REPORT TO IM HEALTH TRUST

Complementary Medicines, Natural Products, Traditional Products, Supplements, Vitamins etc.

You have asked me to research and review Coronial records re the above products together with prescription and other drugs, to identify if they have been involved in Coronial Inquests and deaths.

In my capacity as Acting Chair of the Coroners' Council, I enquired of all Coroners as to whether or not from a search of their Coronial findings they could find any instances where there had been a problem with any of the above products. They were asked to provide any information from inquests where these products had been involved in the inquests whether or not a death had resulted.

At the same time the Coronial records held by the Ministry of Justice in Wellington were searched at my request by ministry staff.

Apart from a couple of replies from Coroners indicating that they had on-going inquests relating to party pills, and the matter referred to in the next paragraph, there has been no death or incident involving any of these natural products reported by Coroners. A search of the Coronial records held in Wellington has similarly revealed no incidents.

There is one more recent inquest in 2003 relating to a large vitamin tablet which was too large for a 3yr old child to swallow. It caused the death of a child be getting stuck in the throat and the child choked to death despite the frantic efforts of the mother administering the tablet. That is more the form of delivery of the product rather than any reaction to the product itself.

In March 2006, Close Up ran a story of a woman who was pregnant with her 3rd child. She knew from her baby book she needed to take folic acid. She said she thought she was taking the right precautions to prevent defects such as spina bifida. At the 5 mths scan she learnt her child was spina bifida and had an enlarged brain. The pregnancy was terminated on advice the baby would die.

The programme explained as follows:

"By taking folic acid pills Wendy thought she was taking the right precautions. They decreased the chances of birth defects like spina bifida. What she didn't realise is the Ministry of Health recommends taking 800 mg per day. The pills like these ones which are sold in health food shops and supermarkets, only have 300 mg so for Wendy to get the right dosage she would have to go to the pharmacy. "

There were no warnings on the labels nor any instructions about how many to take. The applicable regulations are the Dietary Supplement Regulations 1985 which state a maximum level of 300mg folic acid in a dietary supplement. No advice was given on the sale and nothing on the label so the mother, although thinking she was taking folic acid, was way under the requisite minimum dosage level required for her pregnancy. This was product manufactured and sold through health shops and supermarkets. In fact there was available at the time an across the counter folic acid

tablet but only from pharmacies. This was an 800mg tablet and certainty as to this being the actual level of folic acid in the tablet. But with health food products under the Dietary Supplement Regs they are regulated as foods and there is no guarantee that the actual smaller level of folic acid is in fact present in the tablet in any event.

I am also informed of one incident involving an Indian herbal product, K4 apparently sold by direct mail. A Coronial Inquest in NZ ruled there was no case re K4 and left an open verdict of non viral hepatitis as the cause of death. It is understood that the person had a pre-existing prostate cancer condition and had taken a wide variety of substances. An abstract summary is set out below:

"At an inquest in November 1996, doctors and the Ministry of Health linked his death with K4. The coroner adjourned the hearing until April 1997 to give manufacturers of the tablets time to complete toxicological studies, but he was unable to say with any certainty that K4 was the cause of his non-viral hepatitis. The coroner found that the death was due to non-viral hepatitis of unknown origin.
Despite these comments the coroner said that the K4 ban should be extended until a joint study had been done on K4's liver toxicity."

K4 was apparently also implicated in a death in Australia of a 78 yr old man. No post mortem was performed or doctors notes available. Patient apparently had prostate cancer and was on a cocktail of other drugs along with K4, was a regular spirit drinker and a smoker. Death was from massive liver fibrosis.

The MOH newsletter re its concerns is set out below:

ADVERSE REACTION NEWSLETTER 1996:4 Page 1 of 1

The Centre for Adverse Reactions Monitoring (CARM) is receiving increasing numbers of reports of adverse reactions to herbal products. Recently reports of liver damage, including one death, prompted the Ministry to recall "K4", a herbal product promoted for prostate problems. Herbal medicines are not subjected to the rigorous testing given conventional medicines, yet they are often perceived to be without adverse effects by the consumer. It is important that adverse reactions to herbal products are reported to CARM in order for products associated with serious events to be identified early and appropriate action taken.

Liver problems and K4

K4 was advertised for the treatment of prostate problems and only sold by mail order in New Zealand.

K4 contains 25-30 herbs. The Ministry of Health has been unable, to date, to ascertain which ingredient(s) of K4 may be responsible for the reported liver damage.

The Ministry strongly recommends:

1- Patients stop taking K4 and attend a general practitioner for an assessment of liver function; and
2- Medical partitioners report any adverse effects from herbal medicines, especially K4, to the Centre for Adverse Reactions Monitoring.

A Health Risk Expert, recognised by the MOH, has advised of conducting extensive medical literature research throughout the world for incidents with these products. There has also been considerable communication with professors around the world seeking to identify any incidents. The result as advised is overwhelming lack of evidence identifying fatalities/incidents involving natural products.

Subsequently all Coroners, other pathologists and Crown Prosecutors have been emailed to provide their best guess of drug induced / involved deaths. A broad brush percentage was requested. There have been a number of inquests relating to suicides / risk taking in respect of prescription drugs. Party pills are included. Responses have indicated a best guess percentage of 5% of deaths. That is approximately 200 deaths per annum. Contrast this to Natural products etc which has nil deaths per annum. These figures are considered very much on the light side due to the way the Coronial database records are recorded. Unless the Inquest finding words actually refer to the adverse drug event the search will not pick it up. The wording of the findings by Coroners differs markedly and the precise cause of death, although caused by an adverse drug event, may not record this. By way of example the finding may record the cause of death as organ failure but not go on to say as a result of an adverse drug event. .

A recent published study of the deaths in New Zealand with a base year 1998 shows the number of deaths from adverse drug reaction to be 1524 and from highly preventable adverse drug reaction 669. That does not include deaths from suicide relating to drugs.

A recent Australian study shows that 1 in 10 patients presenting to a GP had an adverse drug event in the preceding 6 months with 50% being in the moderate to severe range and 8% hospitalized.

A recent NZ study published on 23 June 2006 highlights avoidable hospital admissions. It shows that 1/3rd of hospital admissions are avoidable. The cost associated with that for Christchurch hospital was put at $96.6M. The study was carried out in the context of the importance of public and primary health measures to improve the health of New Zealanders before they got admitted to hospital. The majority of potentially "avoidable hospitalisation" involved conditions that could have been identified and treated earlier.

Another NZ study reported in July of 2006 and referred to Parliament's Health Committee pointed to previous research suggesting problems such as hospital-acquired infection, drug error and staff mistakes, could cost $870M a year. This prompted the Health Minister to ensure that DHB's gave priority to reducing adverse events. These were clearly mostly identified as drug induced.

The above studies relate to prescription and other drugs and not to traditional/natural/complementary products etc.

Many international studies point to the huge cost from drug-related patient injury and death. In the United States this cost is put at billions of dollars. One study puts complications resulting from medication errors in US hospitals at 1.5 billion every year. Studies also show that prescription drug errors double a person's risk of dying in hospital and cost an estimated 2 billion a year. Another study put the cost of a single adverse drug event to a hospital in the US at $2,500. The estimate of costs incurred by US hospitals as a result of drug-related injury or death was put at 76.6 billion which was three times the cost of all diabetes care.

A recent analysis done of patients being admitted to a major hospital in the Auckland area shows that nearly 50% of patients who come to hospital with more than 5 medicines are admitted with problems relating to ascertaining a way of getting an accurate list of their medicines in a timely manner. In other words 50% of patients are admitted with an error on their charts. Another 50% were estimated as being

non-compliant – i.e. they got an element of their medicine taking wrong. The US estimates put a figure of every $1 spent on medicines; another $1 is spent on sorting the problems that arise out of them.

What is ironic here is that what is being held out as a justification for high regulation and compliance in the area of Complementary Medicines, Natural Products, Traditional Products, Supplements, Vitamins etc, is public safety and risk. Despite a diligent search of Coronial records and the literature, no instances have been found to demonstrate that in fact with these products in NZ there is any serious public health issue or risk to the public. The problem is clearly with prescription and other drugs and no demonstrable risk at all with these natural products. Having said that, the folic acid and K4 incidents highlight the need for better regulation and controls in this whole area, updating of regulations and appropriate dosage levels, labelling and advice on sale.

The Coronial and literature searches in so far as natural products etc are concerned and linkages to public safety and risk can be described legally as De minimis non curat lex. That is-- of minimal risk importance. The law (regulations etc) does not and should not concern itself with trifles.

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18 July 2006

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