Standardised packaging and new enlarged graphic health warnings for tobacco products in Australia—legislative requirements and implementation of the Tobacco Plain Packaging Act 2011 and the Competition and Consumer (Tobacco) Information Standard, 2011

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ABSTRACT
This paper describes the development, content and implementation of two pieces of Australian tobacco control legislation: one to standardise the packaging of tobacco products and the other to introduce new, enlarged graphic health warnings. It describes the process of legislative drafting, public consultation and parliamentary consideration. It summarises exactly how tobacco products have been required to look since late 2012. Finally, it describes implementation, most particularly, the extent to which packs compliant with the legislation became available to consumers over time.

DEVELOPMENT OF LEGISLATION
In 2008, the Australian Government established a national taskforce to recommend measures to reduce the burden of disease caused by the preventable risk factors of smoking, alcohol abuse and obesity.1 Among a large number of educational and regulatory measures, and based on consideration of a growing body of international research, plain packaging of tobacco products and enlarged graphic health warnings (GHWs) were proposed later that year in a technical paper on tobacco6 prepared for the National Preventative Health Taskforce. After consultation on a discussion paper4 and consideration of submissions,4 the proposals were included as recommendations in a draft preventive health strategy released by the Taskforce in September 2009.5 The proposal for plain packaging was vigorously opposed by the tobacco industry6,7: accounts of the tobacco industry’s campaign strategies and of activities by health groups over the late 2000s are available elsewhere, for instance (see http://www.tobaccoinaustralia.org.au/chapter-11-advertising/11-10-tobacco-display-as-advertising1). Table 1 provides a timeline of legislative milestones in the development and implementation of plain packaging and enlarged GHWs in Australia.

Plain packaging
On 29 April 2010, the Prime Minister announced that the Government would adopt tobacco plain packaging and immediately increase tobacco excise and customs duty by 25%. This position was detailed in full in the Government’s formal response to the Taskforce released several days later.7

The Department of Health and Ageing commissioned a set of studies8 to establish the impact of existing packaging design on appeal and attractiveness and to establish optimal colour for packaging and the optimal size and colour for standardised font indicating brand and variant names.9 10 These and related studies on GHWs were conducted between December 2010 and March 2011 and involved regular smokers aged 18–65 in two face-to-face focus group studies (38 groups in total) and four online quantitative surveys (ranging from n=205 to n=455).11 In addition, face-to-face interviews were conducted with retailers aged 40 years and older to establish legibility of brand names in the retail environment.11

An ‘exposure draft’ of the Tobacco Plain Packaging Bill was released in April 2011.12 A Consultation Paper was released at the same time outlining the Government’s response to design testing and targeted consultations,13 and explaining the most important provisions of the draft Bill (2011) and associated regulations.14

The Explanatory Memorandum that accompanied the Bill tabled in Parliament on the 6 July 201113 stated that the legislation aimed to prevent tobacco advertising and/or promotion on tobacco product packaging in order to: reduce the attractiveness and appeal of tobacco products to consumers, particularly young people; increase the noticeability and effectiveness of mandated health warnings; reduce the ability of the tobacco product packaging to mislead consumers about the harms of smoking; and through the long-term achievement of these objectives as part of a comprehensive suite of tobacco control measures, contribute to efforts to improve public health by reducing smoking rates.13

The Government conducted further consultation on the detail of the proposed design features for the plain packaging of non-cigarette tobacco products in October 201116 and also on the Tobacco Plain Packaging Regulations. The Tobacco Plain Packaging Act 2011 (the Act)17 18 and associated Trade Marks Amendment (Tobacco Plain Packaging) Act 201119 received Royal Assent on 1 December 2011. The Tobacco Plain Packaging Regulations 2011 (Regulations) approved by the Government’s
Table 1  Timeline of adoption and implementation of tobacco plain packaging legislation in Australia

| Year | Event |
|------|-------|
| 2009 | 30 June  | National Preventative Health Taskforce final report to Australian Government for consideration  
1 September | Health Minister releases final report |
| 2010 | 29 April | Prime Minister Kevin Rudd announces Australia will adopt tobacco plain packaging |
| 11 May | Release of Australian Government’s formal response to recommendations |
| 21 August | Australian general election |
| 2011 | 7 April | Release of exposure draft of legislation for consultation Tobacco Plain Packaging Bill 2011 |
| 6 July | Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 and Tobacco Plain Packaging Bill introduced and read in House of Representatives. House refers Bills to Standing Committee on Health and Ageing |
| 4 August | Hearings of the House of Representatives Standing Committee on Health and Ageing |
| 18 August | Senate refers Trade Marks Amendment (Tobacco Plain Packaging) Bill 2011 to Legal and Constitutional Affairs Committee which calls for submissions (by 2 September) |
| 22 August | House of Representatives Standing Committee on Health and Aged Care tables the report on its Inquiry into Tobacco Plain Packaging |
| 13 September | Hearings of the Senate’s Legal and Constitutional Affairs Committee |
| 17 September | Release of consultation paper on new graphic health warnings for tobacco products |
| 19 September | Legal and Constitutional Affairs Committee provides report to Senate |
| 26 October | Release of Proposed mandatory standard for tobacco labelling (graphic health warnings): second round consultation paper |
| 2 November | Health Minister, announces that the implementation of tobacco plain packaging will be delayed until 1 December, 2012 as a result of delays in the Senate review of the bill |
| 14 November | Release of Proposed mandatory standard for tobacco labelling (graphic health warnings): draft regulation for comment |
| 21 November | Final passage of amended Bill through House of Representatives |
| 1 December | Bill received royal assent and became law—Tobacco Plain Packaging Act 2011 |
| 2012 | 1 December | British American Tobacco initiates proceedings in Australia’s High Court to test the validity of the law as it relates to property rights of two brands, Winfield and Dunhill. Press release |
| 6 December | Imperial Tobacco similarly initiates proceedings |
| 15 December | Japan Tobacco files a Writ of Summons against the Australian Government alleging that the plain packaging law infringes its trademark rights |
| 20 December | Philip Morris Australia files a Writ of Summons in the High Court against the Australian Government alleging that the plain packaging law infringes its trademark and property rights |
| 22 December | Release of new Information Standard specifying enlarged graphic health warnings for tobacco products Competition and Consumer (Tobacco) Information Standard 2011 to start phase in from 1 January 2012 |
| 2013 | 17–19 April | High Court case hearing of Full Court opens in Canberra |
| 27 June | Introduction of Customs Amendment (Smuggled Tobacco) Bill 2012 |
| 15 August | High Court of Australia announces tobacco industry’s case against Australian Government has failed and awards costs to the government. Judgement to be released at later date. Further information |
| 1 October | All packs manufactured to be plainly packaged |
| 6 November | Assent of Customs Amendment (Smuggled Tobacco) Act 2012 |
| 1 December | All packs sold to be in plain packaging with prescribed enlarged health warning. Only the first set of graphic health warnings are to be displayed on retail packaging of cigarettes and most other smoked tobacco products (excluding cigars and bidis). Cigars and bidis are required to display different product specific warnings |
| 2014 | 1 February | Automatic (biannual since 1985) indexation of tobacco excise/customs duty in line with increase in Consumer Price Index June 2012 to December 2013 |
| 1 August | Automatic (biannual since 1985) indexation of tobacco excise/customs duty, in line with increase in Consumer Price Index December 2012 to June 2013 andGraphic health warnings from the second set of warnings start to be displayed on relevant packaging; packs with warnings from the first set of warnings may continue to be manufactured until the end of November 2013 |
| 1 December | 12.5% increase in excise/customs duty. Only packs bearing one of the second set of graphic health warnings may be manufactured from this date |
| 2015 | 1 March | First of automatic indexation increases in excise and customs duty in line with changes in Average Weekly Earnings |

Source: a more detailed timeline can be viewed on the Plain Facts website, Cancer Council Victoria, at https://www.cancervic.org.au/plainfacts/browse.asp?ContainerID=timelineandinternationaldevelopments.
Executive Council on 7 December 201120 21 set out requirements for the retail packaging and appearance of cigarettes and were amended in early 201222 to incorporate the additional specifications for plain packaging of non-cigarette tobacco products. The legislation was challenged by tobacco companies in the High Court of Australia which heard the case in April 2012 and upheld the legislation in its ruling released in August 2012.23

New enlarged GHWs
GHWs have been required on most tobacco products in Australia since 2006. Prior to late 2012, cigarette packs and cartons had displayed GHWs on 30% of the front of pack and 90% of the back in two rotating sets of seven warnings. An information message was also required on the side of the pack.24 Evaluation of these health warnings conducted in 200825 suggested that while the new graphic warnings had greater impact with consumers than the previous text-only warnings, effectiveness could be further improved with larger and larger, front-of-pack warnings, updated and refreshed images and simple and clear text messages in larger, clearer font and simplified side-of-pack text. The evaluation report also recommended extension of GHWs to other tobacco products and introduction of plain packaging to remove conflict and competition between the pack design and health warnings.25

During 2010 and 2011—the same period that plain packaging legislation was being drafted—the Department of Health and Ageing commissioned further market research to guide development of new, larger GHWs.26–29 This research examined potential new images and warning statements, more detailed explanatory messages to appear on the back of pack and information messages to appear on the side of packs. This and related research also tested different colours and layouts for warning messages and options for various sizes of GHWs.8 27 29 This research demonstrated that the proposed 75% front-of-pack GHWs were more immediately noticeable, serious and difficult to avoid than the previous 30% warnings.8 11

Prior to finalising the new health warnings, the Australian Competition and Consumer Commission undertook three public consultations between September 2011 and December 2011 and the new Competition and Consumer (Tobacco) Information Standard 2011 prescribed under the Australian Consumer Law in Schedule 2 to the Competition and Consumer Act 2010 was made on 22 December 2011.30

REQUIREMENTS FOR PLAIN PACKAGING
Figure 1 depicts Australia’s leading brand of cigarettes (A) before and (B) after the introduction of tobacco plain packaging in Australia.

Packaging colour
Eight different colours were market tested for plain packaging and a drab dark brown was found to be the least appealing and attractive, had the lowest potential for the pack to mislead consumers about the harms of tobacco, and increased the impact of GHWs.9 Regulation 2.2.1 (2) specifies that Pantone 448C is the exact shade of drab dark brown which must be used on the outer surfaces of tobacco packaging.

Specifications for display of brand names
Market research determined the font style, size and colour to be used for brand and variant names as well as their location on the packaging that provided for legibility in the retail setting while maintaining the public health objectives of the Act.9 The Regulations detail how brand and variant names must appear on tobacco packaging.21 For retail packaging of cigarettes, Regulation 2.4.1 specifies they must be in Lucida Sans font type and that the brand name can be no larger than 14 points in size and the variant name no larger than 10 points in size. The font must be normal weighted regular font and in a light grey colour known as Pantone Cool Gray 2C. Only the first letter in each word may be capitalised and no other upper case letters may be used. Regulation 2.4.2 stipulates similar provisions for non-cigarette tobacco products.

The placement of the brand and variant name on the packaging is also tightly regulated under Sections 21 (2) and (3) of the Tobacco Plain Packaging Act 2011. The brand name may appear once only on each of the front, top and bottom surfaces of cigarette packs, must appear across one line only, oriented horizontally and centred in the relevant space beneath the health warning. The variant name must appear horizontally and immediately below the brand name—see front of pack in figure 1B. Regulations 2.4.3 and 2.4.4 set out corresponding requirements for non-cigarette packaging.

Cigarette packaging features
Market research determined that innovative packaging shape, size and opening affected the level of appeal and brand personality of cigarettes9 (confirmed by experimental research31 32) and, as a result, the dimensions, shape and opening of cigarette packs were restricted. ‘Soft packs’—demonstrated in the research to be perceived as more masculine—were also prohibited. Under Section 18 of the Act, cigarette packs must also be made of rigid material and must not have any decorative ridges, embossing or embellishments. Regulation 2.1.1 specifies minimum and maximum height, width and depth for cigarette packaging and that packs must have a flip-top lid.

Allowable information on cigarette sticks
In light of results of market research which showed that branding and decorative features are strongly associated with level of appeal and brand personalities,9 Section 26 of the Act bans trademarks or other marks from appearing on tobacco products, thus outlawing brand or variant names and other embellishments from appearing on cigarette sticks (see figure 2). Regulations require the paper casing for cigarette sticks to be all white or white with a cork tip (Regulation 3.1.1). While they allow an alphanumeric code in a specified font style, size, colour and location to appear on sticks, the type of code is restricted, including a requirement that it must not constitute tobacco advertising or promotion (Regulation 3.1.2).

Other information allowable
The Tobacco Plain Packaging Regulations also allow for a ‘measurement mark’ as required by Division 4.4 of the National Trade Measurement Regulations 200933 to be placed on the side of the pack along with the name, address and phone number of the person who packed the product or on whose behalf it was packed (see Regulations 2.3.4, 2.3.8 and 2.3.9). This information must be in the typeface known as Lucida Sans, no larger than 10 points in size, normal weighted regular font and in a light grey colour known as Pantone Cool Gray 2C.

A barcode is also allowed on the side of packs under regulation 2.3.5. The barcode must be coloured either black and white or the colour Pantone 448C (drab dark brown) and white—see example here. It must not form a picture, symbol or design.

An ‘origin mark’ is also allowed to assist with strategies to prevent counterfeiting and illicit trade. Regulation 2.3.2 states that the origin mark must be either covert and not visible to the naked eye or an alphanumeric code—see example here.
REQUIREMENTS FOR ENLARGED GHWS

Health warning size and elements

Similar to the 2004 Regulations, the Competition and Consumer (Tobacco) Information Standard 2011 (the Standard) requires that retail packaging of most tobacco products contain a combination of warning statement, graphic image, explanatory message and information message. The size of GHWs on cigarette packaging increased from 30% to 75% of the front surface—see figure 1. The 2011 Standard maintained 90% of the back surface for warnings including text, image and explanatory messages on cigarette packs and cartons—see figure 1. An increase to 75% of the front and back surface was required of most other tobacco products including roll-your-own (RYO) and pipe tobacco pouches, cigar packs and shisha (tobacco for use in water pipes).

The side-of-pack Information Message (previously a single message required to be white text on a black background) from...
1 December 2012 onwards now has to be one of several rotating messages (with information about chemicals in tobacco smoke, paired with, and relevant to, the particular GHW on each pack) presented in black text on a yellow background—see here for image. This requirement was in line with market research which determined this updated format to be more noticeable.82 6

Quitline logo
The Quitline logo and phone number, ‘Quitline 137 848’, is required to appear overlaid on the graphic on the back of tobacco packages that have them (Part 1, Section 1.3 (6))—see back-of-pack images in figure 1—and on the graphic on the front of cigar packs.

Health warnings for different types of tobacco products
The new GHWs developed as a result of market testing covered a broader range of topics and mix of image styles than the previous warnings, including a stronger emotional component and a greater emphasis on morbidity than mortality. Fourteen warning statements with corresponding graphic images, explanatory messages and information messages are required on cigarettes and smoking tobacco (RYO tobacco and pipe tobacco) as specified in the Standard in Part 3 (items 3.2–3.8; the first set of health warnings; figure 3) and Part 4 (items 4.2–4.8; the second set of health warnings; figure 4). Each of the warnings can be viewed at: http://www.comlaw.gov.au/Details/F2013C00598/Html/Text#Toc363806248. All tobacco products including packs of cigars and single cigars, bidis and smokeless tobacco are required to bear health warnings. Hence, the Australian Standard is aligned with Article 11 Guidelines for the WHO Framework Convention on Tobacco Control which state that “there should be no exemptions for small volume companies or brands or for different types of tobacco products” (see WHO FCTC Article 11 Guidelines, Product Category Considerations, Section 46).

The five graphic warnings for retail packaging for cigars (other than cigar tubes) as detailed in Part 5 (items 5.2–5.6) of the Standard are ‘Cigar smoking causes mouth cancer’, ‘Cigar smoking causes lung cancer’, ‘Cigar smoking is not a safe alternative’, ‘Cigar smoking causes throat cancer’ and ‘Cigar smoking damages your teeth and gums’. Part 6 of the Standard states that the same five cigar warning statements are required on single cigar tubes as a text-only warning—see example here. The warning statements in Part 6, item 6.2 can be viewed at: http://www.comlaw.gov.au/Details/F2013C00598. Part 9, Division 4 of the Standard provides diagrams of how the individual requirements for the health warnings should be set out for different package formats.

LEGISLATED TIMING OF TRANSITION TO PLAIN PACKAGING AND ROLL-OUT OF NEW HEALTH WARNINGS
Plain packaging
All tobacco packs manufactured or packaged in Australia for domestic consumption from 1 October 2012 and all packs sold from 1 December 2012 were required to be in plain packaging as described in detail above.17

Health warnings
The Competition and Consumer (Tobacco) Information Standard 2011 (the Standard)10 allowed a ‘phase-in’ period. Between 1 January 2012 and 30 November 2012 inclusive, suppliers could choose to comply with the Standard10 or with the 2004 Regulations24 previously in force. All tobacco products supplied to consumers had to be in packaging that complied with the Standard from 1 December 2012.

Rotation requirements for the health warnings are set out in Part 9 of the Standard for cigarettes and other smoked tobacco products. The first set of warnings (described in Part 3 of the Standard) could be displayed on packs sold in retail outlets

Figure 3 Winfield Blue 25s: packs showing the first set of seven health warnings. Source: Quit Victoria pack collection, December 2012.

Figure 4 Winfield Blue 25s: packs showing the second set of seven health warnings. Source: Quit Victoria, December 2013.
between 1 January 2012 and 30 November 2012 (prior to the full implementation of tobacco plain packaging) and were the only warnings that could be displayed between 1 December 2012 and 31 July 2013, with near-as-possible-to-equal frequency required for all seven warnings in this period (and for 8 months starting 1 December for each subsequent even-numbered year).

The second set of health warnings (described in full in Part 4 of the Standard) could be displayed on packs manufactured from 1 August 2013 to 30 November 2014 and each had to be displayed with as near-as-possible-to-equal frequency for the 8 months starting 1 December 2013 (and for 8 months starting 1 December of each odd-numbered year).

Either set of warnings could be displayed on packs manufactured from 1 August to 30 November 2013. This pattern—8 months of the first set only, 4 months of both, 8 months of the second set only—will continue for the life of the Standard.

REAL-WORLD TRANSITION TO PLAIN PACKAGING AND ROLL-OUT OF NEW HEALTH WARNINGS

The transition to plain packaging and the roll-out of Set 2 warnings was monitored as part of a national continuous cross-sectional survey with approximately 100 interviews completed per week between April 2012 and March 2014, detailed in Wakefield et al15 in this volume. Telephone interviews with adult (18–69 years) smokers and recent quitters (quit in the last year) were conducted using a dual-frame sample design, with half of respondents approached via landline random digit dialing (RDD) and half by mobile phone RDD (overall response rate 57%). All participants who smoked daily or weekly were classified as smokers and those who smoked less often (monthly or less-than-monthly) were allowed to self-identify as either a current smoker or recent quitter. Transition to plain packaging was assessed among 7659 cigarette smokers.

Over the entire survey period, cigarette smokers—smokers of either factory-made (FM) cigarettes or RYO cigarettes—were asked whether or not their current cigarette pack or RYO pouch was a plain dark colour with all of its logos removed. We did not correct or exclude obvious reporting errors occurring in a small minority of respondents, such as packs being reported as plain many months prior to October 2012. In order to monitor the roll-out of the second set of health warnings, from August 2013 to the end of the survey period, cigarette smokers were asked to report the health warning on their current pack using two questions. The first asked current smokers if they have their current pack with them, with those answering ‘yes’ asked to read out the bold white warning statement on the front of their pack.

As described in detail in Scollo et al16 in this volume, smokers were also asked about current brand smoked. Brands were then coded by manufacturer and market segment (premium, mainstream or value, based on classifications adopted by the Retail World magazine).

Analyses of the proportion of packs that were plain and the proportion of packs with Set 2 warnings were undertaken by month or week using logistic regression, adjusting for age (18–29; 30–49; 50+ years), sex, education (less than high school; high school or some tertiary; tertiary and above), and area socioeconomic status (low, mid and high using the 2011 index of relative disadvantage37) and Heaviness of Smoking Index (0: low to 6: high38).

Figure 5 shows the adjusted proportion of current tobacco packages (including cigarette packs and RYO pouches) purchased in Australia which were self-reported as plain over each of the weeks in October, November and December 2012. Plain packs began to be used by smokers from mid-October, so that in the last half of

Notes: Transition to plain packs: Cigarette smokers (total n=8679; analysed and plotted n=7659). We excluded n=49 who currently smoked unbranded ‘chop-chop’ tobacco and n=234 who did not report their current brand name and thus did not get asked the plain packaging question. We also excluded those who purchased duty free or overseas (n=74), or did not know where the pack was purchased (n=1553). We excluded n=13 who currently smoke unbranded ‘chop-chop’ tobacco, and thus did not get asked to identify their pack’s health warning, those who purchased duty free or overseas (n=8), did not know where the pack was purchased (n=23), who reported a non-Australian or no health warning (n=52), those who refused or did not know (n=21), and with missing demographic information (n=56).
October 2012, a total of 21.2% of packs were reported as plain. This accelerated rapidly, increasing to 57.4% in the week beginning 11 November. 73.4% in the last half of November and then 91.9% in week beginning 2 December. In interaction analyses, the rate of transition over each of the weeks in October, November and December 2012 did not differ by state of residence (F=0.94, p=0.565), cigarette type (FM to RYO; F=1.17, p=0.313), or market segment (premium, mainstream, value; F=1.00, p=0.455) or tobacco manufacturer (British American Tobacco Australia (BATA), Philip Morris (PM), Imperial Tobacco, other; F=1.06, p=0.386) of the current brand, suggesting that plain packs emerged at a similar rate throughout the market.

The roll-out of Set 2 GHWs on plain packs was also examined among the 1533 cigarette smokers interviewed from August 2013 to March 2014. In August 2013, 17.8% of packs depicted a Set 2 warning, compared with 30.3% in September, 64.3% in October and 76.8% in November. From 1 December 2013, on average, 89.8% of packs were reported to have a Set 2 warning, with 96.2% of packs having a Set 2 warning by March 2014. Over the period from August 2013 through December 2013, the proportion of packs per week with the second set of health warnings did not differ by state of residence (F=0.93, p=0.628), cigarette type (FM or RYO; F=1.23, p=0.235), market segment (premium, mainstream, value; F=1.00, p=0.465) or tobacco manufacturer (BATA, PM, Imperial Tobacco, other; F=1.34, p=0.107), suggesting that Set 2 warnings emerged at a similar rate throughout the market.

It was notable that, well after full implementation of plain packaging (on 1 December 2012), about 5% of cigarette smokers consistently reported their tobacco packs were not ‘a plain dark colour with all logos removed’. This could not be explained by cigarette smokers buying their packs from overseas as such smokers were excluded, so some might interpret this as an indication of use of non-compliant packs or even use of illicit tobacco, an issue explored in more detail in Scollo et al19 in this volume. However, we consider it more likely that a large component of this 5% would be misreporting (not completely understanding the question). Respondents were asked “is the pack/package you are currently smoking from a plain dark colour with all of its logos removed?”. Interviewers were instructed to code ‘no’ if the respondent indicated that some logos remained. It is probable that some smokers interpreted the brand or variant name (still allowed under the plain pack) or packaging—conversely reported that they did possess a pack that was plain dark brown with all logos removed despite plain packs not being on the market at this time.

Studies evaluating the impact of plain packaging and enlarged GHWs need to take account of the very gradual roll-out of the Set 2 health warnings.

What this paper adds

- The Tobacco Plain Packaging Act 2011 and the Competition and Consumer (Tobacco) Information Standard 2011 have comprehensively altered the appearance of tobacco products in Australia.
- Manufacturers implemented enlarged graphic health warnings at the same time as plain packaging though they were free to introduce them earlier.
- Overall, plain packaging transitioned as intended over a relatively short period between the required dates of manufacture and retail sale in late 2012. The second set of enlarged graphic health warnings rolled out gradually from August 2013 with almost all packs bearing the second set of warnings by the end of February 2014.
- The new standardised packs were available and likely already exerting an impact in the Australian market from October 2012 onwards, well before the 1 December mandated introduction date.

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