence resulting in a successful programme over the past seven years. Carmela thanked the group for their excellent support of the programme and noted there is likely to be ongoing collaboration and overlap with community work.

18 Programme quarterly update

An update was provided on programme activities over this last quarter. Leadership and network strengthening has been ongoing with NZF recently adding an ex-officio representative to the MSEAG. The partnership with HISO has continued working towards digital standards setting and

integration of standardised information in clinical settings. Public comment is being sought on the Australian national guidelines for on-screen display of clinical medicines.

A meeting was held with Central TAS to discuss joint primary care and ARC project opportunities, and information meetings were also attended to discuss the pharmacy services agreement for integrated pharmacist services in the community. Catherine Proffitt from PHARMAC presented the equity work to Commission staff to bring increased awareness and networking across other related programmes. Discussions are underway to develop a potential project on medicines access equity in the Commission's Whakakotahi primary care initiative.

Meetings were held with other medication safety teams (NSW Clinical Excellence Commission and Queensland Health) to discuss areas of alignment and share programme workstreams and priorities. The WHO global patient safety challenge remains an ongoing priority and work continues on a cross-sector matrix to detail the work across the NZ sector supporting this challenge.

Work continues on the safe use of opioids including regular teleconferences and sub-group discussions. The implementation guide, frequently asked questions, and data collection forms will be revised following further refinement of some of the definitions, the group is working towards July 2018 to implement outcome measures using National Minimum Dataset data, and October 2018 for process and balance measures. The three DHBs (Northland, Whanganui, Bay of Plenty) with the highest regional opioid usage as identified through the Opioid Atlas, have been invited to collaborate with a view to using LifeQI.

The Commission received a letter from the Australian and New Zealand College of Anaesthetists on their recent statement addressing concerns about slow-release opioids in the management of acute pain. The statement has been publicised on the websites of ANZCA and the Commission.

The Ogilvy medication discharge project to improve consumer experience continues and once completed, will be evaluated. It is anticipated there will be potential to create resources and scale interventions for wider impact. A planning process has been completed to identify and document equity actions for the medication safety programme to align with the Commission's internal equity action plan.

Following the forum in December to discuss the future of medication error reporting in NZ and the existing MERP programme, an action group was formed however no funding/governance group emerged. With the recent internal restructure of programmes, adverse events monitoring including the medication safety programme will now be embedded into a new patient safety group, with priorities focused on areas of high patient harm. The safe and quality use of medicines will continue to be an integral part of future discussions and priority areas for action.

The interim aged residential care medication chart implementation and training guide update has been completed and the eMeds infographic of high level benefits for the eMeds programme under the Ministry of Health oversight group was completed and uploaded to the Commission's website. A strategy paper on digital platforms for health services is being prepared for the Minister of Health.

On-going discussions are in place with the adverse events team to increase collaboration and ensure a future vision of integrated medication incident reporting within adverse events reporting. Work has continued in scoping the ARC programme which will likely include significant cross programme work with medication safety. There will be a medicines management project in the mental health and addictions programme next year, and work has commenced in advance care planning.

This quarter the medication safety programme has continued work across all workstreams, and completed a draft plan for priorities and programme focus for 2018-19 and beyond. This next

phase will be a transition time as the new patient safety group moves from specific topic focus to a cross sector focus. The programme will continue to respond to sector enquiries and needs, deliver on core services to ensure an ongoing sustained focus on national medication safety.

Action 180513: MSEAG chair to write to director general of health regarding the MSEAG's support for the MERP programme and the future of medication error reporting and learning in NZ

19 Meeting dates 2018

Future meetings for 2018 will be in Wellington

29 August 2018
28 November 2018

Meeting closed 3.34pm