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**Australian Government**  
**Department of Finance and Deregulation**  
**Office of Best Practice Regulation**

Reference: 11336  
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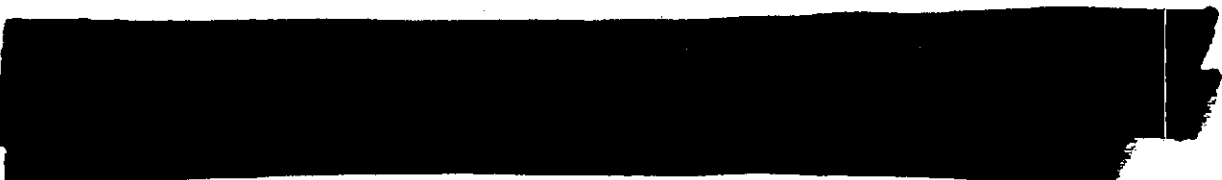
Dear Penny

Thank you for the draft Regulation Impact Statement (RIS) on plain packaging of tobacco products, sent 27 April 2010. As discussed the RIS does not satisfy the Australian Government's best practice regulation requirements.

Based on my discussions with you and on the media release by the Prime Minister on 29 April 2010, it would seem that a decision has been made on this proposal and unfortunately there is no capacity now to undertake any further work on the RIS.

As you may be aware, under the Government's best practice regulation requirements: *'The Government has decided that, in the absence of exceptional circumstances as agreed by the Prime Minister, a regulatory proposal with medium compliance costs or significant impacts on business and individuals or the economy (including restrictions on competition) cannot proceed to Cabinet or other decision makers unless it has complied with the Government's regulatory impact analysis requirements. The OBPR is required to advise decision makers on the adequacy of the RIS or quantification of compliance costs where required'*.

The OBPR is required to report this matter as non-compliant in the Best Practice Regulation Report. Under the Government's requirements a post-implementation review will be required to commence within one to two years of implementation.



Thank you for consulting with the OBPR on this matter. The OBPR ID number for this matter for correspondence and compliance reporting purposes is 11336.

Yours sincerely

Radmila Ristic  
Director

4 May 2010

**CABINET IN CONFIDENCE**

**Department of Health and Ageing**

**Regulation Impact Statement: Plain Packaging of Tobacco Products**

**April 2010**

**I. Problem**

*1.1 Description of the problem*

Tobacco smoking presents an unacceptable hazard to human health in Australia.

The National Preventative Health Taskforce, a group of Australia's leading public health experts appointed by the Australian Government in 2008 to provide evidence-based advice on preventative health programs and strategies, examined the evidence on smoking in Australia and found, in its National Preventative Health Strategy of June 2009 that:

- smoking continues to be Australia's largest preventable cause of death and disease;
- while smoking prevalence has declined over a long period, almost three million people – or 16.6 per cent of Australians aged 14 and over – continue to smoke daily. Almost half of Indigenous Australians smoke;
- about half of the smokers who continue to smoke for a prolonged period will die early, half of them in middle age;
- tobacco use causes over 15,000 deaths each year (2003 estimate) and costs the Australian community around \$31.5 billion each year (2004-05 estimate);
- smoking is responsible for 12 per cent of the total burden of disease and 20 per cent of deaths among Indigenous Australians;
- smoking in Australia contributes significantly to social disadvantage. Spending on tobacco products causes financial stress, works against the accumulation of wealth and helps to perpetuate poverty across the generations;
- thousands of young people each year continue to take up smoking. The overwhelming majority of Australians who smoke began as teenagers and most new users are young people, many as young as 14, 13 and even 12 years of age;
- a continuing decline in smoking will require a comprehensive approach, with concerted and sustained measures including: reducing the affordability of tobacco products; eliminating all forms of marketing of tobacco products; clear information for consumers; vigorous education campaigns; and affordable assistance to smokers to quit;
- the more comprehensive the approach, the more likely it is that prevalence will decline among all social groups.

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Governments and non-government organisations (NGOs) across Australia are making significant efforts to try to reduce rates of smoking:

- the Council of Australian Governments (COAG) agreed in the 2009 National Healthcare Agreement to a target of, by 2018, reducing the national smoking rate to 10 per cent of the population and halving the Indigenous smoking rate;
- COAG also agreed in its 2009 National Partnership Agreement on Preventive Health to a performance benchmark of reducing the "state baseline for proportion of adults smoking daily commensurate with a two percentage point reduction in smoking from the 2007 national baseline by 2011 and a 3.5 percentage point reduction from the 2007 national baseline by 2013;
- the Australian Government is investing record amounts in tobacco control with a focus on public education campaigns to support smoking prevention and cessation, and pharmaceutical supports for smokers to quit, including:
  - \$15 million over four years from 2008-09 to reinvigorate the National Tobacco Strategy;
  - \$61 million over four years from 2009-10 for anti-tobacco social marketing campaigns under the COAG Preventive Health National Partnership and significant additional transfers to the States and Territories to support workplace and community healthy living programs;
  - the rebadging and refocusing of the \$27.8 million National Tobacco Youth Campaign over four years from 2010-11 to target high-risk and hard-to-reach groups;
  - \$14.5 million over four years from 2008-09 for pilot projects to address the high rates of smoking in indigenous communities through the Indigenous Tobacco Control Initiative;
  - \$100 million over four years from 2009-10 for tackling smoking in indigenous communities under the COAG Closing the Gap in Indigenous Health National Partnership; and
  - more than \$60 million per annum in subsidies under the Pharmaceutical Benefits Scheme for smoking cessation supports.
- State and Territory governments continue to fund anti-smoking public education campaigns in partnership with NGOs and to implement regulatory reforms in the areas of tobacco retailing and exposure to second-hand smoke, including most recently and notably: restrictions and bans on point of sale advertising and retail displays of tobacco products; and bans on smoking in cars and other environments in which children may be exposed to secondhand smoke.

However, according to the findings of the National Preventative Health Taskforce, the smoking reduction targets agreed by COAG will not be achieved without significant additional reform:

1. to make tobacco products significantly more expensive. Possible increases to the excise on tobacco are being considered separately by the Department of the Treasury; and
2. to end all remaining forms of advertising and promotion of tobacco products.

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Tobacco advertising and promotion in most forms is currently prohibited under the *Tobacco Advertising Prohibition Act 1992* ("the TAP Act"). However, the TAP Act contains a number of exceptions to the general ban including, most notably, the words, signs or symbols on a tobacco product or its packaging. The National Preventative Health Taskforce found that:

- In Australia and other countries that have already banned traditional forms of tobacco marketing, packaging has become a cornerstone of marketing strategy;
- Brand names and package design enable the communication of personal characteristics, social identity and aspirations, and are a crucial aspect of marketing tobacco products;
- Market-testing studies show that package design – through the use of varying colour and other design elements – induces smokers to expect, and then actually experience, their cigarettes to be lower strength, lower in tar and lower in health risk than exactly the same cigarettes presented without this packaging;
- A paper presented at the 2009 meeting of the Society for Research into Nicotine and Tobacco found that substantial proportions of UK adult smokers and children reported false beliefs about health risk based on packaging. For instance, around half of adults thought that Marlboros in gold packaging posed less of a risk to health than Marlboros in red packaging. Around one-third thought that Marlboro Golds would be easier to quit than Marlboro Reds. Around half of adults thought that Mayfair Smooth posed less of a risk to human health than Mayfair Kingsize. Almost 40% of youth said that they would be more likely to try the Smooth than the Kingsize variant. Around a third of smokers thought it would be easier to quit. The research found that false beliefs were independently associated with descriptors and colour/imagery. The number of people who indicated that there was probably no difference in health risks between brand variants increased substantially when brands were presented in plain packaging. For instance, the percentages who indicated that there was probably no difference in health risks posed by Lambert & Butler King Size compared with Lambert & Butler Gold increased from 58% to 75%. The percentage indicating that there would be no difference in how hard it would be to quit using the product increased from 68% to 83%;
- Consumer research indicates that decreasing the number of design elements on the package reduces its appeal and perceptions about the likely enjoyment and desirability of smoking;  
*need references. need to set at base for research -> surveys -> research/labels.*
- An experimental study of the effects of packaging on the image of smoking and characteristics of tobacco products found that smokers of plain packs were rated as significantly less trendy/stylish, less sociable/outgoing and less mature than smokers of the original pack. Compared with original packs, smokers inferred that cigarettes from plain packs would be less rich in tobacco, less satisfying and of lower quality tobacco;  
*age - need to discuss the study*
- Plain packaging would increase the salience of health warnings: research subjects show an improved ability to recall health warnings on plain packs.  
*evidence*

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### 1.2 Consequences of no action

In the absence of action:

- tobacco companies will continue to use tobacco product packaging to market their product to Australians, including to associate tobacco with status and social aspirations;
- consumers will continue to be misled by packaging about the health impacts of smoking, particularly the relative health impacts of differently branded products;
- branding and other design features of tobacco packaging will continue to detract from health warnings;
- the combined impact of the above continuing phenomena will reduce the effectiveness of government and non-government efforts to prevent smoking uptake and encourage quitting;
- a key recommendation of the National Preventative Health Strategy, and an important plank in a comprehensive approach to tobacco control, will remain unaddressed;
- the smoking reduction targets in the COAG Preventive Health National Partnership and the National Healthcare Agreement are less likely to be met; and
- the rates of death and disease caused by smoking will remain higher than could otherwise have been achieved.

This situation will not be corrected by the market itself because of information asymmetry and the addictive nature of smoking. According to the National Tobacco Strategy 2004-2009:

- While consumers are generally aware that tobacco smoking is harmful, many still underestimate the extent of the danger relative to other lifestyle risks. Few smokers are able to accurately estimate their chances of dying in middle age. Most are able to name only a handful of the numerous diseases caused by smoking.
- Smokers also have little understanding of how tobacco-related illnesses could affect the quality of their lives. Few, for instance, understand that emphysema – one of the most common diseases caused by smoking – is irreversible, life-threatening and incurable. Many young women do not know that smoking reduces fertility. Many young parents do not know that smoking around children increases their risk of meningococcal disease.
- Evidence from internal tobacco company documents released as part of settlements by tobacco companies with US state Attorneys General, indicates that, for years, companies were aware of the harmful effects of tobacco and the dependence-producing qualities of tobacco-delivered nicotine, but have failed to adequately warn consumers about the risks.
- The addictive nature of tobacco products further compromises consumers' ability to make an informed choice. Addiction by its very nature distorts thinking processes, giving prominence to thoughts which justify continuing the addictive behaviour, and minimising or excluding consideration of reasons for ceasing it.

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As part of a comprehensive package of measures – including the measures being undertaken by governments and NGOs as outlined at page 2 above – regulation to introduce plain packaging can make a significant difference to this situation.

### 2. Objectives

The objectives of regulation to introduce plain packaging of tobacco products would be to prevent tobacco advertising and/or promotion on tobacco product packaging in order to:

*has  
revised  
the  
warning  
scheme*

- reduce the attractiveness and appeal of the product to consumers, particularly young people;
- reduce the ability of the tobacco packaging to mislead consumers; and
- increase the impact of mandated health warnings.

### 3. Options

The option of doing nothing is not realistic. While the Government is investing heavily in public education campaigns, the message from the National Preventative Health Strategy is clear: comprehensive measures are needed across a range of areas, including to eliminate one of the last key remaining forms of tobacco advertising – on tobacco packaging – if the COAG targets for smoking reduction are to be met.

Self-regulatory and quasi-regulatory options are not viable nor consistent with Australia's international obligations under the WHO Framework Convention on Tobacco Control (FCTC). It is not in tobacco companies' commercial interests to produce packaging that is unappealing and indicates clearly the adverse health impacts of smoking.

- The tobacco industry has had a history of actively seeking to suppress the evidence of the adverse health impacts of smoking (see for example the WHO paper: 'The Tobacco Industry Documents: What they are, what they tell us and how to search them: a practical manual' at [www.who.int/tobacco/communications](http://www.who.int/tobacco/communications)).
- Article 5.3 of the FCTC requires that 'In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law'.

The regulatory approach proposed is to:

#### In 2010

- Conduct consumer-focused research on the optimal form of plain packaging to: reduce its attractiveness, particularly to young people; reduce its capacity to mislead; increase the impact of graphic health warnings; and minimise any unintended consequences (for example, potential difficulties for retailers in identifying individual products; implications for counterfeiting and the illicit trade). This will build on research already commissioned

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by the Department of Health and Ageing to update the current graphic health warnings on tobacco products and to explore the feasibility of publication of ingredients and emissions data to better inform consumers; and

- Consult the tobacco industry, distributors, retailers and other stakeholders on the impact of regulation to introduce mandatory plain packaging, particularly to ensure any unintended consequences are identified and the impact minimised.

### In 2011

- finalise and introduce legislation to introduce mandatory plain packaging based on the above research and consultation findings.

Alternative regulatory approaches would be to:

- support the Plain Tobacco Packaging (Removing Branding from Cigarette Packs) Bill 2009 currently being considered by the Senate Community Affairs Committee. However, the Department does not favour this option because of concern that:
  - the objectives of the Bill make excessive claims that would leave the legislation open to challenge in the courts;
  - the Bill has not involved research about the optimal form of plain packaging – so might not be as effective as it could be and may also increase the opportunity for challenge;
  - the Bill and its associated regulations are inconsistent – one refers to all retail packages, the other only to tobacco (excluding pipes, cigars, cig papers, rollers etc);
  - the Bill does not take into account other regulatory requirements for tobacco – including new fire warnings that are now on cigarettes;
  - the Bill does not amend the Tobacco Advertising Prohibition Act which currently includes an exemption for words, signs or symbols on a tobacco product or its packaging.
- introduce regulation to expand the graphic health warnings so that they cover the majority of the pack. The Department does not favour this option because it would require consumer research on a narrower set of criteria than are proposed for the plain packaging approach – with potentially lesser effectiveness against the objectives set out at Part 6 above.

#### 4. Impact analysis

*Who is affected by the problem and who is likely to be affected by proposed solutions?*

- Smokers, their families and friends, and those at risk of smoking are most affected by misperceptions about the adverse health impacts of smoking that can be generated by tobacco product packaging. Young people in particular may be affected in that they may be less inclined to start smoking if the attractiveness of the packaging is decreased. Smokers, their families and friends would see an increase in the impact of the health warnings if the packaging was not able to be coloured in a particular way in order to blend in with the health warnings.

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- Some 16.6 per cent of Australians aged 14 and over smoke daily, putting themselves and others at risk of smoking-related disease and death. This included over 140,000 secondary school students in 2005.
- According to the National Preventative Health Taskforce:
  - while the prevalence of smoking has fallen among adults and teenagers in all age and occupational groups, progress appears to be halting among people with more limited education and those living in the most disadvantaged groups;
  - smoking rates among Indigenous Australians are more than double those in the rest of the community;
  - high rates of smoking are also apparent among other marginalised groups, including people with mental illness, drug users, homeless people and people in prison.
- The proposed legislation to introduce plain packaging will remove tobacco packaging as a source of possible misperceptions about the adverse health impacts of smoking for the above population groups.
- The proposed legislation will also have implications for tobacco manufacturers, importers, distributors, retailers, law enforcement officials, the Government and taxpayers.
- Manufacturers will be required by the legislation to produce packaging to specified design characteristics. This will involve some upfront costs to adjust manufacturing processes for the Australian market and there may be some ongoing costs to maintain separate packaging requirements for the Australian market if the manufacturer sells into other markets. However:
  - Until the proposed research has been conducted during 2010 to establish the optimal design to achieve the objectives of the legislation, it will not be possible to quantify the cost to manufacturers of adjusting their packaging production.
  - Current Australian regulations include significant requirements for packaging design. The Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations 2004 (CPIS Regs) require that mandated graphic health warnings cover 30% of the front and 90% of the back of cigarette packages and 30% of the front and 50% of the back of loose and pipe tobacco pouches. An information message is also required on one full side of a package of cigarettes, on 25% of the side of cigarette cartons and on the inside flap of loose or pipe tobacco. There are also specific requirements for cigars.
  - Mandatory requirements for fire risk warnings have recently been added to the regulations.
  - Article 15 of the Framework Convention on Tobacco Control already requires that national authorities require tobacco product packaging to include markings to indicate the final (country) destination of sale of the product as a measure to help eliminate the illicit trade in tobacco products.
- Manufacturers will also be affected by any reduction in demand for tobacco products as a result of the introduction of plain packaging. This will apply equally to all manufacturers selling to the Australian market. It is not possible to quantify the cost of this impact at this time as a change to mandatory plain packaging has not been implemented anywhere in the world, and the cooperation of the tobacco industry would be needed in quantifying the cost. It is also very difficult to isolate the impact of an individual policy measure

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when a comprehensive suite of measures are being implemented simultaneously to try to reduce demand for tobacco.

- Some manufacturers or their representatives have written to the Australian Government to express concern about the National Preventative Health Strategy recommendation for the introduction of plain packaging, stating inter alia that it is likely to affect the value of their tobacco product brands in which they have invested heavily.
- The issue of branding will be considered in the development of the plain packaging design. Any restrictions on the use of branding will only be implemented to the extent necessary to achieve the public health objectives of the legislation.
- Importers of tobacco products will be affected to the extent that they will need to source product whose packaging meets Australian mandated requirements.
  - This will not have any greater impact than the current mandatory health warning and fire risk statement requirements that are unique to the Australian market.
- Importers will also be affected by any reduction in demand for tobacco products achieved by the measure. Again, this impact cannot be costed at this time.
- Distributors and retailers of tobacco products will be affected to the extent that plain packaging may make it more difficult to identify individual products or brands, potentially increasing handling time.
  - Small retailers and their representatives have written to the Government to express this concern.
  - This impact cannot be quantified until the design of the plain packaging has been settled.
- The Department proposes to address this potential impact, to the extent consistent with public health objectives of the measure, in the research to develop the optimal design for the packaging. It may be possible for individual product names still to be prominent on the packaging – both on bulk packaging and on individual packs – to aid easy identification.
- Distributors and retailers will also be affected by any reduction in demand for tobacco products achieved by the measure. Again, this impact cannot be costed at this time.
- Manufacturers, importers, distributors and retailers of tobacco products, as well as the Australian Taxation Office, Australian Customs and Border Protection Service, the Australian Government more broadly, taxpayers and smokers would all be affected by any change to the trade in illicit tobacco products generated by the move to plain packaging.
  - Manufacturers, importers, distributors and retailers could lose business to the illicit trade if plain packaging made counterfeiting easier.
  - The efforts of the Australian Taxation Office and the Australian Customs and Border Protection Service to collect tobacco excise and customs duty could be affected by the design of the plain packaging.
  - Government revenues could be put at risk if the design of plain packaging made counterfeiting of tobacco easier and enforcement efforts less effective.

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- Smokers' health could potentially be put at greater risk if they consume counterfeit products.
- This potential impact is hypothetical and cannot be costed.
- The Department proposes to address this potential impact by including anti-counterfeiting measures in the design of the mandatory plain packaging. This could potentially improve the efficiency and effectiveness of enforcement of tobacco excise and customs duty collection.
- Smokers could face lower costs of purchasing cigarettes – and higher health impacts and costs associated with higher rates of consumption – if plain packaging leads manufacturers to disinvest in branding and compete solely on price, driving tobacco product prices down.
- The Department does not consider this risk to be significant:
  - The proposal is not to introduce generic packaging, but plain packaging. This is an important distinction. Subject to the outcomes of the research to be conducted later in 2010, manufacturers will still be able to use branding, but its use is proposed to be restricted to ensure that it does not promote smoking or mislead about its health impacts. Products will still be identifiable by their brand.
  - The Government is considering simultaneous measures that may increase the price of tobacco products.
  - There is significant variation in the quality (eg taste) of tobacco products and some studies have shown that, in the face of price increases, consumers focus more on quality than on price.
- Again, this potential impact is hypothetical and cannot be costed.

### *Small businesses*

- Many tobacco retailers are small businesses. As set out above, they will be affected to the extent that mandatory plain packaging:
  - makes it more difficult to distinguish between different products or brands;
  - drives down demand for tobacco products.
- The Department proposes to address this potential impact, to the extent consistent with public health objectives of the measure, in the research to develop the optimal design for the packaging. It may be possible for individual product names still to be prominent on the packaging – both on bulk packaging and on individual packs – to aid easy identification.
- The Government has committed through the COAG targets to reducing the prevalence of smoking (and hence demand for tobacco products) to 10 per cent of the Australian population by 2018, in the interests of public health. This plain packaging measure is intended to contribute to that target. While it is intended to contribute to reducing demand for tobacco products, it is not intended to have any effect independent of the public health target.

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- As stated above, it is not possible to quantify the cost of this impact at this time as a change to mandatory plain packaging has not been implemented anywhere in the world. It is also very difficult to isolate the impact of an individual policy measure when a comprehensive suite of measures are being implemented simultaneously to try to reduce demand for tobacco.

### *Competition assessment*

- Incumbent businesses in the tobacco product manufacturing, import, distribution and retail sectors will all be affected in the same way. As long as manufacturers are able to use branding, albeit in a restricted way, they will continue to be able to compete on characteristics such as price, eg taste, other quality characteristics.
- Entry of new businesses will not be restricted by this measure. Entry to the Australian tobacco products market already includes unique packaging requirements.
- Prices and production. There will be some one-off implementation costs for manufacturers however this is unlikely on its own to lead manufacturers to leave the market. There is no domestic tobacco growing industry in Australia. Demand for tobacco products in Australia has been falling for some years and while this measure is intended to accelerate that fall, it would be difficult if not impossible to isolate its impact. Other policy measures are being considered specifically to increase prices.
- Quality and variety of goods and services – other than variety in packaging – will not be affected.
- Innovation in packaging will be affected. Otherwise there will be no impact on innovation.
- Market growth will be affected. The measure is intended to reduce the demand for tobacco products by making consumers more aware of their health impacts.
- Related markets will be affected. There will be impacts on importers, distributors and retailers as set out above.

### *Trade impact assessment*

- The two tobacco product manufacturers with facilities in Australia are understood to export to New Zealand and Pacific Island countries. The potential impact of this regulation on exports cannot be assessed until after the measure has been announced. It cannot be assessed without the cooperation of the tobacco industry and without consultation with the importing countries.
- However, it should be noted that most countries – including New Zealand – have individual national requirements in relation to tobacco product packaging, for example in relation to graphic health warnings.
- The trade impact with New Zealand will need to be closely assessed. Under the Trans Tasman Mutual Recognition Arrangements, goods for sale in New Zealand must usually

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be accepted for sale in Australia. The Department of Foreign Affairs and Trade has been consulted on this possible measure and does not oppose it.

### 5. Consultation

Tobacco manufacturers, importers, distributors and retailers, smokers and their families, the Australian Taxation Office and the Australian Customs and Border Protection Service and the Australian community more broadly will potentially be affected by this measure.

The National Preventative Health Taskforce consulted broadly in developing its recommendations, including through inviting submissions and conducting targeted consultations on discussion papers. The Taskforce received submissions from the tobacco industry and from other stakeholders.

The Government continues to receive representations from stakeholders – particularly tobacco manufacturers and retailers – about the potential impacts of plain packaging, as set out in the impact analysis above.

The Department acknowledges in particular concerns about:

- possible difficulties for retailers in identifying different brands, and
- possible implications for the illicit trade in tobacco products.

The Department is intending to address these concerns in the design of the plain packaging to be mandated. This design is intended to be finalised by the end of 2010 following consumer research on the optimal design to achieve the public health objectives of the measure.

In addition, the Department proposes to conduct further public consultations on the proposal to implement plain packaging, including through a discussion paper and invitation for submissions.

### 6. Conclusion and recommended option

As set out section 3 above, the Department considers that the best option in response to the problem of tobacco product packaging being used to advertise tobacco products and to lead to misperceptions about the adverse health impacts of tobacco products is for the Australian Government to develop and implement legislation to mandate plain packaging. This would follow the recommendations of Australia's leading public health experts on the National Preventative Health Taskforce. Other approaches would:

- risk not achieving the COAG targets of a reduction in the adult daily smoking rate to 10 per cent by 2018;
- require the cooperation of the tobacco industry, which is neither viable nor consistent with Australia's international obligations;
- risk challenge in the courts and/or lower effectiveness.

The recommended option involves:

#### In 2010

- research to establish the optimal design of plain packaging to address the public health objectives at section 2 above and to minimise unintended impacts, particularly for retailers and for the illicit trade in tobacco products; and

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- further consultation with stakeholders;

### In 2011

- finalisation of legislation with a view to gazettal by 1 January 2012 and implementation of requirements by 1 July 2012.

### **7. Implementation and review**

The proposed process and timing for implementation is set out above.

Once the design of the plain packaging and the legislation is sealed, the Department will prepare communication products for manufacturers, importers, retailers, distributors and consumers to set out the new requirements and assist with the change.

The legislation, once in place, will be administered and enforced by the Australian Competition and Consumer Commission (ACCC).

Evaluation of the effectiveness of the suite of measures being implemented to reduce smoking prevalence in Australia to 10 per cent by 2018 will be conducted as part of the COAG performance monitoring arrangements for the National Healthcare Agreement and Preventive Health National Partnership.

An evaluation strategy will be prepared in consultation with the ACCC to monitor the implementation and effectiveness of this individual measure.

The measure will be reviewed after five years.