Distilled Spirits Industry Council of Australia Inc

Submission on the Initial Assessment Report for Application A576

Labelling of alcoholic beverages with a pregnancy health advisory label

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Distilled Spirits Industry Council of Australia
PO Box 1098
South Melbourne
VIC 3205
Tel: 03-9696-4466
Fax: 03-9696-6648
www.dsica.com.au

Distilled Spirits Industry Council of Australia Inc.

The Distilled Spirits Industry Council of Australia Inc (DSICA) is the peak body representing the interests of distilled spirit manufacturers and importers in Australia. DSICA was formed in 1982, and the current member companies are:

- Bacardi Lion Pty Ltd
- Brown-Forman Australia
- Bundaberg Distilling Company
- Diageo Australia Ltd
- Beam Global Spirits & Wine Inc
- Maxxium Australia Pty Ltd
- Moet Hennessy Australia Pty Ltd
- Suntory (Australia) Pty Ltd
- William Grant & Sons International Ltd

DSICA's goals are:

- to create an informed political and social environment that recognises the benefits of moderate alcohol intake and to provide opportunities for balanced community discussion on alcohol issues; and
- to ensure public alcohol policies are soundly and objectively formed, that they include alcohol industry input, that they are based on the latest national and international scientific research and that they do not unfairly disadvantage the spirits sector.

DSICA members are committed to:

- responsible marketing and promotion of distilled spirits;
- supporting social programs aimed at reducing the harm associated with the excessive or inappropriate consumption of alcohol;
- supporting the current quasi-regulatory regime for alcohol advertising; and
- making a significant contribution to Australian industry through primary production, manufacturing, distribution and sales activities.

EXECUTIVE SUMMARY

DSICA recommends that Application A576 should not proceed and that FSANZ adopt Regulatory Option 1 – maintain the status quo for the following reasons:

- Health advisory statements are ineffective by themselves and do not alter the behaviour of drinkers.
- The evidence for recommending abstinence remains contradictory and there is no consensus among governments or health practitioner organisations as to advising women on low or moderate consumption**.** Without a consensus, labelling will be ineffective.
- Labels are not costless or low cost to industry, government or to women consuming alcohol.
- The resources would be better spent on educating health professionals and improving the advice and treatment of those women most at risk.
- Australia and New Zealand should replicate Canada's comprehensive response to FAS/FASD.
- DSICA could only support labelling if it was part of an established comprehensive public education and health campaign, subject to further conditions:
    a) An effective and thorough monitoring and enforcement program by government
    b) A substantial research program on the target audiences' motivations and the label specifications.

The Initial Assessment Report is comprehensive and includes much of the research that was available in 2007. However, additional research has become available and is cited in parts of this document.

DISCUSSION

1. FSANZ has erred in accepting Application A576 in that this application was in fact subsumed within the earlier application A359 requesting a warning stating 'This product contains alcohol. Alcohol is a dangerous drug'. The requested warning in the current application is more specific in its subject, but it clearly falls within the scope of the earlier proposed warning message. There are no advances in research since the rejection of Application A359 that indicates labelling is effective.

2. There is a strong consensus amongst researchers that labelling by itself does not alter drinking behaviour, but can raise awareness of the issues. There could be spirits industry support for labelling once a wider, integrated and more comprehensive public health campaign is underway, subject to other conditions being met.

   A leading Canadian FAS/FAD public health specialist has stated that labelling may raise awareness but is ineffective at altering the behaviour of 'problem drinkers', who are the women who give birth to children with FASD, and who have an addiction or chemical dependence on alcohol[1].

   The consumers that would heed the advisory statement will have moderated or ceased their consumption, or will support pregnant women to reduce or abstain. Consumers who do not heed the warning at first sighting are drinkers with alcohol addiction and so are very unlikely to take any notice of the warnings on future sightings.

3. Some researchers have argued that the US labelling requirement (which has been in place the longest and is the most studied) has been ineffective in altering behaviour because of its small size and poor placement, but that it has achieved increased awareness.

   However, if the US labelling raised awareness, then it must have been sufficiently sized and placed to be noticed and the text understood. In short, studies on the US experience of labelling can not be discounted on the basis that the labelling was too small or was badly placed.

4. The evidence base for abstinence in pregnancy is contradictory. There is as yet no consensus among Australian Commonwealth and state and territory governments, and between medical and nursing organisations, as to the advice on low to moderate consumption that should be provided to women planning to become pregnant or who are pregnant. Without clear evidence, such a consensus is unlikely, and it is difficult to see how a health advisory statement on bottles could succeed in these circumstances.

5. Labelling at this time would pre-empt any comprehensive, multi-channel public awareness and public health campaign. While the Commonwealth Government has established a FASD Working Party, it is still considering its future response to FAS/FASD. The New Zealand Government is actively preparing a National Alcohol Action Plan as part of the National Drug Policy. However, the National Drugs Policy does not actually mention either FAS or FASD.

   There is a risk that without proper research on the existing beliefs, knowledge, and motivations of consumers, and their ability to alter drinking patterns, the health advisory statement will not fit within, or may even conflict with, any future comprehensive public health campaign.

6. Labelling does not come without substantial costs and risks.

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[1] Dr Gideon Koren, Director, Motherisk Program, Hospital for Sick Children, Toronto. Verbal testimony to the Standing Committee on Health, Canadian Parliament, 4 April 2005

a. There is a risk of creating unfounded fear and anxiety in pregnant women and mothers. Some research[2] has been carried out on this element of alcohol labelling. Canada has declined to use labels in order to, among other things, reduce the incidence of mothers being stigmatised or avoiding treatment. The Australian Government[3] treatment guidelines for drug use during pregnancy recommends against an abstinence policy for this reason.

b. New labelling and re-labelling existing stock will impose substantial costs for industry. Beyond the initial and ongoing financial costs of new labels estimated at between $2.1 and $2.25m, packaging and labelling space is very expensive 'real estate' already used for building brands and presenting the product for maximum effect. Its use for labels that will have no impact on consumer behaviour is a very expensive misallocation of the resource.

c. The Application's proposed phase in period of two-years is not as costless as it is portrayed. There are substantial timing issues as to when labels are introduced by manufacturers. Across any implementation phase, there will be manufacturers who 'turn over' to the new labelling and then lose market share because their products are seen as less safe, or actually risky.

d. Many of DSICA members' products are imported already bottled and packaged. Current stocks already within Australia should be 'grandfathered' from any new labelling requirements.

e. The implementation phase should be a long as possible in order to allow manufactures to run down existing label stock and to allow international suppliers to shift their labelling to the new requirements.

f. There will be a substantial cost of monitoring and enforcement. As a matter of sound public policy, FSANZ should not impose regulation without enforcement. If FSANZ does not have the capacity to adequately enforce the regulation, then it will fall to the national and state governments. Experience has shown it is very difficult to impact on the enforcement priorities of state and territory governments.

g. Labelling will have a distorting effect on the alcohol industry in that large and responsible companies would comply and be monitored, however there would be some small and transient manufacturers who would not. Anecdotally, many imported wines doe not comply with current labelling requirements. If these products do not carry the labels, then consumers could be led to believe these products are less harmful than the properly labelled products.

h. The onus would be on the Government to solve the issue of uniform compliance, and to prosecute non-compliance.

7. The resources that would be allocated to monitoring and enforcement would be more productively spent on increasing the percentage of health professionals who counsel women planning to become pregnant or who are pregnant about their alcohol

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[2] Lou HC et al. Prenatal stressors of human life affect fetal brain Development. Dev. Med Child Neurol. 1994;36: 826-832.
Hanson D, Lou HC, Olson J. Serious life events and congenital malformations: a national study with complete follow up. Lancet 2000; 356; 875-880.

[3] National clinical guidelines for the management of drug use during pregnancy, birth and the early development years of the newborn, pg 26. NSW Department of Health, 2006

consumption. West Australian research[4] has shown that too few health professionals routinely ask about alcohol intake (55%) or discuss drinking during pregnancy (75%). Education for health professionals directly about the risks of FAS/FASD and the importance of counselling women planning to become pregnant or who are pregnant would be targeted and far more effective.

8. There will be great difficulty in designing consistent labelling for the range of packaging sizes used in the spirits industry. Spirits are sold in different sized packages, generally ranging from 1L bottles down to 50ml miniatures. While the Initial Assessment Report leaves the format and wording for later determination, it is difficult to see how a set format and text can be applied across all of the beverage packaging. This is contrast to the tobacco industry where the great majority of products are in a standard sized package.
9. There is very little published research into the incidence of FAS in Australia and New Zealand, and even less on FASD. The Application is largely based on projections from international research and a few research reports. There is uncertainty as to the incidence of FASD but DSICA accepts that it impacts on the population and is a serious health issue. However, FSANZ cannot conduct any meaningful cost/benefit analysis on the likely impact of labelling.
10. Australia and NZ should look to Canada's experience, which is several years ahead in responding to FAS/FASD by using a comprehensive health awareness and treatment campaign. Canada has repeatedly rejected warning labels as ineffective, alarming and a barrier to treatment[5][6].
11. There are substantial limitations on container labelling as a means of exposure of a health advisory statement. The advisory statement will not be seen by women consuming alcohol on licensed premises, or in situations where the container is not presented to them.

[4] Payne J, Elliot E, D'Antonie H, O'Leary C, Mahony A, Haan E, et al. Health Professionals' knowledge, practice and opinions about fetal alcohol syndrome and alcohol consumption in pregnancy. Aust NZ J Public health 2005;29(6):558-64

[5] Mother and Child Reunion - Preventing Fetal Alcohol Spectrum Disorder by Promoting Women's Health (n.d). British Columbia Centre of Excellence for Women's Health. http://www.bccewh.bc.ca/publications-resources/documents/motherchildreunion.pdf

[6] Caprara D, Soldin O, Koren G. To label or not to label: The pros and cons of warning labels in pregnancy. JFAS Int 2004; 2 e9, March 2004.

SPECIFIC RESPONSES TO INITIAL ASSESSMENT QUESTIONS FOR PUBLIC COMMENT

1. What other strategies or programs are there in Australia or New Zealand (initiated by industry, public health, government, and consumer groups) to advise women of childbearing age of the risk of consuming alcohol when pregnant or if planning a pregnancy?

Currently, there is a notable and regrettable absence of nationwide strategies or programs relating to the prevention of FAS/FASD. DSICA is aware of one program aimed at FAS/FASD that is not covered in the Initial Assessment Report:

- Alcohol and Pregnancy Project. *Alcohol and Pregnancy: Health Professionals Making a Difference*. Perth, Telethon Institute for Child Health Research, 2007

2. What information (from industry, public health, government and consumer groups) is available to women planning a pregnancy or pregnant women, about the risk of consuming alcohol?

Australian state and federal health authorities provide some advice on alcohol consumption during pregnancy through health advice websites and publications. However, these communications generally do not emphasise the issue of alcohol consumption during pregnancy above other risks such as smoking. The New Zealand health system provides information in a similar manner and emphasis, although that system uses regional health boards rather than states-based health systems.

However, the most effective and trusted means for Australian and New Zealander women planning to become pregnant or who are pregnant to find out information on healthy pregnancy is through their own GP, midwife, and obstetrician.

Unfortunately, advice to women planning a pregnancy or pregnant women varies between sources.[7]. Most government health advice or alcohol and drug websites advise against consuming any alcohol at any time during pregnancy. In contrast to this advice, the Australian Commonwealth website currently states that not drinking during pregnancy may be considered, but states that if a woman chooses to drink, she should never become intoxicated, or have more than seven standard drinks in a week Health professionals offer conflicting advice, with some advising abstinence and others following the current Australian Alcohol Guidelines.

Both nations have well-developed community sectors providing some level of support services and information.

DSICA itself does not provide any advice on alcohol consumption during pregnancy.

[7] O'Leary, C. Heuzenroeder, L. Elliot, E. and Bower, C. A review of policies on alcohol use during pregnancy in Australian and other English-speaking countries, 2006, MJA 2007; 186:466-471

3. What published and unpublished information is available that may provide answers to the risk assessment questions regarding FASD that will be addressed at Draft Assessment?

DSICA is unaware of any further information on the FASD risk assessment.

4. What other data are available regarding alcohol consumption by women of childbearing age and during pregnancy in Australia and New Zealand?

Additional available research is listed below:

Roche AM, Deehan A. Women's alcohol consumption: emerging patterns, problems and public health implications. Drug Alc Rev2002;21(2):169-78

Chikritzhs T, Catalano P, Stockwell T, Donath S, Ngo H, Young D, et al. Australian Alcohol Indicators 1990-2001 Patterns of alcohol use and related harms for Australian states and territories. Perth: National Drug Research Institute, Turning Point; 2003.

Australian Bureau of Statistics. Alcohol Consumption is Australia: A Snapshot, 2004-05 [online]. 2006.

Australian Bureau of Statistics, Australian Institute of Health and Welfare. The health and welfare of Australia's Aboriginal and Torres Straight Islanders peoples 2005. Canberra: Commonwealth of Australia; 2005.

Eades S. Bibbulung Gnarneep (Solid Kid): Determinants of health outcomes during early childhood of Aboriginal children residing in an urban area. Perth: University of Western Australia; 2003.

5. Are there any other data available on the incidence of FAS/FASD in Australia or New Zealand?

One additional research paper is named below:

Elliot E, Cronin P, Rose D, Zurynski Y. Australian Paediatric Surveillance Unit: Surveillance Report 2002-03. Sydney, NSW: Royal Australian College of Physicians, Paediatrics and Child health Division, 2005.

The lack of credible data on the incidence of FAS/FASD in New Zealand and Australia is a regrettable lapse by the health research bodies of both nations. Its absence makes it impossible to have a rational and informed debate about the impact and cost-effectiveness of any possible interventions, including health advisory statements, and the foreshadowed New Zealand public health campaign.

6. Are there any other data available relating to the level of awareness amongst women of childbearing age of the risk of consuming alcohol when planning to become pregnant and during pregnancy in Australia and New Zealand?

DSICA is unaware of any further available data on the level of awareness amongst women of child bearing age of the risks associated with consuming alcohol while pregnant or becoming pregnant. This re-enforces DSICA's insistence that a substantial research program be conducted before labelling can be introduced.

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?

DSICA submits that a health advisory statement about the risk of consuming alcohol when planning to become pregnant and during pregnancy on all alcoholic beverage containers should not be required for the following reasons:

1. In the absence of an established comprehensive public education and health campaign, health advisory statements are ineffective in altering alcohol consumption. Researchers have suggested that labelling may have an impact on behaviour if used in conjunction with a broader and more comprehensive public awareness and education campaigns. ALAC itself has made this point in 2002 in its Policy Statement 2: Warning labels on Alcoholic Beverages.

   However, any such campaigns are only in the planning stage at this time in New Zealand. Any Australian campaigns are much further off. Until such a campaign is committed to and implemented by government, it is impossible for DSICA to support labelling.

2. The incidence of FAS/FASD in Australia and New Zealand is unknown. At best, the Application is based on extrapolating international estimates of FASD onto New Zealand and Australia populations, and a few studies of FAS in Indigenous populations and in Western Australia. Research on FAS/FASD assumes that FAS is under-reported, based on practitioners' difficulties when diagnosing and lack of awareness. This situation would be even worse for the less obvious FASD conditions.

   It is impossible to quantify the health risk that the Application is intended to reduce or mitigate, or to conduct a proper risk analysis. FSANZ should not impose new regulation without a proper analysis of risks and costs v benefits.

3. There is widespread inconsistency between the states, territories, and Commonwealth, and between the Australian medical and nursing organisations on what advice to give women on low to moderate alcohol consumption during pregnancy. Until health professionals reach a consensus on the evidence of the potential harm from low to moderate consumption and the best advice to provide, it is unlikely that a broader public education campaign can be successful in Australia and New Zealand. Labelling alcohol packaging will have no impact and would possibly be contradictory to the advice women receive from their health professionals.

4. Canada, which is well advanced in terms of the prevention and treatment of FAS/FASD, has considered and rejected labelling on several occasions, most recently in 2005.

5. The target population for reducing FASD (women of child-bearing age who drink) have not been adequately researched in terms of their attitudes, current knowledge and beliefs, motivations, and ability to act in terms of alcohol and pregnancy. In the absence of a sound research base about prevalence of drinking during pregnancy, motivations, and circumstances of drinking, a properly designed and effective advisory statement will be unlikely. This is a key reason why DSICA cannot support the Application.

8. What further evidence is available about the use and/or effectiveness of a health advisory statement on alcoholic beverage containers regarding the risk of consuming alcohol when planning to become pregnant and during pregnancy?

Further evidence that DSICA has located is:

Agnostinelli G, Grube J. Alcohol counter-advertising and the media – a review of recent research. National Institute on Alcohol Abuse and Alcoholism. 2002.

Grude JW, Nygaard P. Adolescent drinking and alcohol policy. Contemporary Drug problems, 28: 87-131. 2001.

Alcohol Advisory Council of New Zealand (ALAC) *Policy Statement 2. Warning Labels on Alcoholic Beverages*. Wellington. 2002.

Public Health Agency of Canada. Research Update - Alcohol Use and Pregnancy, section 6.3. Updated 2007

Educ'acool. Brief concerning Bill C-206 submitted to the House of Commons Standing Committee on Health, Ottawa. 2005.

World Health Organisation. Expert Committee on Problems related to Alcohol Consumption, 2nd Report, pg 32. WHO Technical Report 944. 2007

Babor T et al. *Alcohol: no ordinary commodity. Research and Public Policy*, pg 193. Oxford, Oxford University Press, 2003.

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?

Without accepting that labelling by itself would be effective in altering consumption patterns or behaviour, DSICA suggests the use of this statement the United Kingdom is adopting in 2008:

"Avoid alcohol if pregnant or trying to conceive".

The statement is clear and unambiguous, avoiding words such as 'can' or 'may' that leave ambiguity in the minds of the reader.

The message states a positive behaviour that women can do (i.e. not drink), rather than a negative or alarming message stating that alcohol is harmful or damaging to the foetus, or may cause birth defects. Those statements are concern risk and damage and will cause alarm. Ultimately, alarming statements are easily ignored if there is no supporting evidence of harm or damage to reinforce the message.

This statement is preferable to messages that relate solely to pregnancy as it includes women trying to become pregnant. The word 'conceive' also indicates that the time between becoming pregnant and becoming aware of the pregnancy is also an issue that women should be aware of. During this time the foetus is particularly vulnerable to alcohol.

However, DSICA opposes the use of a textual statement because it would not reach non-English speaking women, or those with very low education levels. Given the much higher prevalence of FAS among Indigenous Australians, and the high number of immigrants with both New Zealand and Australia, reaching these target groups must be a priority.

A pictorial image would be the preferred option if health advisory labels were mandated, specifically the French symbol of a pregnant woman with glass in hand, overlaid with a red stripe.

10. What further evidence is relevant to the wording of such a statement, such as its likely effectiveness or appeal to women of childbearing age and/or understanding of the statement by women of childbearing age?

At present there is no evidence to support the use of such a statement; however its use in the United Kingdom later this year will provide some evidence of its effectiveness while Australia and New Zealand goes through a transition period.

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?

While not accepting that any form of labelling on its own would be effective in altering consumption levels or behaviour, a pictorial image would be the preferred option if advisory labels were mandated.

The disadvantage of written statements (or several statements if a rotation of statements was mandated) is that they require the ability to read English. This reduces its impact with groups who are hard to reach through other channels, particularly the functionally illiterate and non-English-speaking groups. Evidence cited in the Application shows that a large percentage (~ 80%) of pregnant women abstain from drinking spontaneously. These women are likely to be those who actively seek information by other communications channels (media/internet/health professionals/social networks) and have functional literacy skills. Consequently, labelling should have a greater emphasis on meeting the needs of women who do not seek information from those channels.

Text warnings also tend to use vague words (may, can, excessive, moderation) or words that are not easily comprehendible to many people (cirrhosis, hazardous, impaired). A good understanding of risk is not common in the general population and the clear and concise communication of risk is difficult to achieve to a necessarily broad audience.

The advantages of a pictorial image are that the image does not require the ability to read or understand English. The French picture cited in the application is universally understandable by the entire human race. A written statement would not be as effective at reaching the most ‘at-risk’ groups, who have less access to other sources of information such as the internet and written publications.

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

The ABV percentage should be equivalent to that which requires labelling as an alcohol beverage: 0.5% ABV. It would be difficult to suggest that any other ABV would be appropriate.

13. What is the likely impact on consumers, industry, and/or government if the *status quo* was maintained?

Consumers
As there is no evidence that health advisory statements have any positive impact on consumption or behaviour, the status quo would have no negative impact on consumers.

Government/Industry
There would be no impact on the industry or government if the status quo was maintained.

14. What is the likely impact on consumers, industry, and/or government if an advisory statement on the risks of consuming alcohol when planning a pregnancy and during pregnancy is required on alcoholic beverage containers?

Consumers
The international experience of labelling is that it does not have an impact on consumption levels. There would be no positive impact on consumers as health advisory labelling has been shown to be ineffective in terms of altering drinking behaviour.

The Application concedes this point and argues that the impact would be to raise awareness of foetal alcohol harm, and to act as an ongoing reminder.

Unfortunately, labelling as an awareness raising exercise is fatally weakened due to the fact that those women who have the greatest likelihood by far of continuing to drink during pregnancy have a chemical dependency on alcohol, and are unable to abstain.

Further mitigating the desirable effect of awareness raising is the reality of how alcohol is consumed. In order for the health advisory statement to be viewed, the consumer has to see the package. Labels would not be seen by women who consume alcohol served to them on licensed premises (i.e. spirit and mixer drinks, cocktails, beer and wines) poured into a glass. For example, women at sporting venues or music concerts where containers are not served will not see the labels.

The additional labelling costs would either be passed onto consumers, as would monitoring and enforcement costs through taxation, or absorbed by the industry. The costs would be much higher (relatively speaking) for smaller producers and for small volume production runs such as liquors and niche spirits.

While not accepting that a simple and effective message can be created, any such health advisory label could create concern, and even fear, in the minds of women who find themselves pregnant and have consumed alcohol in the previous months[8].

To quote the *National clinical guidelines for the management of drug use during pregnancy, birth and early development years of the newborn,* pg 26[9]

> An abstinence-based approach is not recommended, in part because it could result in disproportionate anxiety among women with an unplanned pregnancy, many of whom consume before they know they are pregnant, but usually without harmful consequences for the infant. Anxiety about alcohol consumption has sometimes resulted in precipitous decisions to terminate a pregnancy.

It is not labelling per se that is the problem, it is labelling without access to other sources of information, or ideally a health professional, that creates problems.

The risk is that if women have been advised about alcohol and pregnancy solely through the health advisory label, upon discovering the pregnancy, women will immediately review their alcohol (and tobacco/drug) consumption in the previous one to two months. If the warning label states that the child could or may have been damaged, or is at risk of having neurological defects, this will likely create a sense of fear and guilt. This concern would be particularly acute for first-time mothers, or those without strong social support networks, or with other drug dependencies[10].

Further factors that would heighten concerns is where the woman has poor social or communication skills (including speaking languages other than English), or lack confidence in their ability to go through the pregnancy and then cope with supporting the child, or simply low socio-economic status.

It is likely that a small number of women would enter a state of denial about their pregnancy. A number will suffer from depression. It is highly likely that some expectant mothers would suffer from a sense of guilt at having risked their child's physical and mental development, and their future potential for a successful and full life, because of their own drinking for pleasure.

Some expectant mothers may be so concerned or in such a state of depression and guilt as to terminate the pregnancy based on their expectation that the foetus has been damaged[11]. This risk has been recently commented on by the Royal Australian College of Obstetricians and Gynaecologists[12].

Post-birth, these mothers are likely to seek out some confirmation of such alcohol-related neurological and physiological damage, either through seeking opinions from health professionals or though their own observation. This would be particularly acute for first-time

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[8] Koren G. Canadian Family Physician. Vol 42, pg 2121-43: November 1996.
[9] Ministerial Council on Drug Strategy. National clinical guidelines for the management of drug use during pregnancy, birth and the early development years of the newborn. Sydney: NSW Health and Commonwealth of Australia, 2006.
[10] Public Health Agency of Canada. *Research Update - Alcohol Use and Pregnancy*, section 8.2. 2007
[11] O'Brien P. BMJ, Vol 335, pg 856. October 2007
Abortion fear over no-alcohol in pregnancy advice. The Age, 15 November 2007

mothers, those without experience of sibling infants, and those without strong maternal support networks that can provide reassurance.

All of these impacts would be mitigated or removed by contact with healthcare providers who could offer a balanced appreciation of the risks and likely outcomes. However, there will be some pregnant women, particularly if they have other drug dependencies, who do not discuss their alcohol consumption with their health providers due to feelings of guilt, stigma and fear of child protection intervention[13].

FASD conditions are difficult to detect even for specialist child health professionals. The normal developmental process of infants can easily be read as slow or delayed, so indicating FASD. For a mother with heightened concern and accompanying guilt, this could have devastating impact.

Recent media coverage in Australia of FASD has highlighted that FASD-related conditions include problems which become apparent quite late in adolescence, such as abstract thinking and difficulty in forming and maintaining relationships. Thus, parents could be searching for several years for signs that maternal drinking has damaged the child.

While the wording of any label may indicate that neurological damage is not a foregone conclusion, women will take the fact that the labels exist as a sign that the risks are substantial. DSICA is unaware of any research of the mental health impact on expectant mothers or mothers of the pregnancy warning labels in the United States.

Industry

It is important to recognise that the industry is not uniform and in fact consists of different sizes and types of company. Companies also vary in their breadth of product range and the variety of packaging sizes.

DSCIA does not accept the Application's contention that labels are re-generated every two years and hence that a two-year time frame would be costless. Many products, particularly premium bottled spirits, do not change their labelling for long periods, if at all. In addition, some spirit and wine products are bottled years in advance of their sale, and these products would need to be re-labelled unless products were grandfathered on the basis of being within Australia at the end of the implementation period.

Based on estimates provide by its member companies, DSICA believes that health advisory statements implemented over a two-year period on domestically produced and imported products would impose an direct financial cost on the spirits industry of between A$2.1m and A$2.25m.

In addition to the direct financial costs of re-labelling and new labels, greater costs would be imposed through the loss of packaging space through placement of health advisory statements, which removes that space for packaging and building of the brand image.

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[13] Public Health Agency of Canada. *Research Update - Alcohol Use and Pregnancy*, section 8.2. 2007
Poole, N., & Isaac, B. (2001). Apprehensions: Barriers to treatment for substance using mothers. Vancouver: British Columbia Centre for Women's Health
Swazey, M. & Reynolds, W. (n.d.). Reducing the impact: Working with pregnant women who live in difficult situations. Toronto: Ontario Best Start

Space on beverage containers is limited and is used by companies to display their products in the best possible manner and so promote them. Competition between rival products is fierce and the product's visual appeal on the shelf is a large element of consumers' final purchase decision. In many ways, the container packaging is the product's best advertisement because it is in front of a potential purchaser.

This problem would be particularly acute for miniature bottles of spirits containing 50ml of spirits. These bottles are typically 10cm high by 3.5cm wide. It will be very difficult to design a label carrying health advice in text of visible size that did not crowd out other labels.

The costs of labelling to the spirits industry would increase as the complexity of the labelling requirements increased, for example use of colours, size of text, amount of text, rotation of statements, etc.

Government

The New Zealand Government and the Australian state and territory governments would face the additional costs of monitoring and enforcement above that which they carry out already.

This would include monitoring of products, and measurement of warning labels to ensure consistency. If the absence of an ongoing monitoring program, the various government agencies would have to have the ability to receive and investigate complaints.

The costs of monitoring would increase in line with the complexity of the required labelling. The higher the number of statements to be used, and the more precise the requirements in terms of size and placement, the greater the complexity of monitoring and enforcement.

While DSICA's membership comprises large and reputable companies, there are many small and transient suppliers of spirit beverages who already push the boundaries of acceptable packaging. These suppliers would present an enforcement problem in terms of detecting, tracking, evidence gathering, and prosecution.

The onus would lie with government to have proper monitoring and enforcement measures in place and in effective operation.

In DSICA's view, the governments' resources would be better spent on increasing health professionals' awareness of FAS/FASD, and how to identify and treat those mothers most at risk, as part of a comprehensive public health campaign.

15. How would labelling 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?

The Applicant has argued that the purpose of labelling is not to alter behaviour but instead to promote awareness and discussion.

Where labelling has been used, some research indicates that it has raised awareness and increased discussion of the subject matter, but even this research concedes that it has not measurably altered the behaviour of women consuming alcohol. It is clear that merely increasing awareness is not sufficient to reduce FAS/FASD, and that consideration of measures of raising awareness is somewhat pointless.

International evidence has consistently shown that labelling is ineffective at altering drinking behaviour. DSICA can find no research indicating that labelling has an enduring impact in the number of women consuming alcohol during pregnancy, or their pattern of alcohol use.

It should be clear that if labelling is not effective at altering behaviour, then it cannot be considered by any means cost-effective.

DSICA seriously questions whether FSANZ should consider labelling as part of promoting awareness and discussion, which more properly lies within public education campaigns, which are in turn part of a coherent public health strategy.

The research literature suggests that health advisory labelling could only be effective if part of a much larger and more comprehensive public health campaign. The Applicant is a Crown-owned entity and has responsibility within New Zealand for public policy and consumer education on alcohol issues, and has indicated that labelling would be part of such a promised campaign.

However, there is no indication that such a campaign is yet contemplated within Australia; therefore within Australia (approximately 80 per cent of trans-Tasman consumption) the labels would merely be ineffective gesture towards an important health problem.

Pregnancy is a complex medical issue, and one that varies from woman to woman. Given this complexity, it is unwise, possibly risky, to attempt to provide simple and universal advice without accompanying medical guidance at a time when many women already have heightened concerns about their health and that of their future child.

General practitioners, obstetricians, midwives, and community health nurses are the most trusted sources of advice and guidance because they provide relevant, balanced and comprehensive advice. They can also provide reassurance and a balanced appreciation of the risks for those women who have consumed alcohol before they realised they were pregnant, for those women who are consuming alcohol during pregnancy, and those women who did consume during pregnancy.

West Australian research[14] has shown that too few health professionals routinely ask about alcohol intake (55%) or discuss drinking during pregnancy (75%). A better use of resources would be to educate the health professionals directly about the risks of FAS/FASD and the importance of counselling women planning to become pregnant or who are pregnant.

Further reducing the cost-effectiveness is the fact that for those regularly consuming alcohol (both male and female), most of their sightings of the advisory statement will be repetitive, and simply informing them of that they already know.

The consumers that heed the advisory statement will have ceased their consumption, or will support pregnant women to reduce or abstain. Consumers who do not heed the warning at first sighting are drinkers with alcohol addiction and so unlikely to take any notice of the warnings on future sightings.

[14] Payne J, Elliot E, D'Antonie H, O'Leary C, Mahony A, Haan E, et al. Health Professionals' knowledge, practice and opinions about fetal alcohol syndrome and alcohol consumption in pregnancy. Aust NZ J Public health 2005;29(6):558-64

Behavioural change is much harder than becoming aware of the issue. The British Columbia Centre of Excellence for Women's Health is a leading health and research centre that has carried out substantial research on FASD/FASE prevention and treatment. To quote the centre's paper on FASD prevention[15]:

> Evidence shows that binge drinking creates the greatest risk of FASD and that other factors such as malnutrition, stress, use of other drugs, exposure to violence, and many other factors relating to women's health and well being have been shown to influence the risk of women giving birth to a child affected by FASD. Prevention messages have tended to oversimplify this reality. They often focus only on alcohol use and imply that any level of alcohol use is highly dangerous. More critically, they often imply that it is a simple matter for all women to "just say no" to alcohol during pregnancy, ignoring the dynamics of addiction and the burden of other health and social problems that many women face. Finally, many prevention messages even imply that women are ignorant or callous when they are unable to stop using alcohol during pregnancy.

Further Canadian work on FASD prevention was summarised by the Public Health Agency of Canada in 2005 in a summary report for a national FASD workshop.

> At one end of the spectrum are single-message prevention activities and products; at the other end are a few coordinated multilevel campaigns. At best, prevention activities to date have aimed at promoting healthy choices in pregnancy to achieve healthy birth outcomes. At worst, prevention messaging has oversimplified the problem by suggesting that any woman can "just say no," "FASD is 100% preventable" or that "any amount of alcohol during pregnancy will cause FAS."
>
> Growing evidence suggests, however, that FASD prevention requires integrated programs that deliver culturally sensitive perinatal services to high-risk women, neonatal screening, and prompt and sustained intervention for affected children and mothers. Furthermore, these programs should be based on an understanding of the determinants of health and factors that contribute to alcohol use in pregnancy and addiction.[16]

It should be clear that in the absence of a coordinated public health campaign, labelling is ineffective and probably counter-productive in preventing FASD.

DSICA cannot support the Application unless labelling is part of an established, comprehensive public education and health campaign, and that the required change to the Standard 2.7.1 is accompanied by effective labelling enforcement and a substantial research base.

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[15] Mother and Child Reunion - Preventing Fetal Alcohol Spectrum Disorder by Promoting Women's Health, pg 5. British Columbia Centre of Excellence for Women's Health. http://www.bccewh.bc.ca/publications-resources/documents/motherchildreunion.pdf

[16] Summary Report National Thematic Workshop on FASD. Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/fasd-ntw-etcaf-atn/app_e.html#app3.