



**Australian Government**

**Department of Health, Disability and Ageing**

# **Tobacco Act Compliance Strategy**

DRAFT for consultation (May 2026)



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# Summary

*The Public Health (Tobacco and Other Products) Act 2023* (the **Tobacco Act**) establishes a modern framework to regulate tobacco products and reduce tobacco-related harm. The Tobacco Act expands and strengthens regulatory controls, including in relation to product design, packaging, advertising, and reporting obligations.

This Compliance Strategy (the **Strategy**) sets out how the Department of Health, Disability and Ageing (the **department**) will undertake compliance and enforcement activities under the Tobacco Act. It provides a risk-based, proportionate, and outcomes-focused framework to guide decision-making, prioritisation, and regulatory action.

The Strategy supports the department to prioritise compliance risks, apply regulatory tools in a consistent and proportionate manner, and contribute to improved public health outcomes by discouraging smoking and the use of tobacco products.

## Regulatory context

Australia's current tobacco control environment is shaped by the presence of an illicit tobacco market, which undermines public health measures and regulatory controls.

Addressing illicit trade in tobacco requires a coordinated, multi-agency response across Commonwealth, state, and territory governments. Commonwealth agencies, including the department, play a key role in disrupting illicit tobacco importation and supply chains through coordinated, multi-agency efforts, including the Australian Border Force (**ABF**)-led Illicit Tobacco National Disruption Group (the **Illicit Tobacco NDG**), established in October 2025.

Within this broader system, the department's role is to address non-compliance within its Tobacco Act remit, including where products or conduct associated with illicit trade, excise evasion, or unlawful supply also breach Tobacco Act requirements. Action taken by the department under the Tobacco Act may support broader disruption efforts, while remaining distinct from excise, border, importation, and criminal enforcement functions led by other regulators. The department also contributes through information sharing, referrals, and coordinated regulatory responses.

There are also areas of regulatory overlap, particularly in relation to e-cigarettes. The department regulates certain advertising and promotion activities under the Tobacco Act, while the Therapeutic Goods Administration (**TGA**) regulates therapeutic vaping products under the *Therapeutic Goods Act 1989* (the **TG Act**). This includes administering comprehensive controls on the importation, domestic manufacture, supply, commercial possession, and advertisement of disposable single use and non-therapeutic vaping goods.

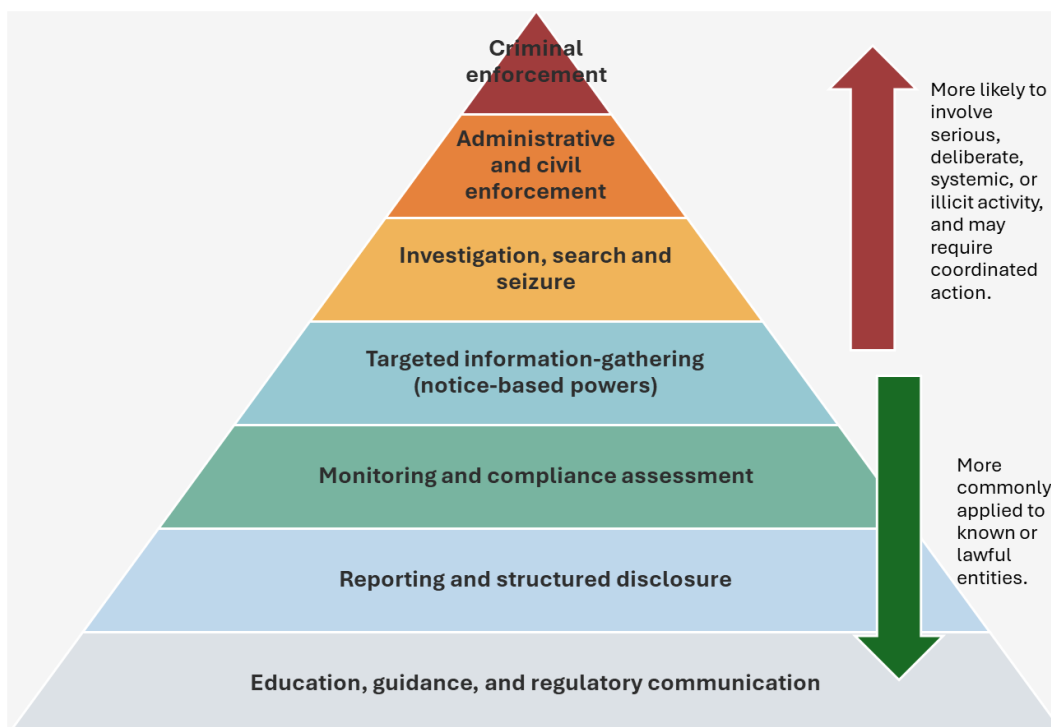
## Regulatory approach

The department adopts a risk-based and proportionate approach to regulation, supported by a focus on public health harm minimisation, a graduated compliance and enforcement model, and a commitment to procedural fairness and transparency.

Regulatory responses (see figure 1 below) are calibrated to the nature and seriousness of non-compliance. Lower-level responses are typically applied to known or lawful entities to

support voluntary compliance. Higher-level responses are more likely to be required where non-compliance is serious, deliberate, systemic, or linked to illicit activity, and may involve coordinated action with other regulators.

**Figure 1: compliance and enforcement spectrum under the Tobacco Act.**



A visible and credible enforcement presence supports deterrence by reinforcing that non-compliance will be identified and addressed. The department will take firm enforcement action where warranted, consistent with its legislative powers and the objectives of the Tobacco Act.

## Compliance and enforcement priorities

The Strategy identifies a set of priority areas for regulatory focus, informed by risk, public health impact, and stakeholder feedback. These priorities are not ranked and may be addressed concurrently. Key priorities include:

- **Illicit trade in tobacco and e-cigarettes** – prioritising compliance and enforcement action within the remit of the Tobacco Act, coordinating with other regulators, and strengthening data, intelligence, and information sharing and referral pathways.
- **Digital advertising, promotion, and online availability** – addressing unlawful or non-compliant digital advertising and promotion, including non-compliant webpage presentation or online sales displays.
- **Sponsorships, brand extensions, and promotional association activities** – addressing indirect promotion that may normalise tobacco use.
- **Packaging, health messaging, and presentation** – ensuring compliance with requirements designed to reduce product appeal and communicate health risks.

- **Product and accessory regulations, including ingredients, flavour, and device restrictions** – addressing non-compliance that increases product attractiveness or undermines regulatory controls.
- **Mandatory reporting obligations** – targeting systemic or repeated failures that limit regulatory visibility of supply chains.

The department will also maintain ongoing monitoring of emerging risks, including novel tobacco products and accessories and evolving promotional practices and behaviours.

# 1. Introduction

## 1.1. Purpose of the Strategy

The Strategy sets out the approach of the department to compliance and enforcement under the Tobacco Act. The Strategy is intended to:

- identify compliance and enforcement priorities within the scope of the Tobacco Act;
- support consistent, risk-based, and proportionate regulatory decision-making; and
- support compliance outcomes under the Tobacco Act by promoting compliance, deterring and responding to non-compliance, and applying enforcement action where appropriate, in order to support the public health objectives of the Tobacco Act.

The Strategy is strategic in nature. It does not prescribe operational procedures or case-specific actions. Rather, it establishes the principles, priorities, and decision-making framework that guide how the department exercises its regulatory functions.

## 1.2. Legislative and policy context

The Tobacco Act establishes a modernised Commonwealth framework for regulating tobacco products and certain aspects of related products, including e-cigarettes. It consolidates and replaces earlier legislative schemes, and its objectives are to:

- improve public health by:
  - discouraging smoking and the use of regulated tobacco items;
  - encouraging people to give up smoking, and to stop using regulated tobacco items;
- give effect to certain obligations that Australia has as a party to the World Health Organization (**WHO**) Framework Convention on Tobacco Control (**FCTC**);
- address the public health risks posed by vaping and the use of e-cigarette products; and
- combat the trade in illicit tobacco and e-cigarette products (through the establishment of the Illicit Tobacco and E-cigarette Commissioner, the **ITEC**, within the ABF).

The Tobacco Act is supported by the Public Health (Tobacco and Other Products) Regulations 2024 (the **Tobacco Regulations**), which prescribe detailed requirements relating to matters such as product standards, packaging, health messaging, and advertising in permitted contexts.

Compliance and enforcement activities under the Tobacco Act are supported by the Regulatory Powers (Standard Provisions) Act 2014 (the **Regulatory Powers Act**), which provides a consistent legislative framework for monitoring, investigation, and enforcement powers across Commonwealth regulatory regimes.

This Strategy is situated within a broader national policy context, including the National Tobacco Strategy 2023–2030, which sets out a comprehensive, evidence-based framework to reduce tobacco use and its associated harms across Australia. Compliance and enforcement under the Tobacco Act represent a key regulatory component of this broader effort.

## 1.3. Scope of the Strategy

The Strategy applies to compliance and enforcement activities undertaken by the department under the Tobacco Act framework. The Strategy focuses on the department's role to:

- monitor and assess compliance with the Tobacco Act requirements;
- identify and respond to non-compliance with the Tobacco Act; and
- apply a range of regulatory tools to promote and enforce compliance.

The Strategy also recognises that tobacco control in Australia operates within a multi-jurisdictional environment involving Commonwealth, state, and territory laws and regulators.

The Strategy does not:

- prescribe operational procedures, investigative methods, or case management processes;
- address in detail the roles and powers of other regulators, except where relevant to coordination and regulatory interfaces; or
- replace or override legislative requirements, which remain the authoritative source of legal obligations.

Where responsibilities intersect with those of other regulators, such as in relation to illicit trade in tobacco, border control, therapeutic goods regulation, or state and territory enforcement, the Strategy supports a coordinated and complementary approach. This is to ensure that compliance and enforcement action is undertaken under the most appropriate legislative framework, and that duplication or inconsistency is minimised.

## 1.4. Role of the department

The department is the primary Commonwealth regulator responsible for administering and enforcing compliance with the Tobacco Act. The department adopts a national perspective, focusing on compliance risks with broad reach or impact, including risks that may disproportionately affect young people, priority populations, or communities experiencing higher tobacco-related harm. This includes risks arising from advertising, packaging and health messaging, product standards, permanently banned products, and reporting obligations.

Within the context of a multi-jurisdictional and multi-framework regulatory environment for tobacco control, the department:

- works with other regulators to support appropriate delineation of responsibilities;
- supports lawful information sharing and referral pathways, including the sharing of intelligence and personal information where authorised and appropriate; and
- promotes coordinated and complementary regulatory action, including where responsibilities may overlap (for example, with the TGA in relation to e-cigarette advertising).

While the department does not have primary responsibility for border control, importation, excise enforcement, or criminal investigation of illicit trade, it may take compliance and enforcement action under the Tobacco Act where products or conduct associated with illicit

trade also breach Tobacco Act requirements. This action may support broader disruption efforts, alongside information sharing, referrals, and collaboration with other regulators where matters involve overlapping responsibilities.

The department exercises its functions in accordance with the regulatory approach set out in Section 4, with the objective of supporting improved public health outcomes (see Section 3).

## 1.5. Regulatory roles and responsibilities

Tobacco control in Australia involves multiple regulators operating across different legislative frameworks. These roles are complementary and, in some areas, intersecting, particularly in relation to e-cigarettes, advertising, and illicit supply chains.

The department's role under the Tobacco Act is focused on specific regulatory functions, and effective outcomes depend on coordination with other regulators, particularly where conduct spans multiple legislative frameworks or jurisdictions.

In practice, this means the department acts within its remit and works with other regulators to ensure matters are addressed under the most appropriate legislative framework, including through referral or coordinated action where required.

The TGA, part of the department, is the Australian Government's authority responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods. Under the TG Act, the TGA regulates the importation, domestic manufacture, supply, commercial possession and advertising of all vaping products.

Accordingly, there are areas of regulatory overlap, particularly in relation to e-cigarettes. For example, the department regulates certain advertising and promotion activities related to e-cigarettes and their use under the Tobacco Act, while all forms of advertising of vaping goods are prohibited unless authorised by the TGA under the TG Act.

Table 1 overleaf provides a high-level overview of regulatory responsibilities across some key domains. It is intended to support clarity on the department's role within the broader system and to highlight areas where coordination is required.

**Table 1: high-level regulatory roles across tobacco control domains.**

Tobacco control domains	Department of Health, Disability and Ageing (Cth)	Therapeutic Goods Administration (Cth)	Australian Border Force, and the ITEC (Cth)	Other Commonwealth entities (e.g. ATO, AFP, ACIC, ACCC)	State and Territory Governments
Advertising, promotion, and sponsorship	✓	✓ (vaping products)	✗	✓ (consumer law aspects)	✓ (local enforcement)
Packaging and health messaging	✓	✓ (therapeutic vaping goods)	✗	✓ (consumer law aspects)	✓ (limited contexts)
Product standards, ingredients, flavour, and device restrictions	✓	✓ (therapeutic vaping goods)	✗	✓ (product safety aspects)	✗
Permanently banned products (Tobacco Act)	✓	✗	✓ (border enforcement)	✓ (complementary role)	✗
Reporting obligations (Tobacco Act)	✓	✗	✗	✗	✗
Tobacco excise and illicit supply chains	✓ (complementary role)	✗	✓	✓	✓ (local enforcement)
Point of sale regulation and licensing	✗	✗	✗	✗	✓
Smoke-free laws	✗	✗	✗	✗	✓

## 2. Illicit trade in tobacco and regulatory context

### 2.1. The illicit tobacco environment

Illicit trade in tobacco represents a significant challenge within Australia's tobacco control environment. It undermines key public health measures, including pricing, product regulation, and advertising restrictions, and can weaken the effectiveness of reforms introduced under the Tobacco Act.

Available evidence indicates that illicit tobacco currently accounts for a material proportion of total tobacco consumption in Australia, with associated impacts on public health outcomes and government revenue. Illicit tobacco products may:

- avoid excise and regulatory controls, reducing the effectiveness of price-based deterrence and potentially indicating related non-compliance with the Tobacco Act;
- circumvent product standards, including requirements relating to ingredients, packaging, and health messaging; and
- be distributed through informal, concealed, or online channels, including alongside other non-compliant or prohibited products.

Illicit trade in tobacco is linked to organised and coordinated supply chains, including importation, domestic distribution, and retail-level activity. These activities may also intersect with the supply of illicit e-cigarettes and with conduct regulated under the Tobacco Act, including advertising, packaging, product standards, and permanently banned product requirements.

### 2.2. Whole-of-government response

Addressing illicit trade in tobacco requires a coordinated, multi-agency response across Commonwealth, state, and territory governments.

At the Commonwealth level, this includes operational and intelligence-led initiatives led by the ABF, including the Illicit Tobacco Taskforce (**ITTF**). The ITTF brings together Commonwealth agencies to disrupt illicit importation and supply chains, target organised criminal activity linked to illicit trade, and support coordinated enforcement outcomes across jurisdictions.

Complementing this, the ABF-led Illicit Tobacco NDG supports cross-agency coordination, including intelligence sharing, alignment of enforcement activity, and identification of national priorities for disruption efforts, including in the post-border environment.

Other Commonwealth agencies, including those responsible for border control, taxation, and criminal enforcement, play primary roles in addressing illicit importation, excise evasion, and organised criminal activity.

State and territory governments also play a critical role, including through regulation of retail environments, enforcement of smoke-free laws, and action against localised distribution of illicit products.

## 2.3. Role of the department relating to illicit trade

Within this broader context, the department does not have primary responsibility for border control, importation of tobacco products, excise enforcement, or criminal investigations relating to illicit trade in tobacco.

However, products or conduct associated with illicit trade, excise evasion, or unlawful supply may also involve non-compliance with the Tobacco Act. In these circumstances, the department may take compliance or enforcement action within its legislative remit.

Actions taken by the department to address Tobacco Act non-compliance involving illicit trade may also support broader disruption efforts by reducing the availability, visibility, and appeal of non-compliant products, and by contributing to a coordinated regulatory response.

The department may also support broader disruption efforts through information sharing, referrals, and participation in coordinated regulatory responses where another regulator has primary responsibility or stronger legal authority.

This approach ensures the department contributes to the broader response to illicit trade while remaining focused on its statutory role under the Tobacco Act.

## 2.4. Implications for the Strategy

The presence of significant illicit tobacco trade has important implications for the department's compliance and enforcement approach. The Strategy recognises illicit trade in tobacco as both a priority area for regulatory focus, and a cross-cutting risk, which may intersect with and amplify other forms of non-compliance.

Accordingly, the Strategy places emphasis on:

- targeting high-risk and deliberate non-compliance under the Tobacco Act, including products or conduct associated with illicit trade that also breach Tobacco Act requirements, and where departmental action can support broader disruption efforts;
- supporting visible and credible enforcement responses where non-compliance is systemic, coordinated, or deliberate; and
- strengthening coordination and information sharing with other regulators where matters involve excise, border, criminal, therapeutic goods, retail, or other regulatory responsibilities, to ensure that action is taken under the most appropriate legislative framework.

## 3. Compliance and enforcement objectives

### 3.1. Strategic objective

The objective of compliance and enforcement under the Tobacco Act is to support the effective operation of the legislative framework and contribute to improved public health outcomes. This is achieved through a risk-based, proportionate, and nationally consistent<sup>1</sup> approach to regulatory activity that:

- identifies and addresses areas of highest compliance risk and public health harm;
- promotes voluntary compliance through education, engagement, and clear regulatory expectations;
- detects and responds to non-compliance in a timely and effective manner; and
- applies graduated enforcement actions to deter unlawful conduct and reinforce regulatory integrity.

Compliance and enforcement activities are directed toward achieving sustained compliance and behavioural change among entities. This includes preventing non-compliance where possible, identifying and responding to non-compliance where it occurs, and taking enforcement action where appropriate.

### 3.2. Public health outcomes

Public health outcomes provide the primary policy driver for compliance and enforcement under the Tobacco Act. The department's role is to support those outcomes by promoting compliance with the legislative framework and responding to non-compliance where appropriate.

In this context, compliance activity contributes to:

- reducing the prevalence of smoking and tobacco use;
- limiting the appeal, accessibility, and uptake of tobacco and related products, including among young people and communities experiencing higher levels of tobacco-related harm;
- supporting individuals to quit smoking and cease use of tobacco products; and
- addressing the public health risks posed by the use of e-cigarette products.

The regulatory controls established under the Tobacco Act, including restrictions on advertising, product design, ingredients, packaging, and requirements for reporting, are designed to influence behaviour across the supply chain. Effective compliance and enforcement ensure that these controls operate as intended, thereby supporting the achievement of public health outcomes.

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<sup>1</sup> In the context of this Strategy, 'nationally consistent' refers to a consistent approach by the Commonwealth across Australia, rather than consistency between Commonwealth and jurisdictional approaches.

# 4. Regulatory approach

## 4.1. Overview

The department adopts an outcomes focused approach to compliance and enforcement under the Tobacco Act, ensuring that regulatory effort is:

- directed toward achieving compliance outcomes that support the public health objectives of the Tobacco Act;
- directed to areas of greatest risk and public health impact;
- applied in a manner that is fair, consistent, and informed by evidence; and
- responsive to changes in the regulatory environment, including novel developments and emerging innovation in tobacco products, behaviours, and market dynamics.

The department recognises that many entities seek to comply with the law. Accordingly, the regulatory approach supports voluntary compliance wherever possible, while maintaining the capacity to take timely and effective enforcement action where warranted.

This approach is guided by a set of core principles that underpin the department’s use of its powers and its overall regulatory posture.

## 4.2. Principles guiding compliance and enforcement

Compliance and enforcement activities under the Tobacco Act are guided by the following principles in Table 2 below.

**Table 2: principles guiding compliance and enforcement activities.**

Principle	Approach
Public health harm minimisation	The primary objective of regulatory activity is to reduce tobacco-related harm. Compliance and enforcement decisions are informed by the extent to which conduct undermines the effectiveness of the legislative framework, or contributes to increased harm, uptake, or exposure to tobacco and related products.
Risk-based and proportionate regulation	Regulatory effort is prioritised based on an assessment of the likelihood of non-compliance and the potential impact on public health and regulatory outcomes. Regulatory responses are proportionate to: <ul style="list-style-type: none"><li>• the seriousness of the conduct;</li><li>• the level of harm or risk; and</li><li>• the behaviour of the entity.</li></ul> This ensures that regulatory effort is directed to areas where it is likely to have the greatest effect.
Graduated and responsive enforcement	The department applies a graduated and responsive approach to enforcement, selecting regulatory responses that are appropriate to the circumstances of each matter. Responses may escalate or de-escalate depending on: <ul style="list-style-type: none"><li>• the nature and severity of the conduct;</li><li>• the compliance history and behaviour of the entity; and</li><li>• the effectiveness of prior interventions.</li></ul>

Principle	Approach
Transparency and accountability	The department promotes transparency in its regulatory approach by clearly communicating compliance expectations and providing appropriate information about regulatory activities and outcomes. Regulatory decisions are made in a manner that supports accountability and public confidence in the integrity of the regulatory framework.
Procedural fairness and consistency	Regulatory decisions are made in accordance with principles of procedural fairness and administrative law. This includes: <ul style="list-style-type: none"> <li>ensuring decisions are based on relevant evidence;</li> <li>providing affected parties with an opportunity to respond where appropriate; and</li> <li>applying regulatory approaches consistently across similar circumstances, while allowing for differences in risk and impact.</li> </ul>
Timeliness	Regulatory action is undertaken in a timely manner to: <ul style="list-style-type: none"> <li>address risks to public health;</li> <li>prevent or limit the continuation of non-compliant conduct; and</li> <li>maintain confidence in the effectiveness of the regulatory framework.</li> </ul>
Coordination	The department works with other Commonwealth, state, and territory regulators to support a coordinated and complementary approach to tobacco control. This includes: <ul style="list-style-type: none"> <li>sharing intelligence and information where appropriate and lawfully authorised, including personal information where permitted under applicable legislation and privacy requirements;</li> <li>aligning regulatory responses to address cross-jurisdictional risks; and</li> <li>recognising the respective roles and responsibilities of different regulators.</li> </ul>

### 4.3. Risk-based and outcomes focussed regulation

The department adopts a risk-based approach to compliance and enforcement, recognising that not all forms of non-compliance present the same level of risk or harm. Risk is assessed having regard to factors including the:

- the scale and reach of the conduct;
- the nature of the products or activities involved;
- the potential impact on public health, including impacts on young people, priority populations, or communities experiencing higher levels of tobacco-related harm; and
- the likelihood and persistence of non-compliance.

This approach prioritises systemic or widespread non-compliance, conduct that undermines key regulatory controls, and emerging risks. In applying this approach, the department focuses on outcomes, including whether regulatory action reduces harm, improves compliance behaviour, and supports the long-term effectiveness of the Tobacco Act. This includes prioritising serious, deliberate, or systemic non-compliance with the Tobacco Act, including where products or conduct are associated with illicit trade or unlawful supply and departmental action within its legislative remit can support broader disruption efforts.

## 4.4. Graduated and responsive enforcement model

The department applies a graduated and responsive model of regulation (see Summary and Section 7), with responses calibrated to the nature and seriousness of non-compliance. This recognises that different compliance issues require different regulatory responses.

Regulatory responses are selected from across a spectrum of available tools, including:

- education and guidance, to support understanding of legal requirements and prevent non-compliance;
- monitoring and information gathering, to assess compliance and identify risks;
- investigation, where there are reasonable grounds to suspect non-compliance; and
- enforcement action, including administrative, civil, or criminal responses where appropriate.

The department may escalate or de-escalate its response over time, depending on the effectiveness of prior actions, changes in the level of risk or compliance behaviour, and developments in the broader compliance environment.

This model supports both voluntary compliance and effective deterrence, consistent with the objectives of the Tobacco Act.

## 4.5. Deterrence and visibility

A visible and credible compliance and enforcement presence supports effective deterrence by reinforcing that non-compliance will be identified and addressed.

The department adopts a graduated approach to enforcement, recognising that some non-compliance may be inadvertent and can be addressed through education and engagement. However, non-compliance is not always the result of error. Conduct may be deliberate, systemic, or designed to circumvent regulatory controls, including where products or conduct associated with illicit trade also breach Tobacco Act requirements.

In such cases, the department will take proportionate but firm compliance or enforcement action, consistent with its legislative powers under the Tobacco Act and the seriousness of the conduct. This may include investigation and enforcement responses where non-compliance is repeated, deliberate, high-impact, or linked to the distribution of illicit or non-compliant products. Where relevant, this action may also support broader disruption efforts by complementing the work of other regulators.

The department will also seek to enhance the visibility of compliance and enforcement activities, including through public communication of regulatory expectations and outcomes where appropriate.

## 5. Understanding compliance risk

### 5.1. Overview of the compliance risk environment

The department operates in a complex and evolving compliance environment, characterised by diverse entities, multiple supply channels, and changing product and marketing practices.

As outlined in Section 2, the presence of an illicit market for tobacco introduces additional risks to public health and regulatory outcomes. While excise, border, importation, and criminal enforcement are primarily matters for other agencies, products or conduct associated with illicit trade may also breach Tobacco Act requirements, including in relation to advertising, product standards, packaging, and supply-related conduct.

Compliance risks also arise from:

- the use of digital, online, and innovative channels to promote or supply products;
- the development of products and features designed to increase appeal or circumvent regulatory intent; and
- cross-jurisdictional activity, where conduct spans multiple regulatory frameworks.

### 5.2. Key compliance risk domains

The department has identified a set of key compliance risk domains under the Tobacco Act, within its remit, which reflect areas where non-compliance is most likely to undermine public health objectives or the effectiveness of the regulatory framework.

These domains are derived from the legislative requirements and policy settings established under the Tobacco Act and Regulations and are supported by a detailed risk assessment. In some areas, particularly in relation to illicit trade, e-cigarettes, and digital advertising, compliance risks may intersect with other legislative frameworks and regulatory responsibilities, requiring coordinated regulatory approaches.

The key compliance risk domains within the department's remit are outlined in Table 3 below. These domains provide a structured basis for assessing compliance risk and inform the identification of compliance and enforcement priorities.

**Table 3: key compliance risk domains under the Tobacco Act.**

Compliance risk domain	Description of non-compliance / risk
Advertising, promotion, and sponsorship	Non-compliance increases exposure to tobacco and related products and undermines restrictions designed to reduce demand and prevent uptake and relapse. Risks include digital advertising, targeted advertising, and indirect promotion. Regulatory responsibility often intersects with other legislative frameworks.
Packaging and health messaging	Non-compliance reduces the effectiveness of measures designed to limit product appeal and communicate health risks. This includes missing or altered health warnings, on-product health messages and health promotion inserts, and other non-compliant packaging.

Compliance risk domain	Description of non-compliance / risk
Product standards, ingredients, flavour, and device restrictions	Non-compliance with product standards and design requirements may increase product appeal, facilitate initiation or continued use, or introduce additional risks. This includes prohibited ingredients, flavour profiles, or device features, as well as products that do not meet regulatory specifications.
Permanently banned products	The manufacture, supply, sale, or possession of permanently banned tobacco products (chewing tobacco and snuffs intended for oral use) presents a direct risk to public health and undermines the effectiveness of the Tobacco Act framework.
Reporting obligations	Non-compliance with mandatory reporting requirements reduces regulatory visibility of product characteristics, supply patterns, and market behaviour, limiting the department's ability to identify risks and respond effectively.

### 5.3. Drivers of non-compliance

Compliance risks under the Tobacco Act are influenced by a range of behavioural, structural, and market drivers. Key drivers include:

- financial incentives for non-compliance, particularly where unlawful conduct may increase profitability or market share;
- the complexity and novelty of regulatory requirements, particularly in relation to new product categories and technical standards;
- the presence of illicit markets and supply chains, which may operate outside established regulatory controls;
- the evolving nature of products and innovation in marketing practices, including the use of digital channels, targeted or restricted-access advertising (such as content delivered through closed or paywalled platforms);
- varying levels of awareness and capability to comply among entities; and
- willingness to comply, including ambivalence to requirements due to perceived low risk of penalty due to lack of enforcement, compliance outcomes, or other deterrents.

Understanding these drivers supports the development of targeted regulatory responses, including both preventive measures and enforcement action.

### 5.4. Relationship between risk and prioritisation

The identification and assessment of compliance risks provide the foundation for determining compliance and enforcement priorities. Risk assessment informs:

- which areas require targeted regulatory focus;
- where enhanced monitoring and intelligence gathering is appropriate; and
- how regulatory effort should be allocated and applied.

Higher-risk areas, particularly those associated with significant public health impact, disproportionate impact on particular populations or communities, widespread or systemic

non-compliance, illicit trade, or emerging risks, are prioritised for targeted compliance and enforcement activities, proactive monitoring and intelligence-led interventions, and the potential application of stronger regulatory responses. This may include the lawful use and sharing of intelligence with other regulators where necessary to support coordinated action.

Lower-risk areas may be addressed through education and guidance, routine monitoring, or responsive action where issues arise.

This approach ensures that compliance and enforcement activity is risk-based and proportionate, aligned with the objectives of the Tobacco Act, and capable of adapting to changes in the risk environment over time.

## 6. Compliance and enforcement priorities

The department has identified a set of compliance and enforcement priorities to guide regulatory focus under the Tobacco Act. These priorities support the effective allocation of resources and ensure that regulatory effort is directed to areas of greatest risk and public health impact, including where non-compliance may disproportionately affect particular populations or communities.

The department distinguishes between:

- **focus priorities**, which are subject to targeted and proactive compliance and enforcement activity; and
- **ongoing monitoring priorities**, which are subject to routine oversight and responsive action where required.

Focus priorities are informed by:

- the level and nature of compliance risk;
- the extent of non-compliance;
- the potential for regulatory intervention to achieve meaningful outcomes; and
- available data, intelligence, and operational considerations.

The focus priorities are outlined in Table 4 overleaf. These priorities are not ranked, may be addressed concurrently, and are not exhaustive. The department will continue to monitor the compliance environment and may adjust priorities over time in response to emerging risks.

Ongoing monitoring priorities include other areas of potential non-compliance that do not currently warrant targeted intervention but may be elevated to focus priorities where risk or impact increases.

**Table 4: compliance and enforcement (focus) priorities.**

Priority	Risk focus	Priority statement	Rationale
Illicit trade in tobacco and e-cigarettes	Products and conduct associated with illicit trade or unlawful supply; cross-border and domestic distribution; gaps in intelligence and coordination; fragmented enforcement responses across jurisdictions.	The department will prioritise compliance and enforcement action, within its Tobacco Act remit, in relation to illicit tobacco and e-cigarette products that are also non-compliant with Tobacco Act requirements. This will be undertaken in coordination with lead agencies responsible for enforcement against illicit trade, and supported by strengthened data, intelligence, and information sharing.	<p>Illicit trade in tobacco and e-cigarettes represents a significant and systemic risk to the effectiveness of the Tobacco Act. Products associated with Illicit trade may also breach Tobacco Act requirements by:</p> <ul style="list-style-type: none"> <li>• circumventing packaging, health messaging, product standard, or advertising controls;</li> <li>• enabling distribution of non-compliant or potentially harmful products; and</li> <li>• limiting regulatory visibility across supply chains.</li> </ul> <p>While other regulators have primary responsibility for excise, border, importation, and criminal enforcement, the department may take compliance or enforcement action where products or conduct breach Tobacco Act requirements. This action may support broader disruption efforts by reducing the availability, visibility, and appeal of non-compliant products.</p>
Digital advertising, promotion, and online availability	Digital advertising and promotion; influencer and lifestyle-based promotion; restricted-access and closed platforms; non-compliant webpage presentation or online sales displays; regulatory overlap with the TGA.	The department will prioritise compliance and enforcement action in relation to unlawful or non-compliant digital advertising and promotion, including non-compliant webpage presentation or online sales displays for tobacco products within scope of the Tobacco Act.	<p>Digital environments present a rapidly evolving and high-impact compliance risk. While tobacco products may be sold online, online sales environments must comply with strict requirements. Key risks include:</p> <ul style="list-style-type: none"> <li>• targeted and algorithm-driven advertising;</li> <li>• use of influencers, user-generated content, and indirect promotion;</li> <li>• promotion within closed, paywalled, or restricted-access environments;</li> <li>• non-compliant webpage presentation or online sales displays; and</li> <li>• integration of advertising and promotional content with online purchasing pathways, including cross-border access.</li> </ul> <p>For e-cigarettes, the department’s role is limited to matters within the scope of the Tobacco Act. Online supply of e-cigarettes and</p>

Priority	Risk focus	Priority statement	Rationale
			vaping products may fall within the remit of the TGA. Where responsibilities intersect, the department will coordinate with the TGA or other relevant regulators to support a complementary and non-duplicative response.
Sponsorships, brand extensions, and promotional association activities	Sponsorship arrangements; event-based promotion; brand stretching and association activities; indirect promotion of tobacco or related products through partnerships or affiliations.	The department will prioritise compliance and enforcement action in relation to sponsorship, brand extensions, and association activities that promote or normalise tobacco use in contravention of legislative restrictions.	<p>These activities can operate as indirect forms of advertising, particularly where direct promotion is restricted. They may:</p> <ul style="list-style-type: none"> <li>reinforce brand recognition and loyalty;</li> <li>associate tobacco use with desirable lifestyles, events, or social identities; and</li> <li>reach audiences, including young people, through less visible or less regulated channels.</li> </ul> <p>Targeting these practices reduces pathways for indirect promotion and supports the effectiveness of advertising restrictions.</p>
Packaging, health messaging, and presentation	Non-compliant packaging; missing, altered, obscured, or incorrectly displayed health warnings, on-product messages and inserts; prohibited terms, branding, design elements, or other presentation features; packaging or presentation practices that may reduce the effectiveness of Tobacco Act requirements.	The department will prioritise compliance and enforcement action in relation to packaging, health messaging, and product presentation that does not comply with Tobacco Act requirements.	<p>Packaging, health messaging, and presentation requirements are a central to reducing product appeal and communicating health risks. Non-compliance may:</p> <ul style="list-style-type: none"> <li>reduce the visibility and effectiveness of health warnings, on-product messages and inserts;</li> <li>increase product attractiveness or perceived quality;</li> <li>mislead consumers about product characteristics; and</li> <li>undermine the standardised presentation required by the Tobacco Act framework.</li> </ul> <p>Where products associated with illicit trade or imitation branding also fail to meet Tobacco Act packaging, health messaging, or presentation requirements, the department may take action within its legislative remit and coordinate with other regulators as appropriate.</p>

Priority	Risk focus	Priority statement	Rationale
Product and accessory regulations, including ingredients, flavour, and device restrictions	Use of prohibited ingredients or additives; flavour profiles that increase product appeal; non-compliant product design or device features; conduct that increases attractiveness or facilitates uptake.	The department will prioritise compliance and enforcement action in relation to non-compliance with product standards, including ingredients, flavour, and device-related requirements.	<p>Product composition and design directly influence product appeal and use. Non-compliance may:</p> <ul style="list-style-type: none"> <li>• increase attractiveness through flavours, sensory characteristics, or design features;</li> <li>• facilitate initiation or continued use; and</li> <li>• introduce additional or poorly understood health risks.</li> </ul> <p>Emerging product designs may also be used to circumvent regulatory intent, including through technical or marginal modifications that increase appeal while maintaining apparent compliance.</p>
Mandatory reporting obligations	Failure to comply with reporting requirements; inaccurate, incomplete, or delayed reporting; repeated or systemic failures by entities.	The department will prioritise compliance and enforcement action in relation to systemic or repeated failures to meet mandatory reporting obligations.	<p>Mandatory reporting supports regulatory oversight and intelligence-led decision-making. Non-compliance may:</p> <ul style="list-style-type: none"> <li>• reduce visibility of product characteristics, supply patterns, and market behaviour;</li> <li>• limit the effectiveness of intelligence-led regulatory activity; and</li> <li>• delay or prevent timely identification of compliance risks.</li> </ul> <p>Ensuring compliance in this area supports effective targeting and prioritisation of regulatory activity.</p>

# 7. Applying the Compliance Strategy

## 7.1. Application of priorities

The application of compliance and enforcement priorities will be supported by:

- targeted compliance and enforcement activities aligned to the priorities and the department's legislative remit;
- the use of data and intelligence to inform risk assessment and prioritisation; and
- transparent communication of regulatory expectations and outcomes.

Consistent with a risk-based approach, the department will apply a graduated range of regulatory responses, while ensuring that serious or systemic non-compliance is addressed in a timely and proportionate manner.

## 7.2. Decision-making framework

The department applies a structured and risk-based decision-making framework to guide compliance and enforcement activities under the Tobacco Act. Decisions are informed by the interaction of:

- compliance risk, including the likelihood and impact of non-compliance (Section 5);
- compliance and enforcement priorities (Section 6);
- available regulatory powers and tools (Section 7.4); and
- data and intelligence, including information from internal and external sources, handled and shared in accordance with applicable legal and privacy requirements (Section 7.5).

This framework supports consistent and proportionate decision-making by:

- directing regulatory attention to areas of greatest risk and impact;
- ensuring that responses are aligned to the nature and seriousness of conduct; and
- enabling the department to adapt its approach in response to changing circumstances.

The framework supports both proactive regulatory activity, including targeted compliance initiatives, and reactive responses, including the investigation and enforcement of suspected non-compliance.

## 7.3. Triage and prioritisation approach

The department applies a triage approach to assess and prioritise compliance matters. Triage supports the consistent and transparent assessment of matters by considering factors such as:

- the level of public health risk, including potential harm and scale of impact;
- the nature and seriousness of the conduct;
- whether the conduct is systemic, repeated, or deliberate;
- the compliance history and behaviour of the entity; and
- the extent to which the matter aligns with compliance and enforcement priorities.

Matters assessed as higher priority may be subject to targeted compliance and enforcement action, enhanced monitoring and intelligence gathering, or escalation to investigation and enforcement pathways.

Lower priority matters may be addressed through education and guidance, routine monitoring, or responsive action where issues arise.

## 7.4. Use of regulatory tools

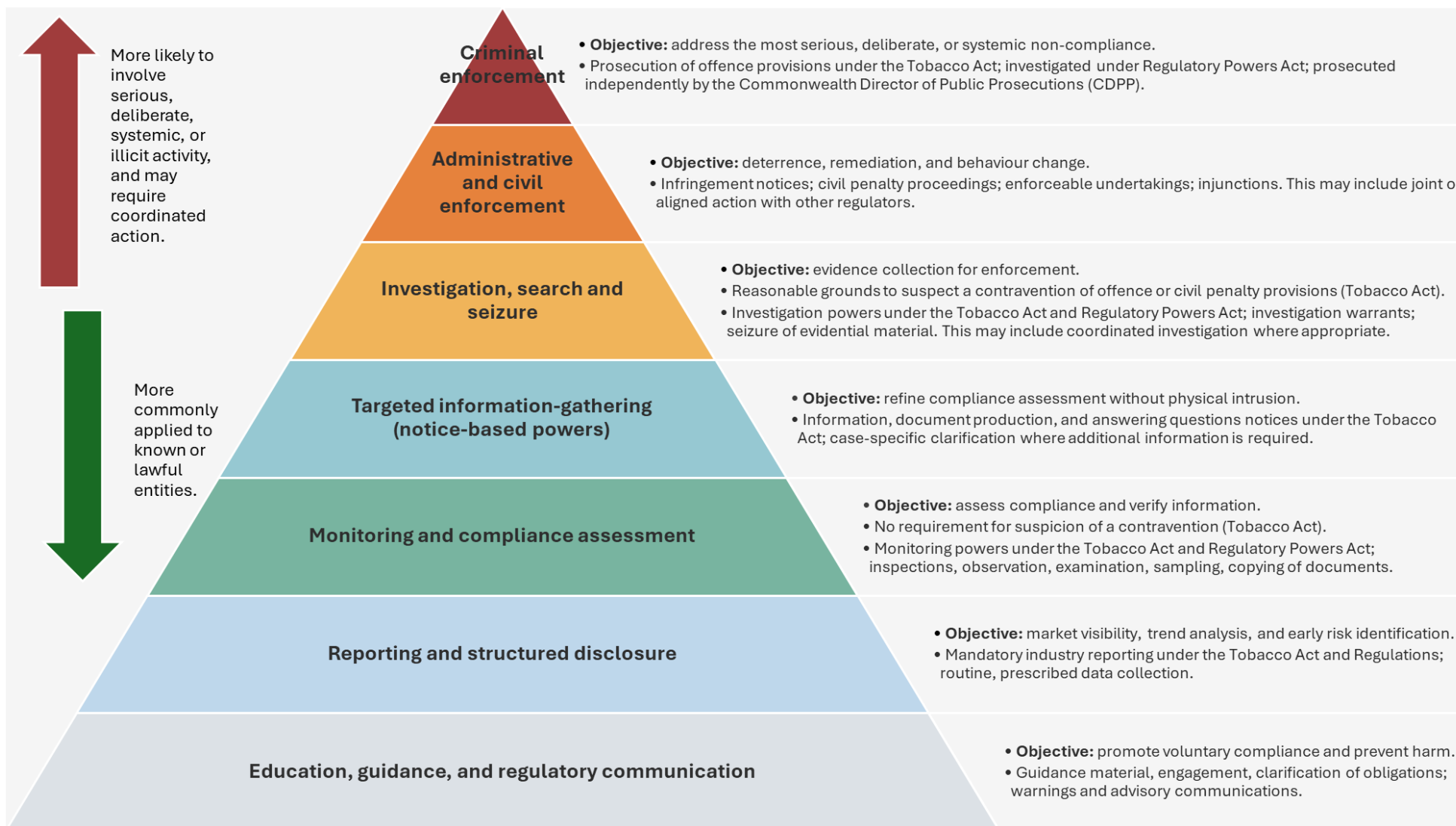
The department applies a graduated and proportionate approach in selecting regulatory tools, consistent with the principles outlined in Section 4. Regulatory tools are applied across a spectrum as outlined in Figure 2 overleaf.

The selection of regulatory tools is informed by the:

- level of risk and potential harm;
- nature and intent of the conduct;
- behaviour and compliance history of the entity; and
- need to achieve deterrence and compliance outcomes.

Regulatory responses may escalate or de-escalate over time, depending on the effectiveness of prior interventions, and changes in the risk or behaviour of the entity.

**Figure 2: compliance and enforcement spectrum (detailed) under the Tobacco Act.**



## 7.5. Role of data and intelligence

Data and intelligence are central to the department's compliance and enforcement approach. The department draws on a range of data and intelligence sources to:

- identify and assess compliance risks;
- inform prioritisation and targeting of regulatory activity;
- detect and respond to non-compliance; and
- evaluate the effectiveness of regulatory interventions.

These sources may include:

- complaints and referrals from the public, stakeholders, and other regulators;
- monitoring and surveillance activities; and
- information shared through inter-agency collaboration, including through the Illicit Tobacco NDG where it relates to illicit trade in tobacco and e-cigarettes.

The department may also share intelligence and information with other regulatory and enforcement agencies where authorised and appropriate, including to support coordinated responses, referral pathways, or action under the most appropriate legislative framework.

Any collection, use, or disclosure of personal information will be undertaken in accordance with applicable legal requirements, including the *Privacy Act 1988*, the Australian Privacy Principles, secrecy provisions, and any relevant statutory authorisations or information-sharing arrangements.

The department adopts an intelligence informed approach, recognising that compliance risks may evolve over time, and effective regulatory responses require timely, accurate, and relevant information.

## 8. Governance and Review

### 8.1. Governance arrangements

The department will implement the Strategy within existing governance and decision-making arrangements. These arrangements support clear accountability, consistent application of the Strategy, and appropriate oversight of compliance and enforcement activities.

The department will also engage with other Commonwealth, state, and territory regulators through established coordination mechanisms to support consistent and complementary regulatory approaches, particularly in relation to cross-jurisdiction risks, including illicit trade.

Governance arrangements will also support appropriate oversight of information sharing, including the handling of intelligence and personal information in accordance with legal, privacy, and procedural requirements.

### 8.2. Review of the Strategy

The department will review this Strategy periodically to ensure it remains effective, relevant, and aligned with the objectives of the Tobacco Act.

The review process will consider:

- the extent to which compliance and enforcement activities are aligned with identified priorities;
- changes in the compliance risk environment, including novel developments and emerging innovation in tobacco products, behaviours, and market trends;
- developments in regulatory practice, legislative settings, and broader government policy;
- information from compliance activity, data and intelligence, and stakeholder or regulator feedback; and
- whether the Strategy continues to support effective, proportionate, and risk-based compliance and enforcement.

The Strategy may be updated as required to reflect changes in legislation or policy, shifts in compliance and enforcement priorities, operational experience, or improvements in regulatory capability and approach.

This review process will support continuous improvement and ensure the Strategy remains aligned with evolving risks and the department's regulatory objectives.

## 9. Relationship to supporting documents

This Strategy operates within a broader framework of Commonwealth regulatory policy and practice. In particular, the Strategy aligns with:

- relevant whole-of-government frameworks relating to regulatory policy, practice, and performance;
- the Australian Government Investigations Standard (**AGIS**), where compliance and enforcement activities involve investigation; and
- relevant findings and recommendations relating to the management of non-compliance under comparable regulatory regimes.

The Strategy also provides a foundation for the development and refinement of operational policies and guidance, including enforcement policies and procedures.

Following implementation, the department will review relevant compliance and enforcement policies to ensure alignment with this Strategy.

# Glossary

The glossary provides plain-English explanations of key terms used in this Strategy. The definitions are intended to support readability and consistent interpretation of the Strategy. They do not replace or modify the meaning of terms defined in the Tobacco Act, Tobacco Regulations, or any other relevant legislation.

**Table 5: glossary of terms.**

Term	Description
ABF	The Australian Border Force.
ACCC	The Australian Competition and Consumer Commission.
ACIC	The Australian Criminal Intelligence Commission.
ATO	The Australian Taxation Office.
CDPP	Commonwealth Director of Public Prosecutions.
Compliance	Actions or behaviours that meet the requirements of the Tobacco Act, Tobacco Regulations, and related obligations.
Compliance activity	Activities undertaken by the department to promote, assess, monitor, or respond to compliance with the Tobacco Act.
Compliance and enforcement	The full range of regulatory activities used to promote compliance, detect and respond to non-compliance, and take enforcement action where appropriate.
Compliance risk	The possibility that conduct, products, or practices may not comply with the Tobacco Act and may undermine regulatory or public health objectives.
Coordination	Working with other Commonwealth, state, and territory regulators to support complementary and effective regulatory responses.
Cross-jurisdictional risk	A risk that involves conduct, products, entities, or supply chains operating across more than one jurisdiction or legislative framework.
The department	The Department of Health, Disability and Ageing.
Deterrence	The use of visible and credible regulatory action to discourage non-compliance by entities.
E-cigarette	As defined in the Tobacco Act, a device (whether or not containing nicotine or tobacco) that generates or releases, or is designed or intended to generate or release, by electronic means, an aerosol or vapour for inhalation by its user in a way that resembles, or produces an experience similar to, smoking.
Enforcement action	Formal regulatory action taken in response to non-compliance, where available and appropriate under the Tobacco Act or related legislation.
Graduated enforcement	An approach where regulatory responses are calibrated to the seriousness, risk, and context of the conduct, ranging from education through to enforcement action.

Term	Description
Illicit tobacco	Tobacco products that are supplied, possessed, imported, manufactured, or sold in contravention of relevant laws. For the purposes of this Strategy, the term is used broadly and may include products associated with excise evasion, unlawful importation and unlawful supply, as well as non-compliance with Tobacco Act requirements.
Illicit Tobacco NDG	The Illicit Tobacco National Disruption Group, led by the ABF.
ITTF	The Illicit Tobacco Taskforce, led by the ABF.
Illicit trade	Unlawful activity associated with the importation, manufacture, supply, distribution, or sale of tobacco or related products.
Information sharing	The lawful exchange of information or intelligence with other regulators or enforcement agencies, where authorised and appropriate.
Intelligence-informed	Use of available data, intelligence, risk indicators, and regulatory information to guide prioritisation and decision-making.
ITEC	The Illicit Tobacco and E-cigarette Commissioner.
Non-compliance	Conduct, products, omissions, or practices that do not meet requirements under the Tobacco Act or related regulatory framework.
Priority populations	Groups or communities that may be disproportionately affected by tobacco-related harm or compliance risks, including young people or communities experiencing higher tobacco-related harm.
Proportionate regulation	Regulation where the response is calibrated to the seriousness of the conduct, level of risk, potential harm, and behaviour of the entity.
Public health harm minimisation	A regulatory focus on reducing tobacco-related harm and limiting conduct that increases exposure, appeal, uptake, or continued use.
Regulatory Powers Act	The <i>Regulatory Powers (Standard Provisions) Act 2014</i> .
Regulatory response	The action selected in response to a compliance matter, including education, guidance, monitoring, information-gathering, investigation, enforcement, coordination, or referral.
Risk-based regulation	An approach where regulatory effort is prioritised according to risk, including likelihood of non-compliance and potential impact on public health or regulatory outcomes.
TGA	The Therapeutic Goods Administration, which is part of the department.
TG Act	The <i>Therapeutic Goods Act 1989</i> .
Tobacco Act	The <i>Public Health (Tobacco and Other Products) Act 2023</i> .
Tobacco Regulations	The Public Health (Tobacco and Other Products) Regulations 2024.
Triage	A structured process for assessing and prioritising compliance matters based on risk, impact, behaviour, history, available powers, and coordination considerations.
Whole-of-government response	Coordinated action involving multiple Commonwealth, state, or territory agencies to address complex regulatory risks, including illicit trade in tobacco and e-cigarettes.

Term	Description
WHO FCTC	The World Health Organization Framework Convention on Tobacco Control.

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All information in this publication is correct as at May 2026

