New Zealand College of Midwives
TE KĀRETI O NGA KAIWHAKAWHANAU KI AOTEAROA

18 April 2019

Therapeutic Products Regulatory Scheme

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The New Zealand College of Midwives is the professional organisation for midwifery. Members are employed and self-employed and collectively represent over 90% of the practising midwives in this country. There are approximately 3,000 midwives who hold an Annual Practising Certificate (APC). These midwives provide maternity care to, on average, 60,000 women and babies each year. New Zealand has a unique and efficient maternity service model which centres care around the needs of the woman and her baby.

Midwives undertake a four-year equivalent undergraduate degree to become registered followed by a first year of practice program that includes full mentoring by senior midwives. The undergraduate curriculum meets all international regulatory and education standards. Midwives are authorised prescribers in relation to their Scope of Practice as determined by the Midwifery Council.

Midwives provide an accessible and primary health care service for women in the community within a continuity of carer model as Lead Maternity Carers. Midwives can also choose to work within secondary and tertiary maternity facilities, providing essential care to women with complex maternity needs.

The College offers information, education and advice to women, midwives, district health boards, health and social service agencies and the Ministry of Health regarding midwifery and maternity issues. Midwives interface with a multitude of other health professionals and agencies to support women to achieve the optimum outcome for their pregnancies, health and wellbeing.

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Ministry of Health
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Therapeutic Products Regulatory Scheme

The New Zealand College of Midwives (the College) welcomes the opportunity to provide feedback on the Therapeutic Products Regulatory Scheme.

Introduction

Midwives work on their own professional responsibility to provide women with the necessary care, support and advice during pregnancy, labour and birth and the postpartum period up to six weeks within their Scope of Practice. The midwife, in the provision of primary midwifery care, is an autonomous practitioner regardless of her workplace. The midwifery Scope of Practice includes the promotion of evidence-based care, and prescribing is one of the competencies of a practicing midwife, which means midwives will prescribe and administer medications to women and neonates during the normal pregnancy, birth and postpartum experience. Midwives can prescribe, supply, and administer medicine, vaccines and immunoglobulins within their Scope of Practice and relevant legislation. Midwives integrate comprehensive theoretical and scientific knowledge within a legal and ethical framework, and use assessment and diagnostic skills to prescribe appropriately for women and/or their babies within the midwifery Scope of Practice.

The College has addressed the Therapeutic Regulatory Scheme consultation document in terms of specific areas related to midwifery prescribing and practice in our feedback below.

Executive Summary

- The College recognises the need for legislative changes and supports the overarching need for high level legislation and more lower level regulatory changes which can be more easily amended as necessary.
- The College supports the legislative changes around prescribing if the changes are enabling of current prescribing practice and if midwife prescribing is not altered or limited during any transition.
- With the exception of controlled drug medication, which is governed by the Misuse of Drugs Act, there is no requirement for a list of drugs or further limitations to be put in place to regulate the prescribing practice of midwives
- Pre-conceptual care of women is included in the midwifery Scope of Practice.
- The College supports a limited application of midwives being enabled to prescribe for partners of women in their care (limited to situations where the condition of the woman may be negatively impacted by the partner's condition if treatment is not sought – medications for sexually transmitted diseases for example).
- The College supports the dispensing of pharmacy only medicines by midwives which are relevant to their Scope of Practice.
- The College does not support experimental off-label prescribing of medication where there is minimal evidence to support the usage, and where the efficacy and safety of the medication is not clear.
- The College does not support midwives issuing standing orders.
- The College has concerns in a few areas related to maternity and midwifery in relation to medical devices (53d).
- The College supports the option of continuing to allow people to bring prescription (and non-prescription) medications into the country if lawfully prescribed. We would like more information about how any proposed regulatory means to reduce the risks of counterfeit and adulterated medicine will be implemented, and how these channels will be monitored.
- The College does not support direct to consumer advertising (DTCA) and would welcome urgent prohibition of this practice.
- The College has some concerns in terms of the commercialisation of cells and tissues and feel that more details about the approach for prevention of commercialisation, and prevention of harm, is necessary.
- The College supports the 'reserve' category of Type 4 therapeutic products which provides a future-proofing framework.

- The College suggests that the proposed legislative changes provide an opportunity to consider the regulation of vaping products as a prescription medicine, which an increasing evidence base supports as an effective smoking cessation aid.

Feedback

1. Controlled activities listed in section 53 include (a) prescribing, administering and possessing medicines, (d) using medical devices and type-4 products on patients, and (e) issuing standing orders. The College will address these sections separately in the feedback below.

Prescribing

2. The Health Practitioners Competence Assurance Act provides an effective and enabling system of health professional regulation. The College generally supports the proposed legislative changes around prescribing (that prescribing will effectively come under the jurisdiction of the health practitioner regulatory authorities, through amendments to the Scopes of Practice, which will specifically include prescribing within them). The College is supportive of this change only on the proviso that this change is enabling and not prescriptive or limiting of current prescribing practice. We note that there is no requirement for regulatory authorities to undertake consultation in the implementation / transitional phase, when the legislative provisions around prescribing are being transferred from the Medicines Act to the new regime. It is essential that the longstanding and current conditions under which midwives prescribe are not altered or limited with the transition. Any amendments to the midwifery Scope of Practice need to maintain and support prescribing practice, as it currently occurs, under the regime set out in the Medicines Act.

3. Under the Medicines Act, the midwifery Scope of Practice defines the parameters around which midwifery prescribing can be undertaken. As the midwifery Scope of Practice is clear, specific and specialised (as opposed to a generalist Scope of Practice) there is no requirement for a list of drugs or further limitations to be put in place. The exception to this is midwifery prescribing in relation to controlled drugs, which is currently governed by the Misuse of Drugs Act. The Midwifery Council has provided further interpretation regarding the circumstances in which controlled drugs can be prescribed by midwives. The College supports the status quo in relation to midwives prescribing controlled drugs.

4. The midwifery Scope of Practice includes preparing and informing the woman and her family for pregnancy. The College is of the view that pre-conceptual care is included in

the midwifery Scope of Practice and that this would include prescribing relevant to the role, for example prescribing folic acid for a woman planning pregnancy.

5. The College recognises that there are situations that arise during the care of a pregnant woman that may require some prescribing for the partner of the woman. Any such prescribing would be limited to situations where the condition of the woman may be negatively impacted by the partner's condition if treatment is not sought (e.g. medications such as those for sexually transmitted diseases where the partner requires treatment along with the pregnant woman). The College support this limited application of partner prescribing.

6. The proposed legislative changes include the development of a regulatory body which will have considerable powers in relation to overseeing the wider functions of the new Act. It is unclear as to whether this would be a new body, and if so, what relationship this new regulatory body would have related to the health practitioner Councils / regulatory authorities who currently regulate the prescribing practice of health practitioners. The College strongly supports the empowering of the existing Midwifery Council rather than a new external body. The status quo recognises the Midwifery Councils' obligations under the Health Practitioners Competence Assurance Act to protect public safety and keep costs down.

7. The College supports the dispensing of pharmacy only medicines by midwives which are relevant to their Scope of Practice, as previously described.

8. The College does not support experimental off-label prescribing of medication where there is minimal evidence to support the usage, and where the efficacy and safety of the medication is not clear. The College's position related to midwife prescribing is that drugs that are unapproved for use in maternity care or for the newborn should not be prescribed by a midwife on her own responsibility. The College recognises that some unapproved drugs are used in the secondary and tertiary hospital setting. These drugs should be prescribed by a doctor following a comprehensive assessment and diagnosis of the woman and with her informed consent. Midwives may then be required to administer unapproved drugs as a delegated responsibility including during an obstetric emergency in the community.

9. There is an increasing evidence base which supports vaping products as effective smoking cessation aids. Currently vaping products are unregulated. If they were to be classified as a medicine (similar to other cessation aids such as nicotine patches or gum) they could be prescribed at minimal cost to users, thus supporting greater uptake. The College suggests that the newly proposed regulatory regime provides an opportunity to regulate the use of these products.

Standing Orders

10. As midwives are the predominant workforce in maternity and all midwives are able to prescribe, there is no requirement for them to issue standing orders. The vast majority of women also have a Lead Maternity Carer (LMC) who is able to prescribe medications for women when they are in-patients within hospitals or maternity units. Both Lead Maternity Carers (LMC) midwives, and Core (hospital) midwives are able to prescribe for the women under their care. Midwives oversee the practice of nurses in maternity settings, and are therefore able to assess, diagnose and prescribe medications for women who may be under the care of registered nurses in these settings. Standing orders eliminates the requirement for the health practitioner who has issued the order to have direct contact with and assessment of the individual whom they are in effect prescribing for. The College considers that standing orders increase the potential for errors and that direct prescribing is much safer for women and their babies. The College does not support midwives issuing standing orders.

Medical devices

11. In relation to medical devices (53d) the College has some concerns in a few areas related to maternity and midwifery. If a control on medical devices such as pregnancy tests is implemented we wonder where the costs of this change will be borne. This concern is also related to any new regulatory body in terms of costs and the impact on individual midwives. If the costs of changes are carried by industry will this result in higher consumer costs for medicines as well as any devices? The College would be seriously concerned if these costs were passed on to consumers.

12. The College is aware that there is increasing use of hand-held home Doppler ultrasounds purchased by women / families to enable them to hear babies' heartbeats. We have concerns about this ease of access to Doppler ultrasound on two levels. One is the potential issue of overuse and lack of evidence of the safety of non-clinically indicated ultrasound, and excessive use of ultrasound. There have also been some concerns about the stress caused for pregnant women if they are unable to find a fetal heartbeat, and conversely the false reassurance that could occur if women detect their own heartbeat via the Doppler, think it is a sign of baby wellbeing and therefore disregard other indicators and delay contacting their lead maternity carers with concerns. The College would be interested to hear if any regulation or control is being considered for these devices.

13. In regards to medical devices, the College notes that the Global Harmonisation Task Force (GHTF) aims to encourage and support regulatory systems to ensure safety and performance.[1] Although the GHTF suggests that the limits of accuracy of diagnostic devices with measuring functions should be stated by the manufacturer, in reality it is the interpretation of the results and consumer safety that is the issue with home Doppler devices. The GHTF recommend that the skills of the lay person using medical devices needs to be taken into account and that these devices should be manufactured so that that their performance is appropriate to their intended purpose. Regulation and oversight of information and instructions on these devices may need further exploration along with safety testing and regulations. The College notes that there has been a call to ban the sale of these devices to consumers in the UK.

14. The International Medical Device Regulators Forum provides information about labelling principles of medical devices suitable for lay persons.[2] Some regulatory measure would appear to be necessary for home Doppler devices.

15. In terms of other medical devices, the College has some concerns about the regulatory climate that allowed an issue to occur related to the use of surgical mesh. Section 38 of the Medicines Act 1981 permits the Director-General of Health to request safety information from a supplier should there be reason to believe a medical device is unsafe. The section 38 review and restrictions are apparently the strongest actions possible under current legislation and the College is hopeful that some strengthening of the current regulatory process, safety processes and ongoing monitoring of medical devices will be considered.

[1] Global Harmonization Task Force. (2012) Essential principles of safety and performance of medical devices. GHTF
[2] International Medical Device Regulators Forum. (2018). *Principles of Labeling for Medical Devices and IVD Medical Devices*. IMDRF

16. The College supports the 'reserve' category of Type 4 therapeutic products, which includes medical devices, as we are aware there will be overseas products not yet available on the New Zealand market that will require consideration under this category. This future-proofing category provides health and safety protections for consumers.

Personal import of medication

17. The College has considered the options for personal import of prescription medicine into New Zealand via mail or courier and we support the option of continuing to allow people to bring prescription (and non-prescription) medications into the country if lawfully prescribed. In terms of ordering medication via the internet the College is interested in understanding more about how online suppliers would be regulated to reduce the risks of counterfeit and adulterated medicine, and also how, if at all, these channels could be monitored.

Direct to Consumer Advertising (DTCA)

18. The College continues to be concerned about the practice of direct to consumer advertising (DTCA) (Section 83) which is allowed in only two countries, New Zealand and the United States. We consider the Therapeutic Products Regulatory Scheme legislation represents an opportunity to prohibit DTCA. Lisa Schwartz and Woloshin (2019) reviewed the marketing of prescription drugs, disease awareness campaigns, health services and laboratory tests and the related consequences and regulation in the US over a twenty-year period.[3] The most rapid marketing increase was for DTCA and the figure for DTCA for 2016 was reported as being $9.6 million which represents 32% of total medical marketing spending. The College has been unable to find figures related to DTCA, percentage of total pharmaceutical industry marketing costs, or the degree of cost shifting to consumers in New Zealand.

19. DTCA presents a misleading and false picture of the need for prescription medication and creates a need rather than meeting a need. The best interests of the public, avoidance of harm, the medicalisation of normal experiences, overuse of, and inappropriate use of medication, and increasing health care costs, justify government taking the very overdue step of prohibition of DTCA. The Standing Committee on Health in Canada reviewed the health aspects of prescription drugs and stated, "The Health Committee is concerned about the rising cost of health care in Canada and about the role of drug expenditures as a significant factor. It is convinced by research

[3] Schwartz, L. M., & Woloshin, S. (2019). Medical marketing in the United States, 1997-2016. *JAMA*, 321(1):80-96.

evidence suggesting that direct-to-consumer advertising of prescription drugs contributes to these costs." [4]

20. In respect to DTCA, the Standing Committee on Health in Canada specifically recommended:

    - *Health Canada immediately enforce the current prohibition of all industry-sponsored advertisements on prescription drugs to the public;*
    - *Health Canada ensure the provision of independent, unbiased and publicly financed information on prescription drugs to Canadians;*
    - *Health Canada dedicate specific resources to the Health Products and Food Branch Inspectorate for vigorous enforcement of the direct-to-consumer advertising regulations on prescription drugs, including active surveillance of all relevant media, identification of potential infractions, appropriate corrective action, and production of annual public reports;*
    - *Health Canada ensure that all direct-to-consumer advertising complaints about prescription drugs received by Advertising Standards Canada or the Pharmaceutical Advertising Advisory Board are forwarded to Health Canada for investigation and action.*

21. The Therapeutic Products Regulatory Scheme consultation document does not address prohibition of DTCA, and media reports have suggested the Minister of Health sees no urgency in addressing this issue, with recommendations that industry should be socially responsible being made. With respect, the College notes that NZ is an outlier country in terms of evidence-based robust opposition to DTCA and that self-regulation by industry does not address the negative effects of DTCA and the majority, if not all, examples of self-regulation by industry appear to be unsuccessful. We would like to refer to the recommendations made to Health Canada in 2004, outlined in point 19 of this submission, which resulted in the prohibition of DTCA, which has not been reversed by the Canadian Government. As New Zealand is one of only two countries supporting DTCA, the College considers that for the Government to meet their own public health policies, obligations, responsibilities and health budgets, prohibition of DTCA via the Therapeutic Products Regulatory Scheme is essential.

[4] Standing Committee on Health Canada. (2004). *Opening the medicine cabinet: First report on health aspects of prescription drugs.* Ottawa, House of Commons Canada.

Cells and tissue

22. The College has some concerns in terms of the commercialisation of cells and tissues and consider that more details about the approach to prevention of this in New Zealand would be beneficial. We note that information to the public about cord blood banking from private commercial entities who promote autologous cord blood banking has not always provided sufficient accurate information to enable parents to make an informed decision, but rather the information has taken advantage of the vulnerability of new parents and their fears for their infant. As commercial blood banking and any commercial transactions involving cells and tissue have profit making as their main aim, the College is against commercialisation and trading. We also support a much more rigorous approach to procurement, informed consent processes, testing, processing, transport, storage, distribution and import and exports, and also rigorous compulsory documentation and reporting of infection, transmission of disease, and treatment failures. We support the requirement of product approval on engineered cells and tissues.

Conclusion

Prescribing is within the Scope of Practice of midwives and midwives will prescribe and administer medications to women and neonates predominantly during the usual pregnancy, birth and postpartum experience. The College welcomes this opportunity to provide feedback to the Therapeutic Products Regulatory Scheme consultation process and we support the overarching need for regulatory change.

Ngā mihi

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