AUCKLAND WOMEN'S HEALTH COUNCIL

SUBMISSION ON

MEDICINES AMENDMENT BILL

The Auckland Women's Health Council (AWHC) is an umbrella organisation for individual women and women's groups in the Auckland region who have a commitment to women's health issues. The focus of the Council is broad and spans many issues that are of interest to women, particularly those that impact on their health and wellbeing and the health of their families.

Since the release of the Cartwright Report in 1988 the AWHC has had a special interest in the implementation of the recommendations in the Cartwright Report including the rights of health consumers, informed consent processes and the development of the Health Consumers' Code of Rights. As a result the Council was very involved in the establishment of the National Cervical Screening Programme and the NCSP Register, as well as the establishment of the Office of the Health and Disability Commissioner and the development of the Code of Consumers' Rights.

General comments
While the AWHC acknowledges that a major overhaul of the Medicines Act 1981 is long overdue and notes that such a review was attempted by the previous government, the Council has major concerns about some of the proposed amendments in the Medicines Amendment Bill as well as the omission of a number of significant issues that need to be included.

The changes in the Medicines Amendment Act that the AWHC is supportive of are –

1. The revision of definitions to align with international norms.

2. Extending the authorised categories of who may prescribe medicines.

Medical devices
The failure to include the regulation of medical devices in the Bill is one that must be remedied by the Health Select Committee. This omission places the New Zealand public at continued risk and recent events have clearly demonstrated this. The Medicines Amendment Bill therefore represents an important opportunity for the government to put in place the protective legislation and safeguards that are long overdue.

The lack of protection experienced by patients in New Zealand from companies who manufacture substandard or faulty medical devices and then delay

acknowledging the problem, sometimes for years, is a major problem that needs to be addressed immediately.

The response to an enquiry the AWHC made to the Ministry of Health in September 2011 about such medical devices stated that the Medicines Act "does not include provision for any pre-market assessment or approval system for medical devices. Neither is there a requirement for medical devices to be approved by any overseas medical device regulator before they may be supplied here." This leaves the New Zealand public unprotected and at risk in what has been described as a fairly under-regulated environment. Some recent examples of the impact on patients of medical device disasters are as follows:

ASR hip joints

The ASR hip joints manufactured by DePuy, a subsidiary of Johnson & Johnson, is just one recent example of what can and does happen when an untested medical device is unleashed on an unsuspecting public. This device is reported to having been implanted in around 93,000 around the world, including 507 in New Zealand. High levels of cobalt and chromium have been found in blood tests undertaken in many of those with these hip joints. Years of pain as a result of damage to surrounding tissue is one of a number of complications associated with the use of this device.

This situation is unacceptable, especially when the New Zealand Ministry of Health added insult to injury by doing nothing more that referring patients to their doctors while relying on DePuy/Johnson & Johnson to inform New Zealand surgeons of the recall of the ASR hip joints. It was thus left to the media to inform the public that patients with ASR hip joints were at risk.

Thus New Zealand's unregulated environment continues to result in significant harm to New Zealand patients who trust their doctors to know whether the device they are having implanted is safe and effective.

French breast implants

The other major medical devices to have been shown recently to be severely substandard are the breast implants manufactured by Poly Implant Prothese (PIP). As recent publicity about PIP has revealed, the breast implants manufactured by this company were among the cheapest in the world and have now been found to be filled with substandard, industrial grade silicone which has caused considerable harm to large numbers of women. The AWHC is still waiting for a response to our letter asking how many New Zealand women have had PIP implants inserted.

The gynaecological mesh

Problems with the use of gynaecological mesh were brought to our attention when we attended the National Women's Health clinical report day in August 2011. A copy of an article that was written on the issue and appeared in the October issue of the AWHC newsletter is attached as Appendix One.

In researching the article on the use of gynaecological meshes we found a case study on the ACC's website about this device and after posting the article on the AWHC website, the Council was subsequently contacted by a woman who was experiencing severe problems as a result of having the mesh implanted.

The AWHC believes that events such as these demonstrate that New Zealanders need far more protection from untested and unsafe medical devices than is currently being provided. As Medsafe is only able to order the withdrawal of products from the New Zealand market and in the three examples provided above, did not even do that, the health agencies charged with ensuring that patients are safe have clearly failed in their duty. The need to introduce regulations for medical devices is demonstrably one that requires attending to with considerable urgency. It cannot wait until the new Australia and New Zealand Therapeutic Products Authority (ANZTPA) gets underway as this is likely to take years.

The AWHC is therefore recommending that Medicines Amendment Bill include not only a new definition of the meaning of "medical device", it must also introduce significant regulations on the use of all medical devices.

Earlier this year the AWHC produced a critical submission on the new Standard Operating Procedures for ethics committees. One of our concerns was that they gave an ethics committee chairperson the authority to give approval to a research study using new medical devices that are considered Class IIb under the Australian TGA classification system, despite the fact that this category is deemed to be medium to high risk. This is further evidence of the need to include regulations for medical devices in the Medicines Amendment Bill.

Combination products

A member of the AWHC attended the Medical Law conference held in Wellington at the end of March where the issue of nanomaterials, and nanomedical products was brought to our attention in a presentation given by Jennifer Moore. This new technology is resulting in the production of a wide range of combination products, combination products being those that combines a drug or medicine and a device into a single product.

The Council notes that the Bill does not include a definition of "a combination product." In order to regulate such items, whether as medicines or as medical devices, the Bill must include a definition of a combination product.

Nanomedicines are some of the combined products that are already entering the market. It is essential that there is adequate regulation of nanomedicines in order to ensure that in the current unregulated environment the general public is protected from this new technology. The AWHC is now aware that nanomaterials are currently to be found in cosmetics, sunscreens, food packaging and herbal remedies. They are also being used in medicines and medical devices.

It is therefore clear that the Medicines Amendment Act must address the issue of combination products.

The Pharmaceutical Industry

The AWHC has watched with increasing concern the various attempts by the pharmaceutical industry to undermine the systems that New Zealand has in place to provide access to affordable medicines, to provide access to effective and affordable new medicines, and to ensure that patients are adequately informed by their health professionals about the benefits and risks of the medicines and medical devices they use.

The Council believes that New Zealand must retain agencies such as PHARMAC and the Centre for Adverse Reaction Monitoring (CARM), and protect them from any attempts by drug companies or any trans Tasman authorities to undermine or change them. New Zealand needs its own independent pharmaco-vigilance safety monitoring body, and will continue to need it even after ANZTPA become fully functional.

New Zealand consumers are more vulnerable than consumers in nearly all other countries due to the “accident” that resulted in an environment where direct-to-consumer advertising (DTCA) is permitted. DTCA of prescription medicines is legal only in the USA and in New Zealand. In both countries the growth in this form of drug promotion has been spectacular and has rarely been in the best interests of consumers or the New Zealand health system. This situation is exacerbated by the power that the Minister of Health has in regard to the approval of medicines.

The independence of the approvals decision-making process from the hype and electioneering promises that appear during the three-year election cycle, and from pressures or inducements made by the pharmaceutical industry is a vital component of the confidence the New Zealand public needs to have in its health system. A recent example of this was the over-riding during the 2008 general election of the evidence-based decision of PHARMAC’s specialist advisory committee to offer only a 9-week course of the breast cancer drug Herceptin, and promise the introduction of a 12-month treatment regime.

The AWHC is therefore recommending that approvals for all medicines and medical devices should be transferred to the office of the Director-General of Health who already has the power to approve changed medicines. This would remove it from the politicking on health issues that are not evidence-based.

Another issue of concern to the Council is the ongoing hype coming from the pharmaceutical industry during the introduction of new drugs that are usually “me-too” drugs. “Me-too” drugs do not offer any improvement in effectiveness than the previous version of the drug that has just come out of its patent period. The new drug is of course much more expensive than the previous version of the

same medicine, and have often not had a sufficient period of testing to reveal their serious side effects.

The AWHC remains strongly opposed to direct-to-consumer advertising and urges the government to put an end to this practice.

Informed consent and the Code of Consumers' Rights

A major problem with the current unregulated environment as described in our submission is that it does not fulfil the requirements for informed consent as described in the Code of Consumers' Rights.

The issue of informed consent was enshrined in legislation in 1996 as a result of the callous disregard of women's rights at National Women's Hospital during the decades between the 1960s and 1980s. The release of the Cartwright Report in 1988 resulted in both the establishment of the Office of the Health and Disability Commissioner and the development of the Code of Consumers' Rights which came into effect on 1 July 1996. New Zealand patient rights under the Code of Rights are thus enshrined in legislation whereas Australian patients are not protected in the same way. This difference must be borne in mind when the ANZTPA is fully established.

Finally, the AWHC would like to appear before the Select Committee to speak to our submission.

13 April 2012

APPENDIX ONE

The Gynaecological Mesh

The use of mesh to surgically repair uterine and vaginal wall prolapse has been around for more than a decade. It is now a widely-used procedure for pelvic organ prolapse (POP) and for the treatment of stress urinary incontinence.

Pelvic organ prolapse is a common condition that affects many thousands of women worldwide, and surgery rates to correct prolapse have been steadily increasing throughout the western world.

There are two types of mesh used in surgery: biological and synthetic. While the use of mesh quickly became the treatment of choice, there is now considerable anxiety and uncertainty about the long-term outcome of these interventions. Some of the currently available mesh materials and techniques using mesh in gynaecological prolapse surgery have been found to be associated with significant morbidity. (1)

At the National Women's Clinical Report day held on 16 August 2011 guest speaker Professor Julie Quinlivan referred to the problems associated with the use of mesh. During her PowerPoint presentation she posed the question: "Should you be using vaginal mesh outside of a trial setting?" and went on to highlight the concerns that have been raised in medical journals and by the US Food & Drug Administration (FDA). (2)

Prompted by increasing numbers of adverse reports the FDA issued a safety advisory in October 2008 regarding the use of mesh. A new FDA safety advisory released in July 2011 stated that there are serious concerns over the use of vaginal mesh for the treatment of vaginal prolapse and incontinence.

The FDA reported that the occurrence of serious complications with the use of vaginal mesh is not rare**,** and mesh use is not proven to provide improved outcomes when compared with native tissue repairs. The FDA-reported complications associated with vaginal mesh include erosion through the vaginal epithelium, infection, pain, urinary problems, recurrence and/or incontinence, bowel, bladder and blood vessel perforation during insertion, and the requirement for additional surgical procedures.

A New Zealand example of what can happen with the use of vaginal mesh can be found on the ACC website in a treatment injury case study that describes the horrific injuries sustained by "Jane, a 48-year-old mother of three." (3)

In her presentation to those attending the NWH Annual Clinical Report day Professor Quinlivan outlined how medical devices are cleared by the FDA and how some are able to avoid having to undergo clinical trials before they are put on the market.

Medical devices are classified thus:

- Class 1 (low risk)
- Class 2 (Mesh, contact lens sol- ution, external hearing aid, etc)
- Class 3 (high risk)

The process for class 2 has two options. The first option is used by the pharmaceutical industry when they want to market their device as having FDA approval. To obtain FDA approval clinical trials are required, making this option more expensive.

The second option is much cheaper and is referred to as the 510k option. It involves a payment of $US510,000 which clears the product for market without the requirement for clinical trials, but it means that the device does not have the status of having been approved by the FDA and it cannot be marketed as having FDA approval.

When the device is one that is similar to other medical devices already on the market, eg hip joint replacements, the 510k option is used.

The manufacturers of medical devices are of course highly moti-vated to classify any new device as Class 2 and get them quickly on to the market, usually with a massive advertising campaign claiming that it is much better than anything else currently available.

Professor Quinlivan reported that 113 devices were either withdrawn from the market or recalled between 2005 and 2009, and 71% of them were Class 2 “510k” devices! (2)

New Zealand has Medsafe to ensure that the New Zealand public is protected from unsafe medicines and medical devices. Medsafe is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand. (4)

For a medical device to be legally supplied in New Zealand it is required to be notified to a database operated by the Ministry of Health. This database, known as the Web Assisted Notification of Devices (WAND) is used to collect information about the range of medical devices supplied in New Zealand, the manufacturers that produced them, and the individuals or organisations responsible for supplying them.

While the supply of medicines and medical devices in New Zealand is controlled under the Medicines Act 1981, the Act does not include provision for any pre-market assessment or approval system for medical devices. Neither is there a requirement for medical devices to be approved by any overseas medical device regulator before they can be supplied here, says Medsafe senior advisor Robert Jelas. New Zealand relies on medical device regulators in countries with “robust pre-market approval schemes” such as Canada, Australia and the European Union.

So medical devices can be used on the unsuspecting public without having undergone any clinical trials.

References

1. Royal College of Obstetricians and Gynaecologists. “*The Use of Mesh in Gynaecological Surgery*.” Scientific Advisory Committee Opinion Paper 19. April 2010.
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3. www.acc.co.nz/PRD_EXT_CSMP/groups/external_providers/documents/reference_tools/prd_ctrb094968.pdf
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