New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

9 April 2019

Ministry of Health

By email: therapeuticproducts@moh.govt.nz

**Therapeutic Products Bill Exposure Draft and Proposed Regulatory Scheme**

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide feedback on the above consultation. The NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders. Our response has been informed by feedback from our members, Advisory Councils and Board.

**General Comments**

1. The NZMA welcomes the development of the Therapeutic Products Bill and accompanying regulatory scheme which are intended to replace the Medicines Act 1981 and associated regulations. We agree that the Medicines Act 1981 is dated, inflexible and prescriptive, and has significant gaps in coverage. To address current weaknesses, we note that changes in three broad areas are proposed: i) shift to a principles-based legislative framework; ii) coverage expanded to include a range of products (including devices); iii) regulator to be provided with a set of tailored and responsive regulatory tools. We are generally supportive of these high level changes. However, we have a number of concerns relating to specific aspects of the regulatory scheme that are being proposed. We elaborate on these concerns in the following paragraphs.

2. We are generally supportive of the objectives for the regulatory scheme. In particular, we welcome the objective to provide assurance of acceptable safety, quality and efficacy or performance of therapeutic products. We also welcome the objectives to provide regulation that is efficient and cost-effective, flexible, durable, up to date and easy to use, and that ensures high-quality robust and accountable decision-making. However, we have some concerns at the objective to 'support New Zealand's trade and economic objectives' and seek clarification on what this entails. We would be concerned if safety, quality and efficacy or performance of therapeutic products are in any way made, or at risk of being made, subordinate to trade and economic objectives. It is our view that a regulatory scheme for therapeutic products should be insulated, as far as is possible, from possible obligations that could ensue from trade and


26 The Terrace, PO Box 156, Wellington 6140 | Tel: (04) 472 4741 | Fax: (04) 471 0838 | Email : nzma@nzma.org.nz | **www.nzma.org.nz**

investment agreements that could undermine the primary objectives of ensuring safety, quality and efficacy or performance. Equally, it is important, when negotiating trade and investment agreements, to ensure that such obligations do not restrict the government's ability to regulate for health, including in the arena of therapeutic products.

## Specific Comments

### Exclusion of natural health products

3. The New Zealand Medical Association (NZMA) is very disappointed that complementary and alternative medicine products are not being brought under the Therapeutic Products Bill and associated regulatory scheme. We consider this to be a missed opportunity. We have long been concerned about the array of natural health products on the market, with consumers making uninformed choices based on unproven health claims, with no assurance of product safety, quality or efficacy. While the Natural Health and Supplementary Products Bill would have gone some way towards addressing our concerns,[1] this Bill was not reinstated following the change of Government in 2017 with no satisfactory explanation provided.

4. We note that definitions of therapeutic purposes that are made in the exposure draft of the Bill are broad and include purposes such as "alleviating or compensating for a disease or ailment"—purposes that are similar to claims that are sometimes made by natural health products. Given this overlap, it is difficult to understand the logic behind developing exclusion provisions for natural products from this Bill. Health literacy in New Zealanders is often insufficient for many people to know the important differences between approved medicines and complementary and alternative medicines. Furthermore, the currently permitted practice of co-locating complementary and alternative medicine products and evidence-based medicines in pharmacies, with both categories being sold by pharmacists, gives inappropriate legitimacy to natural health products.

5. It is the NZMA's view that natural health products should fall under the regulatory scheme for all therapeutic products, such as is the case in Australia. We believe that complementary and alternative medicine products must also be subject to evidence-based scientific testing. This includes ensuring an adequate assessment of safety, with specific consideration given to post marketing surveillance and adverse reaction monitoring. We have previously called for a two-tier regulatory system to be considered for natural health products, which would provide appropriate safeguards, with pre-market assessment as a requirement for higher-risk products. We note that such a two-tier system operates in Australia. We seek an explanation as to why natural health products are to be excluded from the Therapeutics Products Bill and associated regulatory scheme. We would also like to know more about the options the Government is considering for regulating natural health products, including specific timeframes.

### Medical devices

6. We are supportive of more robust regulation of medical devices than is currently the case. At present, medical devices in New Zealand are not subject to any pre-market regulatory scrutiny to assess safety and performance, and post-market controls are minimal. We note that under the

[1] NZMA. The regulation of natural health products. Submission to the Ministry of Health. 15 February 2016. http://www.nzma.org.nz/__data/assets/pdf_file/0009/47079/NZMA-Submission-on-the-regulation-of-natural-health-products.pdf; NZMA. Natural Health Products Bill. Submission to the Health Committee. 23 February 2012. http://www.nzma.org.nz/__data/assets/pdf_file/0014/1607/sub-naturalproductsbill.pdf

scheme that is being proposed, the intention is to apply the full range of pre- and post-market controls for medical devices in accordance with the risk-based model developed initially by the Global Harmonisation Taskforce and continued and maintained by the International Medical Device Regulators Forum. We support this approach and believe it will bring New Zealand into line with international best practice. However, it will be important to ensure that regulation does not adversely impact the availability of, and support for, medical devices. We also contend that it is necessary to better define the scope of devices that are to be covered as well as build in exceptions to the usual regulatory requirements for certain situations (eg, devices used to diagnose rare conditions or emerging epidemics).

7. While our view is that the additional benefits to public health and safety conferred by stronger regulation of medical devices must remain the main priority, there is a need to give particular consideration to the potential impacts of the proposed regulation on the cost and availability of products. We note that while the split between the costs of regulation recovered from industry and those met by the government has not yet been decided, it is expected that a significant proportion of the costs would be recovered through industry fees or charges. We are aware that PHARMAC, as the funding agency, is expanding its role to assume responsibility for the procurement of medical devices. We would be concerned if these separate, but parallel, developments led to the reduced availability of necessary medical device products in the New Zealand market due to commercial considerations—particularly given the small size of the New Zealand market and the funding environment in which industry operates. We are encouraged that the regulatory scheme that is being proposed would allow the regulator to rely on work done by other recognised authorities. For medical devices, we note that these authorities are expected to be a mix of third-party conformity assessment bodies, such as those designated under the EU system, and national regulatory bodies.

8. We have some concerns that the range of medical devices that would fall under the Bill would be too wide and potentially impractical. Given the definitions of therapeutic purposes that are proposed, a medical device could be anything that is used for "preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for a disease, ailment, defect, or injury". As such, this could be taken to include any piece of laboratory equipment or reagent used for a laboratory test. It could also be taken to include the use by a health practitioner of bathroom scales, or a tape measure (used to measure girth or head circumference). We believe that it would be useful to have a clearly defined limit to the scope of what is covered by the Bill.

9. The proposed regulation of *in-vitro* diagnostic medical devices may be problematic for specialised diagnostic laboratories that provide 'in-house testing' for rare conditions for which no commercial kits are available. Often such assays clearly provide clinical benefit and yet cannot reasonably be validated and rigorously evaluated to the standard that would be expected of a commercial product. Another area where this could cause problems is when new in-house assays need to be developed quickly, for example in response to an epidemic of an emerging infectious disease (eg, SARs, MERs, Ebola, pandemic influenza). Accordingly, it is essential to build clear provisions allowing for exceptions in these situations into the legislation. In addition, diagnostic tests for rare but important conditions will never be commercially attractive but are of course needed. Imposing overly rigorous and onerous constraints on specialised laboratories may make compliance practically unfeasible and this would pose a risk of harm / reduce the quality and scope of diagnostic services, particularly in highly specialised areas and for rare conditions. While protecting safety is the paramount consideration, it is important to keep in mind the principle of beneficence. There is a risk that unduly high regulatory requirements could ultimately reduce access to specialist testing and treatments.

**Direct-to-consumer advertising of prescription medicines.**

10. We are strongly opposed to the draft Bill continuing to permit direct-to-consumer advertising (DTCA) of prescription medicines. Currently, New Zealand and the United States are the only countries in the developed world to allow DTCA of prescription medicines. We believe that the development of the Therapeutics Products Bill represents an important opportunity to end this practice and bring New Zealand in line with the rest of the developed world. Research signals that DTCA provides information that is likely to be biased in favour of benefits over potential harms, leads to unnecessary prescriptions, iatrogenic harm, and increased costs to the taxpayer (particularly through driving demand for costly branded medicines over cheaper effective alternatives).[2] DTCA may also adversely affect the doctor-patient relationship.[3] We refer officials to our position statement on DTCA of prescription medicines for further details.[4]

11. A specific issue which is of particular importance with respect to DTCA is the development of antimicrobial resistance. We draw attention to the New Zealand Antimicrobial Resistance Action Plan,[5] specifically priority action areas one (strengthening public understanding of appropriate antimicrobial use) and two (reviewing and, if needed, amending regulations on advertising of antimicrobials, including DTCA). We contend that continuing to allow DTCA of antimicrobials in light of these critical priority action areas makes no sense and represents policy incoherence.

**Authority to prescribe to be established in, and bounded by, scopes of practice under the HPCAA**

12. We have major concerns with changes to the approach to authorising which practitioner groups may prescribe. Rather than listing practitioner groups in the Act or regulations, we note that authorisation to prescribe would be established via relevant profession's scopes of practice under the Health Practitioners Competence Assurance Act (HPCAA) with the draft Bill defining a 'health practitioner prescriber' as a health practitioner whose scope of practice includes prescribing. We understand that this approach would require amendments to the HPCAA in order to make it explicit that a scope of practice can include prescribing, and that the Minister of Health's approval would be required before a scope of practice could include a new or amended authority to prescribe. We note that the new scheme would no longer have categories of prescribers (such as authorised, designated and delegated prescribers). Where a prescribing authority includes particular restrictions or requirements, this would be reflected in the scope of practice. Where particular health practitioner groups are restricted to prescribing certain medicines, we are aware of a proposed shift away from lists of named medicines to "other logical groupings". We are very concerned that a shift away from formal gazetting of lists of medicines

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[2] Every-Palmer S, et al. Direct-to-consumer advertising of prescription medication in New Zealand. N Z Med J. 2014 Aug 29;127(1401):102-10. https://www.nzma.org.nz/journal/read-the-journal/all-issues/2010-2019/2014/vol-127-no1401/6278; Metcalfe S. Changes to time trends for inhaled corticosteroid use and costs in New Zealand since April 2002. Draft 5, 29 September 2003. Unpublished report for PHARMAC. Available from https://www.pharmac.govt.nz/assets/changes-time-trends-inhaled-corticosteroid.pdf

[3] Robinson AR, et al. Direct-to-consumer pharmaceutical advertising: physician and public opinion and potential effects on the physician-patient relationship. Arch Intern Med. 2004 Feb 23;164(4):427-32. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/216701

[4] Direct-to-consumer advertising of prescription medicines. NZMA position statement. June 2018. http://www.nzma.org.nz/__data/assets/pdf_file/0005/83480/Direct-to-Consumer-Advertising-of-Prescription-Medicines_June-2018.pdf

[5] Ministry of Health and Ministry for Primary Industries. Antimicrobial Resistance: New Zealand's current situation and identified areas for action. 2017. Wellington: 2017. https://www.health.govt.nz/publication/new-zealand-antimicrobial-resistance-action-plan

(as is currently the case with designated prescribing) towards "other logical groupings" under a scope of practice (or even outside a scope of practice as has been suggested) represents a retrograde step—both in terms of a weakening of transparency/public scrutiny and the potential for ambiguity (how is a 'logical group' defined, for example?).

13. We have previously conveyed our concerns with the proliferation of independent prescribing rights for various non-medical health practitioner groups[6] as well as with shifting authorisation of who is entitled to prescribe to Responsible Authorities (RAs) regulating health practitioners under the HPCAA 2003.[7] We continue to believe that existing scopes of practice for most RAs are insufficiently specific to cover safe and appropriate prescribing restricted to a practitioner's competency. Furthermore, given that scopes of practice are self-defined by RAs, an RA wanting to assume prescribing rights for its profession could simply redefine its own scope of practice, undertake a consultation process and then report back to the Ministry which has limited competency to assess clinical considerations. If previous experience regarding changes to an RAs scope is anything to go by, what a profession's RA says tends to be what we end up with. This is of particular concern given that RAs are not set up, or funded appropriately, to be able to appropriately oversee safe prescribing of all allied health practitioner groups. It is likely that only the very worst cases of inappropriate prescribing are likely to be reported to them.

14. If prescribing rights are to be tied to scopes of practice, then we believe it is necessary to acknowledge that most of the current scopes for RAs are inadequate for that purpose (or for that matter many other purposes). If the current proposal is to be progressed, we also consider it essential to establish a system where scopes of practice are not independently determined by the profession's RA, but must instead be agreed by all of the professional groups where there is an overlap of scope. There is a risk that professional groups seeking greater professional independence will look to expand their scopes, including prescribing, on the grounds of improved access but with the potential for negative impacts on patient safety and integration of care. It will be essential for the Ministry or a separate entity to oversee the system of RAs. Furthermore, when seeking a new, or a change in, prescribing authority, relevant RAs must be required to consult widely including with professional groups such as the NZMA.

**Pharmacy ownership, pharmacy activities, licensing and control**

15. The GP sector has been advocating for changes to existing restrictions in these areas for some time to provide better health care to patients and improve the primary care system. Although there are a range of views, we are in favour of modifying the current restriction on prescribers from taking a financial interest in a pharmacy. While the current restriction reflects concerns about the potential negative influence of commercial incentives on prescribers if they could benefit financially from their prescribing decisions, we believe there are several legitimate arguments for change. For example, providing medications to patients at the time they require them, without the extra steps of having to visit a pharmacy, hand over their prescription and then wait or return to collect the medications, should increase adherence (and therefore improve outcomes). Many rural practices already dispense medicines that they prescribe—this is hugely appreciated by patients. Pharmacists already dispense prescribed products that are fully funded (eg, emergency contraceptive pill, trimethoprim for UTI). Even though a prescription is not

[6] Non-medical prescribing. NZMA position statement. July 2013. http://www.nzma.org.nz/__data/assets/pdf_file/0005/16979/Non-medical-prescribing-2013.pdf

[7] Draft options for the regulation of prescribing and dispensing in New Zealand. NZMA submission to the Ministry of Health. 20 January 2016. http://www.nzma.org.nz/__data/assets/pdf_file/0009/46692/sub-draft-options-for-the-regulation-of-prescribing-and-dispensing2.pdf

formally written, the commercial aspects underlying such dispensing are the same in all other respects.

16. Our view is that potential conflicts of interest that could arise from the above change are better viewed as professional and ethical issues. Rather than attempting to legislate for such matters, we believe that health practitioners should be accountable for managing potential conflicts of interest through meeting relevant ethical and professional standards. Health practitioners regularly manage such conflicts of interest. For example, no similar legislative restrictions apply when it comes to taking financial interests in general practice, private hospitals, or private specialist practice. Furthermore, with respect to prescribing activity, audits of prescribing that are currently conducted would be expected to identify aberrant prescribing.

17. The consultation makes a number of unsubstantiated claims regarding pharmacy activities. For example, paragraph 465 asserts that "the need for professional control of pharmacy activities by a pharmacist is clear". Paragraph 471 then goes on to state that the Government is considering two options "to ensure pharmacy activities remain under the control of a pharmacist". We believe that these assumptions about pharmacy activities warrant challenge and we seek evidence to support such statements.

18. With respect to pharmacy ownership, we do not believe that there is a need for pharmacies to be majority owned and effectively controlled by a pharmacist. Currently, a pharmacy license can only be granted to a company if a pharmacist has more than 50% of share capital and is not in effective control of the company. Individuals who are not pharmacists are restricted from holding a pharmacy license or holding a majority interest in a pharmacy. The consultation describes how this approach is not working as originally intended—ownership requirements are not well defined and have allowed a wide range of business arrangements to develop. Yet before proposing options to ensure pharmacy activities remain under the control of a pharmacist, we submit that it is necessary to clearly articulate why this control is necessary. Other health sector services such as General Practice do not have similar requirements.

19. It remains our view that opening up the ownership of pharmacy beyond pharmacists may better facilitate innovation and integration of services. Furthermore, the ability to ensure pharmacy services in rural communities may be improved if a pharmacist majority owner is not required. For example, under an opened-up ownership model, the pharmacy could be co-owned by general practice, a community interest / trust or a PHO (or other business interests).

**Commissioning and funding of pharmacy services**

20. We are not convinced that the Therapeutic Products Bill and accompanying regulatory scheme should attempt to address moves to support new commissioning and funding arrangements of pharmacy services. We note that the stated purpose of the Act is to protect personal and community health by: (a) ensuring acceptable safety, quality, and efficacy or performance of therapeutic products across their lifecycle; and (b) regulating the manufacture, import, promotion, supply, and administration or use of therapeutic products. We cannot see how supporting commissioning and funding arrangements of pharmacy services has any relation to the officially stated purpose of the Act, and therefore question the appropriateness of addressing these areas in this legislation.

21. We do note however that a number of proposed regulatory measures relating to future regulation of pharmacy business activities are intended to support DHBs shift to more tailored commissioning of pharmacist services. The consultation reports that "DHBs are also shifting

from a one size fits all approach to a tiered commissioning model. This would provide national contracts for the supply of medicines and standardised services, while allowing DHBs greater flexibility to commission services locally, based on their specific needs." We have previously conveyed our concerns at proposals to create a new service agreement in parallel with the existing agreement for Community Pharmacy Services.[8] It is useful for DHBs to be able to look at flexible funding models for their pharmacy services that may lie outside the traditional frameworks centred around community pharmacy. If there were to be suggestions that DHBs enter into commissioning or contracting for pharmacy services outside the community pharmacy model, such changes to service design must be informed by a robust evidence-based approach. This work would need to be undertaken before changes are implemented and before new regulatory measures are introduced.

**Categorisation (classification of medicines)**

22. Currently, the medicines classification schedule is used as the tool for enabling wider access to specified medicines in particular categories, with entries such as 'prescription medicine except when supplied by pharmacists with appropriate training". This has been applied to various medicines such as erectile dysfunction drugs, trimethoprim and the combined oral contraceptive pill. The NZMA has had a number of concerns with such provisions.[9] We note that under the new scheme, regulations would instead be used to provide an authorisation, with the class of health practitioner who has the authorisation to perform specified activities listed along with named products or classes of products. We do not believe the proposal addresses our previous concerns but seek more details on this proposal. One particular issue that needs to be considered in any such proposal is the impact of widening access to antimicrobials on antimicrobial resistance. We note that the consultation states the regulator would be able to seek advice from an expert committee in relation to decisions about switching an active ingredient in a medicine from one category to another and therefore change the category of medicines with that ingredient. We submit that the regulator **must** be required to seek advice from an expert committee about such changes.

**Modified approach to the use of unapproved medicines**

23. We note that the draft Bill contains a modified process for accessing unapproved medicines (which include medicines prescribed for an off-label use), with an additional requirement for a special clinical needs supply authority (SCNSA). We note the intention of this modified process is to try to minimise the use of unapproved medicines in New Zealand by making sure prescribers are giving appropriate consideration as to whether unapproved medicines are the best option for the patient. While we agree, in principle, with this intention, we have some concerns relating to both of the main types of SCNSA are being proposed.

24. With respect to the off-label use of medicines that have been approved in New Zealand, we understand the aim is to authorise all health practitioner prescribers to issue a SCNSA for off-label use (as long as the medicine is covered by their scope of practice) with minimal requirements for what that SCNSA would need to involve (potentially a tick box). We believe that it is important to avoid the SCNSA assuming yet another onerous bureaucratic requirement for busy doctors, particularly when the prescription of medicines for off-label use is common

[8] Proposed Integrated Pharmacist Services in the Community Agreement. NZMA submission to TAS. 9 April 2018. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0013/82210/NZMA-Submission-on-Integrated-Pharmacist-Services-in-the-Community.pdf

[9] Agenda for the 51st meeting of the MCC. Submission to Medsafe. 25 March 2014. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0016/26530/sub-agenda-of-51st-meeting-of-the-MCC.pdf

practice. On the other hand, it is arguable whether a 'tick box' SCNSA would add any value. There is often a degree of comfort with off-label prescribing for non-approved indications as safety will have already been established (albeit for different indications). In some instances, however, prescribers may not be aware that a specific indication / population group they are prescribing for is off-label.

25. For medicines that do not have a product approval in New Zealand, we note that the intention is to continue to limit the ability to issue a SCNSA for these products to medical practitioners only, in line with the current approach to such medicines. We support this approach and would be opposed to widening access to unapproved medicines to other health prescriber groups. We note that this approach is also intended to increase awareness of the additional accountability that a medical practitioner takes on when prescribing this type of unapproved medicine. We are comfortable with the proposal that once a SCNSA has been issued, any health practitioner prescriber would be able to prescribe that medicine for the patient as long as it is within their scope of practice.

**Personal importation rules**

26. Under the new scheme, we note that while people will continue to be allowed to import non-prescription medicines from overseas, they will no longer be allowed to import prescription medicines. We recognise that this proposed change reflects a trade-off between balancing people's personal freedoms (by allowing non-prescription medicines to be personally imported) with the management of the risk presented by unknown products (which is more serious in the case of prescription medicines). However, we believe that it is vitally important to ensure that where appropriate, patients are still able to access prescription medicines from overseas that are approved but not funded in New Zealand. Currently, patients can import such medicines providing they obtain a prescription. A small number of patients depend on accessing unfunded medicines from overseas in this way, and such medicines have produced major benefits in terms of reduced relapse rates and improved survival in patients with certain types of cancers, for example. We note that under the new scheme, the ability for parallel importing of approved medicines that are not funded in New Zealand would be curtailed due to safety considerations. However, the consultation document appears to provide scope to authorise parallel importation of approved products "in exceptional circumstances". We seek an assurance that patients requiring access to such medicines will continue to be able to access these under the new scheme, and seek more details about how this would work.

27. With respect to the importation of unapproved prescription medicines, we note that persons wanting to import these would need to consult a medical practitioner to seek a SCNSA. If this is provided, the person would need to obtain the medicine either directly from their prescriber or a pharmacy. The pharmacy or issuer of the SCNSA could import the medicine themselves or obtain the medicine from a licensed wholesaler that was authorised to import and supply unapproved medicines. We note that the rationale for this approach is that those in the regulated supply chain have more knowledge of where they can safely source this product from. It will be important to ensure that importation requirements for prescribers / pharmacies / licensed wholesalers, and the SCNSA process, are as streamlined as possible so that patients who previously imported unapproved medicines that are not funded in New Zealand themselves can, when appropriate, continue to access these.

**Permits**

28. We wish to raise some concerns regarding the content and effect of permits under the proposed new regulatory system. In addition to licensing (the normal process for therapeutic products coming in to New Zealand), SCNSA (requiring application by a health practitioner for a named patient), and the exceptional circumstances being proposed to allow parallel importation of products that are approved in New Zealand, we understand that permits will provide a further way for therapeutic products to (legally) come into New Zealand. While the consultation document states that "permits are intended to be used for shorter-term and/or urgent situations" few details are provided of the purposes for the granting of permits.

Our main concerns about permits extend to the following:
i) the criteria for granting a permit (Section 135 of the Bill) does not reflect use limited to short term and/or urgent situations—in fact, the Bill proposes granting permits for up to 2 years;
ii) The fact that permits can specify by class rather than individual could potentially mean supply to large groups of people;
iii) Anyone can apply for / be granted a permit—unlike for an SCNSA, there does not appear to be any requirement for a health practitioner or prescriber to be involved;
iv) We seek clarification of monitoring requirements for unapproved medicines in use via permits. While license holders (sponsors) are required to participate in pharmacovigilance and processes such as recalls, it is not clear what (if any) monitoring requirements will apply for permit holders;
v) We seek clarification on whether permit holders will be subject to the same sanctions as are proposed for sponsors for similar breaches.
While we accept that the above concerns may be addressed under yet-to-be developed regulations and rules, we are concerned that they represent possible gaps in patient safety arising from circumventing usual processes to ensure product safety and the safe and appropriate use of products.

29. We note that the consultation document states that “a permit may be a suitable approach for buying groups that have identified a suitable and safe supplier”. We seek clarification on whether the Ministry is supportive of this concept, as well as what it would mean for New Zealand's medicines system if an expansion in the use of permits for the purpose of group buying have the effect of diminishing PHARMAC’s role.

**Clinical trials**

30. We have major concerns regarding the proposal to make conducting clinical trials of therapeutic products a controlled activity requiring authorisation. We are not convinced by the rationale for this change, particularly given that the existing requirements for ethics approval already take into consideration matters relating to safety and methodology. We are very concerned that the proposal would represent an additional layer of bureaucracy that would further impede and delay clinical trials, with negative consequences for the researchers and the health of New Zealanders.

31. A number of the proposed criteria associated with the requirement to make clinical trials a controlled activity are unduly onerous or duplicate existing provisions. Currently, there is already a requirement by Ethics Committees for clinical trials to be registered as meeting Good Clinical Practice (GCP). We note the proposed requirement for the licensee to be a fit and proper person and seek clarification on expected time frames to meet this. We also note the proposal for the regulator to have the power to monitor trials and audit clinical trials. We believe that these

proposals are unnecessary as most trials already have Data Safety and Monitoring Boards (DSMBs). We seek further information about the criteria for the proposed monitoring or auditing requirements. In paragraph 424, we note the proposed additional requirements for trials continuing beyond 12 months. Our view is that the idea of a 12 month licence is completely impractical. Most clinical trials take 3 to 5 years, therefore having to reapply to continue every 12 months under the proposed new scheme is completely unnecessary.

**Range of tools available to the regulator**

32. We welcome the wider range of tools that would be available under the new scheme to encourage compliance and deal with serious offending. We agree these would enable more appropriate and timely responses when non-compliance occurs. We note the hierarchy of enforcement tools includes tiered criminal offences, enforceable undertakings and infringement notices. These tools would allow the regulator a wide range of enforcement options, meaning enforcement action could be commensurate with the severity of misconduct, and the regulator's approach could be flexible according to circumstances.

**Pharmacovigilance**

33. We welcome the proposed requirement for sponsors to have explicit legal obligations in relation to post-market monitoring, reporting and risk management for their products. We believe this is an advance on the current situation where such obligations are recommended but not underpinned by legislation. We note that it is proposed that these pharmacovigilance requirements would be set out in regulations, with the intention being that they would be aligned with international norms.

We hope our feedback is helpful and would like to be kept informed of this work as it progresses.

Yours sincerely

Dr Kate Baddock
NZMA Chair