

SUBMISSION TO FSANZ

APPLICATION A576 – Labelling of Alcoholic Beverages with a Pregnancy Health Advisory Label

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Background

Diethylstilboestrol (DES) is a synthetic oestrogen that was developed to supplement a woman's natural oestrogen production. It was first prescribed in 1938 for women experiencing miscarriages or premature deliveries and was originally considered effective and safe. In 1971 physicians were advised to stop prescribing DES to pregnant women because it was linked to a rare vaginal/cervical cancer in female offspring. Since 1971 research has shown:

- Women prescribed DES while pregnant, known as DES mothers, are at a modestly increased risk for breast cancer.
- Women exposed to DES before birth (in the womb), known as DES daughters, are at an increased risk for clear cell adenocarcinoma (CCA) of the vagina and cervix, increased risk for breast cancer after age 40, reproductive tract structural differences, pregnancy complications and infertility. The risk for developing CCA is 1:1,000 DES daughters. Although DES daughters appear to be at highest risk for clear cell cancer in their teens and early 20s, cases have been reported in the 30-50 age groups. This cancer is aggressive and should be detected early.
- Men exposed to DES before birth (in the womb), known as DES sons, are at risk for non-cancerous epididymal cysts.

There is specific preventive health care for DES exposure. (See www.health.nsw.gov.au/des) The cancer risk to DES daughters has not passed, with cases now occurring in the 40s and 50s age groups. (See <http://obgyn.bsd.uchicago.edu/registry.html#accessions>)

Researchers are still following the health of the DES exposed population to determine whether other health problems occur with age. There may be many people who do not know whether they were exposed to DES and some women may not remember taking DES. DES information is important because people who were exposed must be vigilant about their own health care – to detect cancers early, demand high risk obstetric care when pregnant and factor in their exposure when making decisions about HRT use. It is as much part of a person's medical history as a family history toward heart disease or diabetes.

The Australian Adverse Drug Reactions Unit of the Therapeutic Goods Administration (TGA) has data of 17 case reports of DES associated cancer. The failure to report cases has been acknowledged. With the known risk of 1:1,000 DES daughters developing the associated cancer, this means there are conservatively at least 17,000 DES daughters, the equivalent number of DES sons and 34,000 DES mothers, thus totalling at least 68,000 Australians affected. There has been refusal by the TGA to complete regular reciprocal cross-checks of Australian cases that have been reported to the International DES Registry, held in Chicago USA. There are approximately 129 cases of the cancer type associated with DES held in data by the Australian Institute of Health and Welfare, for which DES exposure has not been investigated.

To date there has been no concerted campaign to inform and educate the Australian population about DES. Up until June 2004, there had only been

small intermittent media coverage (not initiated by Government) to inform the public about the danger of DES exposure. As a result of a nation-wide media release containing misinformation by the TGA in June 2004, DES daughters now mistakenly believe that their increased cancer risks have passed and that they no longer require their special annual "DES examinations" for their life-saving cancer prevention. The media release is tragically misleading, since it is known that DES daughters continue to require special care for their ongoing increased cancer risks. The TGA has so far refused to issue an updated media release about DES for the benefit of the population at large, in spite of the overwhelming evidence relayed by DES Action Australia-NSW showing that the TGA's media release was incorrect and potentially harmful. The TGA has recently received correspondence from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Royal Australian College of General Practitioners stating concern on this matter and requesting that the TGA issue an updated media release about DES.

Summary in relation to Application A576

The anti-miscarriage drug, DES (diethylstilboestrol) has wrought havoc on the lives of Australian women who were given DES during pregnancy and also on the lives of their children exposed to the drug in that pregnancy. Living with the effects of reproductive problems and increased cancer risks, the victims of DES know too well the tragic consequences when harmful substances cross the human placenta to the unborn. The plight of DES exposed Australians (and those Australians yet to discover their DES exposure) has been exacerbated, firstly by the lack of publicity about DES, and then by the Government's release of misinformation about DES. The rights of Australians to know the risks attached to DES exposure have unfortunately been ignored. In view of these negative experiences and to help prevent unnecessary suffering to the unborn due to alcohol, our organisation, DES Action Australia-NSW supports the labeling of alcoholic beverage containers with a health advisory label regarding alcohol consumption when planning to become pregnant and during pregnancy. The guideline in *Australian Alcohol Guidelines* in relation to childbearing women should be amended to properly reflect the message that there is no known safe level of alcohol for the developing unborn baby. There should be a separate guideline for women who are breastfeeding. This Assessment has not addressed the very important matter of the sale of portion serves from alcohol beverage containers at licensed venues. There should be consideration in this Assessment for visible signage at licensed venues where alcoholic beverages are served and appropriate measures taken to ensure that consumers of served alcoholic beverages receive the same health advice on signage as that on alcohol beverage containers. As an adjunct to labeling of alcohol beverage containers, health advice in relation to the consumption of alcohol by child bearing women should be a part of wider public health strategy and this should include advice for women who are breastfeeding. All written health advice statements targeting consumers in relation to the consumption of alcohol by childbearing women should be accompanied by an appropriate pictorial image. Our organisation, DES Action Australia-NSW believes strongly that consumers

have a right to know the risks attached to consumer products that are harmful to the developing baby.

We therefore prefer Option 2 –

Amend the Code to require a health advisory label on alcoholic beverage containers advising of the risk of consuming alcohol when planning to become pregnant and during pregnancy.

Comment on draft *Australian Alcohol Guidelines*

The guideline which applies for women planning pregnancy or who are pregnant should reflect the fact that no level of alcohol consumption has been determined as completely low risk for the foetus, ie, there is no known safe level of alcohol for the unborn baby. The draft guideline "Not drinking is the safest option" does not reflect this, but rather suggests that there are alcohol levels in a safety range. The term "safest option" may mislead a person to believe that a small amount of alcohol will not be harmful or even carry the least harm in the instance where fetal alcohol syndrome is not properly understood. The current guideline can be interpreted loosely to be dangerously misleading for women planning a pregnancy or who are pregnant.

Since the risk of Foetal Alcohol Syndrome (a very serious health condition) is a concern exclusively for women planning pregnancy or who are pregnant, it is not appropriate to include women who are breastfeeding (probably with lesser and probably with less definitive risks) in the same guideline as that for women planning pregnancy or who are pregnant.

We therefore suggest that there be one guideline for women planning pregnancy or who are pregnant and one other guideline for women who are breastfeeding.

A preferred wording would be: *For women who are pregnant or planning a pregnancy - Not drinking is the best measure to prevent harm to the unborn baby.*

We believe that the guideline in *Australian Alcohol Guidelines* in relation to childbearing women should be amended to properly reflect the message that there is no known safe level of alcohol for the developing unborn baby. We also believe this guideline should not encompass women who are breastfeeding, but rather there should be a separate guideline for this group of childbearing women.

Comments on some Initial Assessment Questions **(Questions 7, 9, 11, 12, 15)**

Question 7: Do you think a health advisory statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy on all alcoholic beverage containers should be required? Why/why not?

Yes - as well as visible signage at licensed venues where alcoholic beverages are served. The health advisory statement should also be part of a wider public health strategy.

Past media messages have conveyed health benefits of alcohol, without details regarding which specific population groups obtain benefit and which groups do not. For many people this would result in confusion about the safety of alcohol when planning pregnancy or when pregnant, or result in the immediate assumption there would also be health benefits for the developing unborn baby. In Australia there are population groups for whom alcohol consumption in pregnancy is an entrenched behaviour for cultural or other reasons.

There would be people, including pregnant women, who would consume alcohol only in the form of served beverages. This poses the question of whether it is incumbent on liquor licensees to provide appropriate advice where health advisory statements are provided on alcoholic beverage containers. Regardless of the responsibility of licensees in this matter, it would be irresponsible to disregard the rights of people in this consumer category to know the risks of alcohol for the developing unborn baby. The serving of alcohol beverages by liquor licensees is an important matter that should be raised in this Assessment, with view of the provision of visible health advisory signage at licensed liquor venues where alcohol beverages are served.

Literacy levels vary in Australia and there would be people who do not read labels or signage. There would be people who are literate, but who respond poorly to written messages. A wider public health strategy should be considered in this Assessment and this strategy should also include health advice about the consumption of alcohol by women who are breastfeeding.

Question 9: What wording for a statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy would be appropriate on an alcoholic beverage container to raise awareness in pregnant women and women planning to become pregnant?

Wording should be simple to reflect that there is no known safe level of alcohol and that there is risk of harm to the developing baby with any amount of alcohol. The message should eliminate the possibility of people mistakenly believing a small amount of alcohol is safe. The current labeling advice in France provides a reasonable model with a well-rounded, easily understood message. We consider the term "developing baby" has more benefit than the term "developing unborn baby", since it encompasses the post-birth period. This may help encourage people to consider the risk of consuming alcohol when breastfeeding.

Suggestion for wording:

Scientific research shows drinking alcohol, even in small quantities, when planning to become pregnant or during pregnancy can have serious health effects such as mental retardation on your developing baby.

Question 11: What are the advantages and disadvantages of a written statement compared with a pictorial image for conveying the risks of consuming alcohol when planning a pregnancy and during pregnancy?

A comparison of a written statement with a pictorial statement is irrelevant in a country where there is wide variance in literary skills and people of non-English speaking background. Australia is one such country and so in Australia there should be both a written statement and an appropriate pictorial image provided on alcohol beverage containers (as well as on signage at liquor licensed venues) about the risks of consuming alcohol when planning a pregnancy and during pregnancy. By stating advantages and disadvantages of each communication method as a comparison in the context of this Assessment, it would be discriminatory to a sizeable section of the population. This question should not be used in this Assessment.

Question 12: What percentage of alcohol by volume should be used to determine which alcoholic beverages are to carry an advisory statement, if required?

No level of alcohol consumption has been determined as completely low risk for the foetus. Therefore, this question is irrelevant and should not be used in this Assessment.

Question 15: How would labeling alcoholic beverages compare in terms of effectiveness and cost-effectiveness with other public health measures to inform pregnant women of the risks of alcohol consumption during pregnancy?

There would be people, including women of childbearing age, who would not take notice of alcoholic beverage labeling and so would not become aware of health advice, were it not for a publicity campaign. This would especially be the case for people who have familiarity with certain alcohol brands and would likely see no reason to view the label. The huge impact of publicity campaigns in raising public awareness of issues is widely known and has distinct advantages for those with poor levels of literacy or who respond poorly to written messages. Labeling alcoholic beverages provides health advice on the product source of risk and this would be important to consumers in understanding the seriousness of the advice. The implementation of a concurrent publicity campaign would serve as an adjunct. Credibility of a publicity campaign would be lessened if there was absence of health advice on the product source of risk. The public may easily receive the

impression that the publicity campaign message is not accurate, or serious if there is no product labeling to verify the information. The combined effect of both in terms of effectiveness and cost-effectiveness would outweigh the implementation of either on its own. The publicity campaign should also include information about the risk of consuming alcohol when breastfeeding (including a pictorial image).

Clearly, labeling alcoholic beverages without publicity campaign and vice versa, promises a lowered effectiveness of each conducted on its own. This question has ruled out consideration of the effectiveness of labeling alcoholic beverages with an adjunctive wider public health strategy. In seeking a comparison, this question alludes to acceptance of a second rate effort with questionable effectiveness in responsibly providing health advice about risks of alcohol consumption for childbearing women. This question should not be used in this Assessment.

Information Sources

www.cdc.gov/des

www.desaction.org

www.health.nsw.gov.au/des

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Australian Institute of Health and Welfare data: incidence of clear cell adenocarcinoma of the vagina/cervix

Adverse Drug Reactions Advisory Committee Minutes 1971-2003

Australian Drug Evaluation Committee Minutes 1967-1981