

# Submission to Therapeutic Goods Administration Consultation Paper on Potential reforms to the regulation of nicotine vaping products

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## *A. Introduction*

This submission supports reform of regulation of nicotine vaping products (NVPs), noting the stated reform objective of preventing children and adolescents from accessing NVPS and the additional objective of *supporting use* for doctor monitored use of NVPs to cease smoking. It focuses on reform options regarding strengthening product standards, particularly proposals to introduce plain packaging for NVPs which can place special requirements on the use of trade marks by intellectual property owners. Changes to NVP regulation that impact on the exercise of intellectual property rights should clearly articulate the justification for these changes, including identifying any international obligations that support the policy. This submission identifies relevant support and guidance for reform to the regulation of NVPs in international agreements ratified by Australia, including the *Convention on the Rights of the Child (CRC)*, the *International Covenant on Economic, Social and Cultural Rights (ICESCR)* and the *Framework Convention on Tobacco Control (FCTC)*. These obligations should be considered in policy design. Children should be meaningfully consulted in legislative and policy design as part of this process, to ensure the best interests of the child are a primary consideration, consistent with Australia's obligations pursuant to the CRC. Explicit recognition of relevant international obligations and the way any NVP policy change realises these obligations should strengthen justifications for changes to regulation of NVPs and be valuable in the event that changes are disputed by owners of intellectual property related to NVPs or WTO members who trade in NVPs.

I am currently researching intellectual property protection for NVPs in Australia. Initial research indicates that there are more than 300 Australian trade mark registrations in class 34 in relation to ‘e-liquids’ with priority dates as early as 24 October 2013. Changes to regulation of NVPs, including the introduction of plain packaging, could impact the use of these trade marks as they are likely to restrict the manner in which the trade marks are displayed on packaging or if they can be displayed at all. This may prompt disputes about Australia’s compliance with the *Agreement on Trade-Related Aspects of Intellectual Property* (‘TRIPS’),<sup>1</sup> or its obligations to investors pursuant to bilateral or plurilateral trade and investment agreements. My previous analysis of tobacco plain packaging legislation disputes brought against Australia in the World Trade Organization and Uruguay in an investor state dispute brought by Philip Morris has identified the value of recognising relevant international obligations supporting the introduction of legislation that can impact the exercise of intellectual property, particularly in relation to trade marks.<sup>2</sup> Australia’s human rights obligations are relevant to tobacco plain packaging obligations and can strengthen justifications for policies and legislation that restrict the rights of intellectual property owners when these restrictions are contested. Greater attention should be given to Australia’s human rights obligations in relation to children and adolescents in design and implementation of tobacco plain packaging policy.<sup>3</sup> These arguments are also relevant to e-cigarettes and vaping and are discussed in Part B of this submission.

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<sup>1</sup> *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 1C (‘*Agreement on Trade-Related Aspects of Intellectual Property Rights*’) (‘TRIPS’).

<sup>2</sup> Genevieve Wilkinson ‘Packaging Domestic Interests into Intellectual Property Law: Lessons from Tobacco Plain Packaging Disputes’ (2021) 47(2) *Monash University Law Review* (forthcoming). Advance copy available at <https://doi.org/10.26180/21673892>.

<sup>3</sup> Genevieve Wilkinson, ‘Using Tobacco Plain Packaging to Protect the Human Rights of Children’ (2022) 45(1) *University of New South Wales Law Journal* 370.

## B. Regulation of Vaping and Tobacco Plain Packaging

Australia's tobacco plain packaging legislation requires uniform packaging of tobacco products and limited the way that intellectual property rights, particularly trade marks, could be used on packaging.<sup>4</sup> The legislation was opposed by tobacco companies, resulting in three key disputes:

- A domestic dispute arguing that the legislation constituted the acquisition of property by the Commonwealth but this was inconsistent with 51(xxxi) of the Constitution as it was not on just terms. In *JT International*, the High Court determined that the legislation did not constitute an acquisition of property and dismissed the claim.<sup>5</sup>
- An investor state dispute arguing that the legislation was inconsistent with the Australia-Hong Kong bilateral investment treaty in force when the legislation was introduced. The dispute was dismissed in interlocutory proceedings that determined that the action constituted an abuse of process as Philip Morris was aware of the proposed legislation when it reorganised ownership of intellectual property rights so that it had standing to bring the claim.<sup>6</sup>
- A World Trade Organization (WTO) dispute brought by Honduras, the Dominican Republic, Cuba and Indonesia against Australia, alleging that the legislation was inconsistent with obligations found in *TRIPS* and the WTO agreement on *Technical Barriers to Trade (TBT)*.<sup>7</sup> All claims were dismissed in a WTO Panel Report in 2018.<sup>8</sup> Honduras and the Dominican

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<sup>4</sup> See *Tobacco Plain Packaging Act 2011* (Cth), the *Trade Marks (Plain Packaging) Act 2011* (Cth) and supporting regulations.

<sup>5</sup> *JT International SA v Commonwealth* (2012) 250 CLR 1 at 34–5 (French CJ), 61 (Gummow J), 73 (Hayne and Bell JJ), 108 (Crennan J), 128–32 (Kiefel J).

<sup>6</sup> *Philip Morris Asia Ltd v Australia (Award on Jurisdiction and Admissibility)* (Permanent Court of Arbitration, Case No 2012-12, 17 December 2015) 184 [585].

<sup>7</sup> *Marrakesh Agreement Establishing the World Trade Organization*, opened for signature 15 April 1994, 1867 UNTS 3 (entered into force 1 January 1995) annex 1A ('Agreement on Technical Barriers to Trade').

<sup>8</sup> Panel Reports, *Australia — Certain Measures concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Docs WT/DS435/R, WT/DS441/R, WT/DS458/R and WT/DS467/R (28 June 2018) ('*Australia — Tobacco Plain Packaging Panel Decision*').

Republic appealed some of the *TRIPS* and *TBT* findings but the Appellate Body decision in 2020 dismissed the appeal.<sup>9</sup>

Attempts to dispute tobacco packaging in other jurisdictions were also unsuccessful.

Contemporaneously, Philip Morris unsuccessfully disputed tobacco packaging requirements in Uruguay pursuant to the bilateral investment agreement between Uruguay and Switzerland in force at the time. The public health justification for Uruguay's legislation and its reliance on its obligations pursuant to the *FCTC* influenced the majority decision to dismiss the claim.<sup>10</sup> However, the minority judgment found that Uruguay's requirements were not consistent with the requirements of the *FCTC* and Uruguay had breached fair and equitable conduct obligations under the investment agreement.<sup>11</sup>

These disputes are relevant to the proposed changes to regulation of e-cigarettes in Part 3 of the Consultation Paper for several reasons. Trade mark registrations protect e-cigarettes. Although the trade mark registrations for e-liquids identified in Part A differ in multiple respects from the registrations that formed the basis for the disputes brought against Australia and Uruguay such as the length of registration and nature of use of the marks, it is possible that they could be used to contest currently proposed or future changes to regulation of NVPs. The disputed measures of uniform packaging have been proposed by this Consultation Paper as an approach to discourage young people from using NVPs. This was one of the rationales for tobacco plain packaging so the justifications used for these measures may also be relevant to greater regulation of NVPs.

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<sup>9</sup> Appellate Body Reports, *Australia — Certain Measures concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WTO Docs WT/DS435/AB/R and WT/DS441/AB/R (9 June 2020) ('*Australia — Tobacco Plain Packaging Appellate Body Decision*').

<sup>10</sup> *Philip Morris Brands Sàrl v Uruguay (Award)* (ICSID Arbitral Tribunal, Case No ARB/10/7, 8 July 2016) [399-409] ('*Award Decision*').

<sup>11</sup> *Ibid* (Mr Gary Born) [174-179].

The parties that opposed tobacco plain packaging may also have interests in opposing plain packaging of NVPs and other types of regulation. Some tobacco companies have diversified their manufacturing interests to include e-cigarettes. Altria (formerly Philip Morris) is a majority shareholder of Juul which has the largest market share of e-cigarette sales in the United States.<sup>12</sup> Transnational tobacco companies have used litigation to obstruct the implementation of tobacco packaging restrictions.<sup>13</sup> The prospect of lengthy, resource-intensive disputes had a chilling impact on the introduction of plain packaging legislation in other jurisdictions including New Zealand, Mexico and Guatemala.<sup>14</sup>

The intellectual property owners were unsuccessful in all of the disputes identified above. However, differences in the justification for changes to the regulation of NVPs could result in different outcomes in future WTO disputes or investor state disputes. Justification was important to the claims made in the WTO dispute that alleged Australia was in breach of the obligation in TRIPS Article 20 that

‘The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings.’

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<sup>12</sup> The Australian register includes a figurative trade mark registration for JUUL Labs Inc (1932693).

<sup>13</sup> Benjamin Hawkins, Chris Holden and Sophie Mackinder, ‘A Multi-Level, Multi-Jurisdictional Strategy: Transnational Tobacco Companies’ Attempts to Obstruct Tobacco Packaging Restrictions’ (2019) 14(4) *Global Public Health* 570.

<sup>14</sup> See Jennifer L Tobin, ‘The Social Cost of International Investment Agreements: The Case of Cigarette Packaging’ (2018) 32(2) *Ethics and International Affairs* 153, 161–2; Sera Mirzabegian, ‘Big Tobacco v Australia: Challenges to Plain Packaging’ (2019) 4(1) *Business and Human Rights Journal* 177, 182; Lukasz Gruszczynski, ‘Australian Plain Packaging Law, International Litigations and Regulatory Chilling Effect’ (2014) 5(2) *European Journal of Risk Regulation* 242, 244; Eric Crosbie, ‘Constraining Government Regulatory Authority: Tobacco Industry Trade Threats and Challenges to Cigarette Package Health Warning Labels’ (PhD Thesis, University of California, June 2016) 284–9 <<https://escholarship.org/uc/item/7tr077rr#main>>.

Previous analysis of the WTO disputes suggests that the following questions should be explicitly addressed by states in the design and implementation of legislation that imposes special requirements on the use of trade marks:

- ‘1. Does the legislation restrict the legitimate interests of the intellectual property owner? If so, how?
2. Are the restrictions applied to protect societal interests?
3. Is there sufficient support for the application of those restrictions and are the restrictions supported by multilateral consensus found in other international agreements?
4. Is there a readily available alternative that would result in equivalent policy objective outcomes?’<sup>15</sup>

States can then use these answers to justify legislative changes in the event of a dispute. This assessment is particularly important where NVPs are regulated as there are potentially competing interests between protecting children and adolescents from harmful substances and permitting smokers to use NVPs as an effective cessation tool.

In the WTO disputes, the dispute settlement bodies found that special requirements on trade marks can be supported by societal interests. Relevant societal interests are guided by the objective and principles clauses found in *TRIPS* articles 7 and 8. These interests include but are not limited to measures necessary to protect health and nutrition.<sup>16</sup> They can also include the protection of human rights.<sup>17</sup> Human rights obligations can also be relevant to justification of restrictions on intellectual

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<sup>15</sup> Wilkinson, 2021 (n2) Part III (F).

<sup>16</sup> *Australia — Tobacco Plain Packaging Panel Decision* [7.2406].

<sup>17</sup> See Genevieve Wilkinson, ‘Tobacco Plain Packaging, Human Rights and the Object and Purpose of International Trade Mark Protection’ in Susy Frankel (ed), *The Object and Purpose of Intellectual Property* (Edward Elgar, 2019) 182, 209; Christophe Geiger and Luc Desautettes-Barbero, ‘The revitalisation of the object and purpose of the TRIPS Agreement: the plain packaging reports and the awakening of the TRIPS flexibility clauses’ in Griffiths and Mylly (eds) *Global Intellectual Property Protection and New Constitutionalism*

property. In the WTO disputes, weight was given to Australia's objective of using plain packaging legislation to implement the *FCTC*.<sup>18</sup> This submission identifies international human rights agreements that can similarly provide support for reform proposals suggested in the Consultation Paper that may impact intellectual property rights. It is important to consider if proposed reforms to NVPs implement these agreements and, if they do, identify that support as part of the legislative development process.

Justifications for restrictions on intellectual property rights are also critically important to investor state disputes where changes to government policy have negative impacts on protected foreign investors. Although the investor state dispute brought against Australia was dismissed for abuse of process, the findings in the investor state dispute contesting Uruguayan tobacco packaging legislation brought by Philip Morris pursuant to the investment agreement between Uruguay and Switzerland demonstrate the relevance of justification to claims that Uruguay was in breach of fair and equitable conduct obligations. Importantly, the majority judgment accepted that Uruguay could rely on the *FCTC* as justification for its tobacco packaging measures.<sup>19</sup> It is extremely important to clearly identify the justification for reforms to the regulation of NVPs that can impact intellectual property rights that may be protected in investor state disputes.<sup>20</sup> This is also important to ensure measures are consistent with effective realization of human rights obligations.

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(OUP, 2021) 292-294. The potential relevance of the human right to health as a justification for measures regarding the domestic product of pharmaceutical in a WTO dispute regarding national treatment was recently recognised: see *Turkey — Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products*, WTO Doc WT/DS583/12 (28 April 2022) (Notification of an Appeal by Turkey). The Panel's decision was upheld in arbitration: see Decision by the Arbitrators, *Turkey — Certain Measures concerning the Production, Importation and Marketing of Pharmaceutical Products — Arbitration under Article 25 of the DSU*, WTO Doc WT/DS583/ARB25 (25 July 2022).

<sup>18</sup> Panel Reports, *Australia — Tobacco Plain Packaging Panel Decision*, WTO Docs WT/DS435/R, WT/DS441/R, WT/DS458/R and WT/DS467/R [7.2596].

<sup>19</sup> *Award Decision* [393]–[396].

<sup>20</sup> See Wilkinson, 2021 (n 2).

### C. *Relevant Human Rights Obligations regarding NVPs*

Some of the human rights obligations relevant to the regulation of NVPs were identified in the human rights compatibility statement contained in the Explanatory Statement for the Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021. This stated that the amended regulations supported the right to health found in article 12 of the *ICESCR* by ‘enabling the appropriate importation and supply chain movements (including allowing pharmacists to hold stock in anticipation of supply to consumers under prescription and through a special access pathway for unapproved medicines), of nicotine vaping products to support smoking cessation’.<sup>21</sup>

The consultation paper indicates that reform of existing measures is needed because there is emerging evidence that children and adolescents are acquiring NVPs in increasing numbers and many adults are accessing NVPs without a prescription which may be a source of access to NVPs for children and adolescents. Known health risks associated with NVPs include lung injuries and injuries resulting from consumption of vaping liquids. Given the relatively recent introduction of vaping and diverse ingredients in NVPs, further health concerns may emerge. NVPs should be regulated on the basis that they are harmful substances.<sup>22</sup> This engages Australia’s *ICESCR* obligations but these concerns also directly engage a number of *CRC* obligations that should be considered as part of the NVP reform process:

- Article 24 recognises ‘the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health’.

Article 24(2)(f) further provides that, to fully implement the right, states shall take measures

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<sup>21</sup> Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021 Explanatory Statement F2021L01032.

<sup>22</sup> Marie Gispen and Jacquelyn Veraldi, ‘A human rights approach to the regulation of electronic cigarettes’ in Lukasz Gruszczyński (ed) *The regulation of e-cigarettes: international, European and national challenges* (Edward Elgar, 2019). See *ICESCR* obligations to regulate harmful substances in Committee on Economic, Social and Cultural Rights, *General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights)*, UN Doc E/C.12/2000/4 (11 August 2000) paras 15, 36 and 51.



‘[T]o develop preventive health care, guidance for parents and family planning education and services.’

- Article 6 recognises the child’s inherent right to life and that ‘States Parties shall ensure to the maximum extent possible the survival and development of the child.’
- Article 17 recognises ‘the important function performed by the mass media and shall ensure that the child has access to information and material from a diversity of national and international sources, especially those aimed at the promotion of his or her social, spiritual and moral well-being and physical and mental health’. The Committee on the Rights of the Child interprets article 17 to require states ‘to regulate or prohibit information on and marketing of substances such as alcohol and tobacco, particularly when it targets children and adolescents.’<sup>23</sup> Concerns identified in the consultation paper about the naming of vaping brands and use of flavours to encourage children to use e-cigarettes are relevant to packaging and article 17 could justify strong regulation of packaging ‘to reduce...attractiveness and appeal...to...young people’. Children are particularly vulnerable to misleading advertising such as a trade mark that suggests health benefits associated with an NVP that are not established or representations on packaging that a NVP may be less harmful because of its flavour, taste or ingredient.<sup>24</sup>

Recognising these rights are engaged by regulation of NVPs is particularly important because the *CRC* requires that the best interests of the child be a primary consideration ‘in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies’. This requires best interest assessments but to

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<sup>23</sup> Committee on the Rights of the Child, *General Comment No 4 (2003): Adolescent Health and Development in the Context of the Convention on the Rights of the Child*, 33rd sess, UN Doc CRC/GC/2003/4 (1 July 2003) [25].

<sup>24</sup> See John Tobin and Elizabeth Handsley, ‘Article 17 the Mass Media and Children: Diversity of Sources, Quality of Content and Protection against Harm’ in John Tobin (ed), *The UN Convention on the Rights of the Child: A Commentary* (Oxford University Press, 2019) 600, 639.

comprehensively realise children’s human rights, it is not sufficient just to identify rights specifically engaged by the health risks associated with vaping.

A children’s rights-based approach engages three umbrella concepts that underpin protection of their right to health: the best interests of the child, their health capability and the evolving capacities of a child.<sup>25</sup> Explicit incorporation of these principles into health innovation policy and regulatory frameworks is an important part of a rights-based approach that aligns with other human rights principles such as effectiveness and participation as well as the protection in *CRC* article 12 for a child’s right to be heard. Encouraging children to participate in the development of measures that are designed to ensure the best interests of the child, through meaningful consultation, can enhance their health capabilities to enable them to realise ‘health goals they value and act as agents of their own health’,<sup>26</sup> consistent with the right to development found in *CRC* article 6. Where health innovation involves branding and advertising, this also engages specific children’s rights found in *CRC* article 17 to receive health information and to be protected from disinformation and harmful advertising.

Protecting these rights can involve restrictions on the use of trade marks to limit their capacity to mislead children about their health interests, including through plain packaging. The WTO disputes and investor state arbitrations regarding tobacco plain packaging suggest that States need to carefully frame their justifications for these restrictions and adopting this framework may assist States to do so. Explicitly adopting a children’s rights-based approach can not only strengthen the effective protection of children’s rights but help demonstrate that policies that regulate advertising and marketing innovation support societal interests.

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<sup>25</sup> Marie Elske C Gispen and Brigit CA Toebe, ‘The Human Rights of Children in Tobacco Control’ (2019) 41(2) *Human Rights Quarterly* 340, 343.

<sup>26</sup> *Ibid.*

Increasingly, the links between packaging and human rights protection are being recognised. When the Uruguayan government passed legislation that reintroduced limited branding on cigarettes and inside packaging, the Family Court of Uruguay agreed to place a stay on the legislation because it was not consistent with Uruguay's international obligations found in including the *FCTC*, the *ICESCR* and the *CRC*.<sup>27</sup> Given the difficulties identified in the Consultation Paper regarding effective border controls, the decision is particularly relevant to regulation of NVPs as the Uruguayan government argued that the legislative changes were directed towards preventing trade in counterfeit tobacco products.<sup>28</sup> The decision indicates that children's human rights can also be relevant to anti-counterfeiting measures. Future reform proposals should explore the benefits of requiring system-wide tracking and tracing mechanisms for all vaping devices and liquid that does not rely on trade marks. Using technology such as scratch barcodes or blockchain verifiable tracking mechanisms could enable users to independently verify information about the vaping products.<sup>29</sup>

#### *D. Impact on Legislative Development*

Policy reform regarding NVPs that impacts on the exercise of intellectual property rights, including plain packaging, can valuably support Australia to comply with its *CRC* obligations as well as the obligations to protect the right to health found in *ICESCR*. These issues should be considered and clearly articulated as justifications for reform where relevant.<sup>30</sup> Ongoing assessment of these obligations should also occur to ensure compliance with human rights principles of effectiveness, monitoring and accountability.

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<sup>27</sup> *Sociedad Uruguaya de Tabacología v Estado Poder Ejecutivo, Juzgados Letrados de Familia* [Family Court of Uruguay], IUE 2-54452/2022, 19 October 2022 [tr author].

<sup>28</sup> *Ibid.*

<sup>29</sup> More extensive proposals for reform of counterfeiting measures are discussed in Genevieve Wilkinson, *Founding a Global Human Rights Culture for Trade Marks* (Edward Elgar, 2023, forthcoming). Contact author for further details.

<sup>30</sup> See Wilkinson (2021) (n 2).

This submission has identified ways that regulation of NVPs engages Australia’s human rights obligations, particularly those relevant to the *CRC*. These obligations should be considered in policy design as *CRC* article 3 requires that the best interests of the child should be a primary consideration in actions concerning children. The objective of protecting children and adolescents raised by NVPs engage umbrella concepts of the best interests of the child, the evolving capabilities of the child and their health capacity. Recognising the evolving capabilities and health capacity of children requires participation and consultation. Surveys about vaping are important for identifying the scope of the problem but effectively addressing concerns associated with marketing of NVPs can also benefit effective responses to reducing the appeal of NVPs to young people. Reforms should recognise the evolving capacity of the child by being age appropriate and consultation should be broad enough to recognise the diverse capabilities of children with different characteristics. Education that also responds to diversity can help build the health capacity of children to understand the risks posed by NVPs. This can strengthen the effectiveness of direct measures such as packaging requirements.<sup>31</sup> It can also identify new opportunities for reform that may ensure that regulation of NVPs is both effective and consistent with Australia’s human rights obligations.

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<sup>31</sup> Other approaches that strengthen the effectiveness of *CRC* compliance in relation to plain packaging of harmful substances have been explored here: Wilkinson (2022) (n 3) Part IV(D).