

# Conference of the Parties to the WHO Framework Convention on Tobacco Control Eleventh session

Geneva, Switzerland, 17–22 November 2025

Provisional agenda item 4.2

FCTC/COP/11/6

27 June 2025

### **Liability (Article 19 of the WHO FCTC)**

### Report by the Expert Group

### Purpose of the document

This report contains the report of the Expert Group on Implementation of Article 19 of the WHO Framework Convention on Tobacco Control (WHO FCTC) on Liability, re-established by the Conference of the Parties (COP) in decision FCTC/COP10(13), taking into account the work completed by the expert group on liability established pursuant to decision FCTC/COP5(9) and whose mandate was extended in decision FCTC/COP6(7).

### **Action by the Conference of the Parties**

The COP is invited to note the present report, provide further guidance and consider adopting the draft decision contained in Annex 2 of the present report.

Contribution to the Sustainable Development Goals (SDGs): All SDGs; in particular, SDG 3 and Target 3.a.

Link to Workplan and Budget item: None.

Additional financial implications if not included in the Workplan and Budget: 1.1.1.3, 1.1.3.2.

Related document(s): Reports of the first, second and third meetings of the Expert Group on Implementation of Article 19 of the WHO FCTC on Liability; Survey on implementation of Article 19 of the WHO Framework Convention on Tobacco Control on liability (supplementary information).

### **Background**

1. At its Tenth session, the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC) decided to re-establish an expert group on liability, taking into account the work completed by the expert group on liability established pursuant to decision FCTC/COP5(9) and whose mandate was extended in decision FCTC/COP6(7). In decision FCTC/COP10(13), the expert group was mandated:

- (a) to review and collect information in respect of the practice that has evolved at Party level, taking into account the work being done in relevant international fora, and support Parties, as relevant, to strengthen their criminal and civil liability regimes, including administrative measures, to ensure accountability and deterrence, improve access to justice, and allow for effective remedies for those affected by tobacco harms, on a voluntary basis and upon request by the Parties;
- (b) to provide options for Parties to detect and counter tobacco industry efforts to evade applicable liability regimes or to undermine tobacco control, including through corporate reorganization or investments;
- (c) to explore the possible development of a methodology that estimates or quantifies the health-care costs borne due to tobacco use, in order to support Parties in collecting evidence to be used in tobacco-related litigation; and
- (d) to report on its work at the Eleventh session of the COP.
- 2. In decision FCTC/COP10(13), the COP also requested the Convention Secretariat, among others, to facilitate the establishment of the expert group, under the guidance of the Bureau, and to make arrangements for the expert group to complete its work.
- 3. At its first meeting, the Bureau elected at the Tenth session of the COP (COP10) approved the list of experts for the Expert Group on Implementation of Article 19 of the WHO FCTC on Liability, and its terms of reference. The composition of the Expert Group is contained in the report of the First meeting of the Expert Group, available on the WHO FCTC website as supplementary information to this report.<sup>1</sup>

### **Expert Group meetings**

- 4. The First meeting of the Expert Group (held online on 26 June 2024) focused on discussing the mandate of the Expert Group. A Chairperson and officers were elected to facilitate the work of the Group. The experts also discussed access to data, funding and potential external resources to support their work. The experts agreed to benefit from an external consultancy, supported by the University of Bath through an Expert Group member employed by the University, on the possible development of a methodology to estimate or quantify health-care costs borne due to tobacco use, which would inform the report of the Expert Group.
- 5. At its second meeting (held in Geneva, Switzerland, on 9–11 October 2024), the Expert Group discussed key findings from a survey on Article 19 implementation, as well as case studies on specific country experience in Article 19 litigation. The Expert Group also discussed the second element of its mandate as set out in paragraph 1(b) above. In respect of the third element of its

<sup>&</sup>lt;sup>1</sup> COP11 Documentation: Supplementary information (accessed 12 June 2025).

mandate as set out in paragraph 1(c), the Expert Group agreed to consider the application from a diverse team of consultants, the terms of reference and the logistics of their work. The Expert Group agreed on a draft outline of the report for COP11, their task distribution and a proposed timeline of its work.

- 6. At its third meeting (held in Geneva, Switzerland on 29 April—1 May 2025), the Expert Group reviewed the draft report to the COP and agreed on the supplementary documents to be presented at the COP.
- 7. The notes for the record of the three Expert Group meetings are available on the WHO FCTC website as supplementary information to this report.<sup>2</sup>

# Summary of previous work undertaken by the Convention Secretariat and the previous Expert Group on Article 19

- 8. An overview of the work that was undertaken by the COP in relation to Article 19 was included in the Convention Secretariat report FCTC/COP/10/12, considered at COP10.
- 9. The Convention Secretariat had previously produced two reports on Article 19 for consideration by the COP. In report FCTC/COP/4/13, it provided a summary of the experience of Parties in implementation of this provision, as well as an overview of liability issues as considered in international law in the field of the environment. Its report FCTC/COP/5/11 contained information on relevant liability regimes under other treaties, examples of taking legislative action to deal with criminal and civil liability, and possible approaches through which the COP could support Parties in their activities in relation to Article 19.
- 10. At its fifth session, the COP established an Expert Group to report on facts, information and options in relation to implementation of Article 19 in decision FCTC/COP5(9). The COP extended the mandate of the Expert Group in decision FCTC/COP6(7), requesting that it focus on approaches that may assist Parties to strengthen civil liability mechanisms across a variety of legal systems.
- 11. In its first report (FCTC/COP/6/8), the Expert Group highlighted the importance of Article 19, and provided options for developing legislation for Parties to consider in particular, in the context of civil liability. The Expert Group also shared considerations in relation to legislation to strengthen criminal liability. In its second report (FCTC/COP/7/13), the Expert Group underlined the common benefits and challenges in implementation of Article 19 and proposed the content for a civil liability toolkit.
- 12. In decision FCTC/COP7(11), the COP adopted the WHO FCTC Article 19 Civil Liability Toolkit,<sup>3</sup> now available in the six official languages of the United Nations, and requested the Convention Secretariat to work on resources to assist Parties with implementation of Article 19, through developing and maintaining a database of experts on liability (Article 19 Expert Database), both of which are available on the Convention Secretariat's website.<sup>4</sup>
- 13. This report builds upon the work on Article 19 completed by the previous Expert Group.

<sup>&</sup>lt;sup>2</sup> COP11 Documentation: Supplementary information (accessed 12 June 2025).

<sup>&</sup>lt;sup>3</sup> WHO FCTC Article 19 Civil Liability Toolkit (accessed 26 May 2025).

<sup>&</sup>lt;sup>4</sup> Article 19 Expert Database (accessed 26 May 2025).

### Survey on implementation of Article 19 of the WHO FCTC

14. To assess country practice, the Expert Group surveyed Parties, nongovernmental organizations (NGOs) that are observers to the COP and other civil society groups not affiliated with the tobacco industry or those working to further its interests. It generally sought information about the extent of Article 19 implementation; methods adopted for implementing Article 19 including means of cooperation between Parties; any Article 19-related litigation that had taken place in their country or region; and if there had been no, or only partial, implementation of Article 19, the reasons for that. The Expert Group also took the opportunity to ask questions about tobacco industry efforts to evade liability, and methodologies used for estimating the health-care costs of tobacco use.

15. As of 28 January 2025, there had been a total of 91 survey responses, which included responses from Parties and responses from civil society in relation to country practice (in Parties and States non-Parties).<sup>6</sup> A total of 51 Parties responded, which included 50 responses from countries<sup>7</sup> and a response from a regional economic integration organization. Of the 50 country responses, 5 countries indicated that they had achieved full implementation of Article 19, 37 countries reported they had partially implemented Article 19, and 9 countries noted that no action had been taken.

## Important considerations related to the survey on implementation of Article 19

- 16. When considering survey responses on the extent of implementation of Article 19, it is important to distinguish between the obligations and the purpose of the Article, both of which are evident from the text. Article 19 requires that, "for the purpose of tobacco control", Parties are to consider strengthening their legal frameworks through legislation, or promoting their existing laws, to deal with criminal and civil liability including compensation where appropriate; to cooperate with each other to provide information relevant to civil and criminal liability; to provide one another assistance in civil and criminal legal proceedings, subject to a Party's existing legal frameworks; and to consider developments in international fora for these purposes. The purpose of Article 19 includes the promotion of civil and criminal proceedings, which establish liability and where appropriate obtain compensation for the harm caused by tobacco.<sup>8</sup>
- 17. Against that background, the Expert Group recognizes that Parties and NGOs might interpret implementation of Article 19 in different ways. Some might consider that Article 19 has been implemented even if a country has taken no legislative action and provided no assistance to other Parties, and there have been no civil or criminal proceedings related to harms caused by tobacco. Conversely, some respondents might consider that Article 19 has been implemented only if legal

<sup>&</sup>lt;sup>5</sup> The survey on implementation of Article 19 of the WHO FCTC is available on the WHO FCTC website at <u>COP11</u> Documentation: <u>Supplementary information</u> (accessed 12 June 2025).

<sup>&</sup>lt;sup>6</sup> In some cases, multiple submissions were made from different agencies at Party level, and some responses were shared as text submissions – that is, email responses where the survey form was not used.

<sup>&</sup>lt;sup>7</sup> The distribution of State Party responses across WHO's regions was as follows: Region of the Americas, 12; African Region, 7; Eastern Mediterranean Region, 4; European Region, 18; South-East Asia Region, 4; and Western Pacific Region, 5.

<sup>&</sup>lt;sup>8</sup> References to harm caused by tobacco include tobacco production, consumption and disposal, and exposure to tobacco smoke.

proceedings have been brought against the tobacco industry which were successful in establishing civil and/or criminal liability of the industry and resulted in compensation, and the outcomes of which contributed to a reduction in tobacco consumption and exposure to tobacco smoke. Proceedings which result in criminal and civil liability for anyone responsible for contributing to harm caused by tobacco furthers an objective of Article 19, including proceedings that resulted in compensation. Some respondents might go further and assess the quality of liability rulings, including who is held liable; what they are held liable for; and the type of injunctive relief, sanctions and/or amount of compensation that is ordered.

- 18. Civil liability actions can produce a range of outcomes: compensation, a finding on liability from the court, and/or an order that the defendant stop certain practices or take remedial action. The litigation process can also expose information about a defendant's conduct, including through disclosure (discovery) of evidence. It is rare for any single civil liability action to produce all these outcomes. The survey on Article 19 did not identify any such action.
- 19. In civil litigation, claimants in many jurisdictions choose to settle their claims against defendants. Settlements can avoid lengthy and costly litigation, or further cost and delays in litigation, and the risk that the action is unsuccessful. Settlements are, by definition, compromise agreements that usually involve lower amounts of compensation than a court would order if the defendant were held liable. On the other hand, negotiated agreements can produce outcomes that a court does not have the power to order.
- 20. Criminal proceedings also serve multiple purposes: to impose effective and proportionate sanctions, to stop the defendant from engaging in the illegal conduct, to deter others from engaging in such conduct, and/or to provide compensation to victims. For these reasons, many legal systems permit formal or informal negotiations between prosecutors and defendants over whether the defendant will plead guilty to certain offences, whether the defendant provides enforceable undertakings not to continue their unlawful behaviour, and whether the defendant will voluntarily provide redress to victims.
- 21. The power imbalances between the tobacco industry and victims of tobacco-related harm (as well as the regulatory agencies and NGOs who that have standing to bring civil and criminal proceedings against the industry) have implications for the procedures for establishing civil and criminal liability. Settlement and deferred prosecution agreements (discussed in paragraph 36) including plea bargaining negotiations between the tobacco industry and governments must comply with Article 5.3 of the WHO FCTC. Reforms to civil litigation are usually necessary to ensure that there is equality of arms between the parties to the proceedings. These implications have been discussed in previous reports of the Expert Group, and are highlighted where appropriate in this report. Legislative reforms to make it easier to establish civil or criminal liability must also be consistent with national and international fair trial rights of defendants in criminal proceedings and all parties in civil proceedings.
- 22. Liability actions against the tobacco industry can be an effective way of highlighting the tobacco industry's decades-long misconduct in the way it has conducted its business, holding it legally accountable for that misconduct and providing meaningful compensation to victims of tobacco-related diseases and the health-care providers responsible for treating them, and modifying the behaviour of the tobacco companies. In summary, liability actions against the

<sup>9</sup> Guidelines for implementation of Article 5.3 presently do not provide guidance on how the transparency recommendations apply in litigation, where settlement negotiations are typically confidential.

tobacco industry have made contributions to tobacco control, including through "de-normalizing" the tobacco industry and tobacco use. 10

23. This is important context when assessing the extent to which Parties have implemented Article 19, what legislative action Parties can take to deal with criminal and civil liability, and the success or otherwise of litigation regarding harm caused by tobacco.

### Review of practices and policies that have evolved at a Party level

### Review of practices relating to criminal liability

24. Criminal proceedings involving violations of tobacco control legislation are a common means of Article 19 implementation. Parties have pursued criminal liability for tobacco-related harms which do not expressly constitute an offence under tobacco control legislation less often than civil liability actions, for a number of reasons: it is generally not possible to apply criminal laws retroactively to the manufacture, supply or marketing of tobacco products; the burden of proof generally required for prosecuting criminal offences is higher; and a presumption of innocence favours the defendant. A range of criminal offences that could be introduced for implementation of Article 19 were recognized by the previous Expert Group.

### Summary of survey responses on implementation of Article 19 related to criminal liability

- 25. Survey participants were asked about the existence of criminal penalties in tobacco control legislation and general laws that apply to the manufacture, supply and marketing of tobacco products. As shown below, many countries do provide for criminal penalties in such legislation. In terms of other criminal liability practices, survey responses indicated an increase in claims and/or investigations compared to practices reported by the previous Expert Group. Considerations about those practices are set out in the relevant section detailing the specific examples of criminal liability practices reported by survey respondents.
- 26. Overall, in 29 countries, Parties and civil society respondents identified the existence of criminal penalties in tobacco control legislation<sup>12</sup> primarily applied to the following policy measures: import, sales or distribution;<sup>13</sup> tobacco product packaging and labelling; tobacco advertising, promotion and sponsorship; smoke-free environments; and disclosure requirements to government authorities. In two countries, a Party and a civil society respondent also reported that their tobacco control legislation provided for criminal liability against corporate officers and directors.

<sup>&</sup>lt;sup>10</sup> Zhou S, Ricafort E, Bressler D, Devotsu RK. <u>Litigation in tobacco control: past, present and future</u>. Tob Control. 2022;31:291–95 (accessed 26 May 2025).

<sup>&</sup>lt;sup>11</sup> FCTC/COP/6/8, paragraph 13.

<sup>&</sup>lt;sup>12</sup> Note that a December 2024 search on the <u>Tobacco Control Laws</u> website indicated that at least the following numbers of countries included criminal penalties in their tobacco control measures relating to smoke-free places (33), advertising and promotion (66) and sponsorship (52), packaging and labelling (applied to manufacturers) (58), sales restrictions (55), content regulation (22), and content disclosure requirements (33).

<sup>&</sup>lt;sup>13</sup> Examples include sales without a licence, sales to or by minors, sales of products with prohibited content (such as flavoured products), and failure to place required health warnings on product packaging.

27. Regarding the existence of criminal penalties in general criminal laws that apply to the manufacture, supply and marketing of tobacco products, in 31 countries, Parties and civil society respondents identified criminal penalties primarily falling within the following categories:

- (a) customs and excise legislation and general criminal or penal codes providing criminal penalties related to smuggling, tax evasion, counterfeit production or distribution;
- (b) anti-corruption/anti-bribery legislation, anti-competition legislation and antiembezzlement laws;
- (c) anti-money laundering legislation and legislation providing for whistleblower protection;
- (d) workplace protections and labour legislation;
- (e) consumer protection laws or consumer production provisions within general criminal codes;
- (f) criminal law processes applied in enforcement of legislation (such as requiring judicial warrants for inspections);
- (g) violations related to human rights abuses;
- (h) environment crimes legislation; and
- (i) extended producer responsibility imposed on tobacco companies (with a note of caution regarding activities described as "corporate social responsibility" by the tobacco industry and those working to further its interests).
- 28. Further, responses were provided about known relevant enforcement actions over the past decade for violations of tobacco control laws or general criminal laws that apply to the manufacture, supply and marketing of tobacco products. <sup>14</sup> Obstacles identified in the survey responses are summarized in paragraph 100.
- 29. Establishing the criminal liability of individuals or corporate entities for violations of general criminal laws that apply to the manufacture, supply and marketing of tobacco products was not uniformly addressed in the survey responses. Similarly, whether criminal penalties provided effective deterrents was also not addressed uniformly in the responses, despite the critical need to define the deterrent effect of these measures which may vary across different jurisdictions to ensure that liability provisions are both effective and appropriate, taking into account national circumstances. Finally, quasi-criminal administrative procedures (described in paragraph 68) were not specifically addressed in the survey.

### Criminal complaints related to so-called light/low tar cigarettes

30. In the last 10 years, at least three criminal complaints against tobacco companies and/or their executives have been initiated by civil society or smokers in France, Netherlands (Kingdom of

<sup>&</sup>lt;sup>14</sup> Examples include sales without a licence, sales to or by minors, sales of products with prohibited content (such as flavoured products) and failure to place required health warnings on product packaging.

the) and Finland.<sup>15</sup> These have argued broadly that tobacco executives committed a crime by selling so-called light cigarettes, knowing that the cigarette filter ventilation holes result in lower readings of tar, nicotine and carbon dioxide emissions from the machine testing prescribed by law compared to what is delivered to smokers, and thereby misled smokers as to the health effects of their products. The Netherlands' complaint also included a claim that the tobacco companies purposefully designed cigarettes to cause almost immediate addiction, which impaired the "free will" of smokers, leading to serious health effects.

31. Although these criminal claims were not ultimately prosecuted, these cases raised public awareness of the misleading conduct of the tobacco industry and the harms of its products, <sup>16</sup> which the previous Expert Group noted is a means to strengthen implementation of the WHO FCTC. <sup>17</sup> Complaints in France and the Netherlands were reviewed by courts.

### Criminal proceedings related to tobacco advertising and promotion

- 32. In France, two direct summonses were filed by civil society against Philip Morris entities in France and Switzerland (State non-Party) alleging that the companies violated the public health code, which prohibits the direct or indirect advertising of tobacco products. Among other requests, the claimants sought the application of the criminal law's enforcement provisions and a liability award against the Philip Morris companies for the damage caused to the NGOs and to their initiatives to prevent smoking arising from the companies' promotion of tobacco products through their advertising of IQOS in France.
- 33. The court found both Philip Morris defendants guilty, holding that Philip Morris in France marketed IQOS and was thus guilty of illegal advertising, and Philip Morris in Switzerland manufactured and packaged IQOS and thus shared a community of interest with Philip Morris' French affiliate, and thus could be held criminally liable for the illegal act. On appeal, the court upheld the trial court conviction, awarding an indemnity of €5000 to each NGO applicant. It fined Philip Morris in France a repeat offender €500 000, and the Philip Morris Swiss affiliate €400 000.<sup>19</sup> The case is currently pending at the highest court in France (Cour de cassation).
- 34. A second recent ruling by a criminal court in France against Philip Morris found the company and its former CEO guilty of illegal advertising of its products, fining the company €500 000 and the former CEO of Philip Morris France €50 000. This is the first time in France that a court attributed criminal liability to a tobacco company CEO. The appeal in this case is currently pending.

<sup>&</sup>lt;sup>15</sup> In Finland, over 30 doctors and legal experts asked the National Bureau of Investigation to investigate whether tobacco company executives committed the crimes of assault and murder for selling "light" cigarettes, which the experts estimated killed 60 000 people in Finland. The National Bureau of Investigation declined to launch any preliminary investigation, and no further action was taken.

<sup>&</sup>lt;sup>16</sup> Romeo-Stuppy K, Béguinot E, De Kanter W. <u>Criminal liability for tobacco corporations and executives</u>. Tob Control. 2022;31(2):355–7 (accessed 26 May 2025).

<sup>&</sup>lt;sup>17</sup> FCTC/COP/6/8, paragraph 35.

<sup>&</sup>lt;sup>18</sup> These prohibitions do not apply to tobacco shop signs so long as such signs are compliant with an Inter-Ministerial Order regulating their use.

<sup>&</sup>lt;sup>19</sup> Philip Morris France SAS v National Committee for Tobacco Control, Paris Court of Appeal, 22/00519 (2024) (accessed 26 May 2025).

35. Criminal proceedings in France through its national laws could serve as a model for other civil code countries.<sup>20</sup> Under the Code of Criminal Procedure in France, compensation is owed to those who are personally damaged by a crime.<sup>21</sup> The Public Health Code allows civil society tobacco control organizations with no tobacco industry affiliations that have been working for at least five years from the date of the alleged contravention to pursue civil or criminal proceedings against the tobacco industry, distributors and any other natural or legal person for violations of tobacco control measures, and to claim compensation on behalf of victims.<sup>22</sup> In effect, these NGOs can be funded, in part, by damages awarded in those judicial proceedings (where the amount of damages is higher than the cost of the legal action). The judge in a criminal or civil court has discretion over the amount of damages awarded to an NGO for a conviction under the law. Further, in the case of at least one tobacco control NGO in France, the Ministry of Health also financially supports the NGO to bring legal actions to enforce tobacco control measures, which adds to the credibility of these legal actions within the judiciary.

### Criminal investigations into tobacco industry conduct resolved through settlements

- 36. The use of settlements and other non-trial resolutions<sup>23</sup> has become increasingly prevalent in corporate enforcement actions.<sup>24</sup> As a prime example, deferred prosecution agreements and non-prosecution agreements offer prosecutors a middle ground between charging a company or individual with a crime and declining to prosecute altogether. Similar practices are also employed by regulators as an alternative to taking court action to establish civil liability. This approach aims to encourage corporate cooperation and compliance without resorting to full prosecution, but remains subject to criticism.<sup>25</sup> In addition to these considerations, the use of deferred prosecution agreements and non-prosecution agreements in tobacco control presents a unique situation due to the inherent harm resulting from the tobacco industry's activities, the history surrounding the actions of the tobacco industry, and the transparency and cooperation provisions of the WHO FCTC and the Guidelines for implementation of Article 5.3, applying to the whole of government.
- 37. Criminal investigations highlighted by survey respondents included examples involving British American Tobacco (BAT) from Nigeria, the United States of America (State non-Party), and the United Kingdom of Great Britain and Northern Ireland/Kenya.

<sup>&</sup>lt;sup>20</sup> An NGO in France reported to the Expert Group that hundreds of cases have been brought from violations of the Public Health Code, and, in the past 10 years, 65 cases have been monitored by the NGO, and 40 proceedings have been won before the criminal or civil courts related to tobacco advertising, including at the point of sale, and packaging and labelling.

<sup>&</sup>lt;sup>21</sup> Code of Criminal Procedure. Article 2 (accessed 26 May 2025).

<sup>&</sup>lt;sup>22</sup> Public Health Code. Article L3515-7 (accessed 26 May 2025).

<sup>&</sup>lt;sup>23</sup> "Non-trial resolutions refer to a wide range of mechanisms used to resolve criminal matters without a full court proceeding, based on an agreement between an individual or a company and a prosecuting or another authority". Resolving foreign bribery cases with non-trial resolutions: settlements and non-trial agreements by Parties to the Anti-Bribery Convention. Paris: OECD Publishing; 2019 (accessed 27 May 2025).

<sup>&</sup>lt;sup>24</sup> CAC/COSP/WG.2/2016/2\* Settlements and other alternative mechanisms in transnational bribery cases and their implications for the recovery and return of stolen assets. New York: United Nations Conference of the States Parties to the United Nations Convention against Corruption; 2016 (accessed 27 May 2025).

<sup>&</sup>lt;sup>25</sup> Gottschalk P. <u>Deferred prosecution agreements as miscarriage of justice: an exploratory study of corporate convenience</u>. J Econ Criminol. 2024; 4:100059 (accessed 27 May 2025).

#### **Consumer protection investigation in Nigeria**

38. In Nigeria, the federal consumer protection agency investigated BAT Nigeria's violations of Nigeria's consumer protection and tobacco control measures resulting in a cooperation agreement. After a three-year investigation, BAT Nigeria and affiliate companies, including its parent company, entered into a confidential consent order in 2023 requiring the company to pay US\$ 110 million to the agency, and all criminal charges against BAT Nigeria were dropped. The consent order also put BAT Nigeria under a compliance monitoring process for a period of 24 months, and required the company to engage in public health and tobacco control advocacy in a manner compliant with national tobacco control legislation and regulations. Because the consent order was confidential, the public does not know what specific corporate behaviour was investigated in this case.

#### Bank fraud and sanctions investigation in the United States

39. In the United States in 2023, authorities charged BAT with bank fraud and sanction violations for its cigarette business in the Democratic People's Republic of Korea, which involved millions of dollars in profits sent via United States financial institutions from a BAT joint venture in the Democratic People's Republic of Korea through multiple intermediaries for at least seven years. In a publicly available settlement with the United States, BAT paid a US\$ 500 million penalty to the agency responsible for administering and enforcing economic sanctions programmes in the United States. As set out in the settlement agreement, <sup>28</sup> BAT changed its corporate structures to carry out its scheme, and knew internally that the way it was carrying out its cigarette business operations in the Democratic People's Republic of Korea probably violated United States sanctions.

#### **Bribery investigations in the United Kingdom**

40. In the United Kingdom, BAT was investigated for suspicions of corruption over a five-year period.<sup>29</sup> The Serious Fraud Office undertakes almost all enforcement actions (both investigations and prosecutions) under the United Kingdom's Bribery Act.<sup>30,31</sup> After its five-year investigation, the Serious Fraud Office announced that it had concluded its investigations into BAT, finding that the

<sup>&</sup>lt;sup>26</sup> British American Tobacco Nigeria Limited and affiliated companies: investigation into possible violations of the Federal competition and consumer protection act, 2018 and other relevant tobacco control laws/sundry regulations and directives. Abuja: Federal Competition and Consumer Protection Commission; 2023 (accessed 27 May 2025).

<sup>&</sup>lt;sup>27</sup> Salau S. <u>FCCPC combats underage tobacco access, usage</u>. The Guardian – Nigeria. 9 June 2024 (accessed 27 May 2025).

<sup>&</sup>lt;sup>28</sup> Settlement agreement with respect to ENF 54851 between the United States Department of the Treasury's Office of Foreign Assets Control and British American Tobacco p.l.c. and its subsidiaries and affiliates worldwide. Washington, DC: Department of the Treasury; 2023 (accessed 27 May 2025).

<sup>&</sup>lt;sup>29</sup> <u>SFO investigating British American Tobacco Plc</u>. London: Serious Fraud Office; 1 August 2017 (accessed 27 May 2025).

<sup>&</sup>lt;sup>30</sup> Bribery Act 2010 (accessed 27 May 2025). (Under the Act, British nationals or companies incorporated in the United Kingdom may commit a prosecutable offence where a person bribes foreign officials with the intention of securing a business advantage and/or where a commercial organization fails to prevent its employees or agents from engaging in bribery, unless the organization can show that it had adequate procedures in place to prevent persons associated with it from bribing.)

<sup>&</sup>lt;sup>31</sup> For a list of the Serious Fraud Office's cases and investigations, see Find an SFO case (accessed 27 May 2025).

evidence did not meet the evidential test for prosecution under the Code for Crown Prosecutors.<sup>32</sup> The investigation had reportedly lasted over 18 000 hours and cost United Kingdom taxpayers over £2.3 million.<sup>33</sup> The Serious Fraud Office indicated that it would "continue to offer assistance to the ongoing investigations of other law enforcement partners", and thanked its "international law enforcement partners, and in particular the Kenyan Ethics and Anti-Corruption Commission (EACC), for their assistance" in its investigation.<sup>34</sup> An analysis of BAT's payments published by academics revealed that BAT had made 236 potentially questionable payments between 2008 and 2013 totalling US\$ 601 502, affecting 10 countries in East and Central Africa.<sup>35</sup>

### Review of practices relating to civil liability

- 41. Based on survey responses, it appears that less action has been taken in relation to civil liability than criminal liability for most Parties. This is because the only action taken by many countries that could fit within Article 19 implementation is the passage of tobacco control laws that include criminal sanctions for violations, and some level of enforcement of those laws. A significant number of countries have not passed laws which are specifically related to civil liability of tobacco manufacturers and suppliers; in many of those same countries no civil cases have been reported against the tobacco industry for tobacco-related harms.
- 42. A large number of countries confirmed that they had measures in place to facilitate civil liability, including the provision of compensation where appropriate, which apply to the manufacture, supply and marketing of tobacco products. This includes measures such as:
  - (a) making individuals or corporate entities violating tobacco control laws civilly liable for those breaches;
  - (b) making individuals or corporate entities violating general laws that apply to the manufacture, supply and marketing of tobacco products civilly liable for those breaches;
  - (c) assisting victims of smoking-related harms and/or those who have incurred tobaccorelated health-care costs to obtain damages from the tobacco industry; and
  - (d) making their civil justice systems more accessible generally (for example, class action procedures, legal aid support, cost capping rules, discovery obligations on defendants and/or reversing the burden of proof).

<sup>&</sup>lt;sup>32</sup> The <u>Code for Crown Prosecutors</u>, issued under section 10 of the Prosecution of Offences Act 1985, sets out guidance for prosecutors in making decisions about cases, including setting out two stages when making charging decisions: 1) evidential stage: broadly, whether there is sufficient evidence to successfully prosecute; which is followed by 2) public interest stage: broadly, whether it is in the public interest to prosecute (accessed 27 May 2025).

<sup>&</sup>lt;sup>33</sup> Rowell A. What is the government trying to hide about B.A.T? Declassified UK; 3 April 2024 (accessed 27 May 2025).

<sup>&</sup>lt;sup>34</sup> <u>SFO closes British American Tobacco (BAT) Plc Investigation</u>. London: Serious Fraud Office; 15 January 2021 (accessed 27 May 2025).

<sup>&</sup>lt;sup>35</sup> Jackson RR, Rowell A, Gilmore AB, "Unlawful bribes?" A documentary analysis showing British American Tobacco's use of payments to secure policy and competitive advantage in Africa. San Francisco, CA: UCSF: Center for Tobacco Control Research and Education; 2021 (accessed 27 May 2025). The 10 countries affected were Burundi, Comoros, Democratic Republic of the Congo, Kenya, Malawi, Rwanda, Sudan, Uganda, United Republic of Tanzania and Zambia. BAT reportedly used these payments to influence policy in its favour and sabotage its competitors.

43. However, in many of the same countries in which the adoption of measures to strengthen their civil liability regimes was reported, no successful civil liability actions were reported at all, or none against the tobacco industry specifically.

- 44. Although most civil liability cases identified by respondents related to the health consequences of tobacco consumption and exposure, liability actions concerning environmental harm (in the United States),<sup>36</sup> illnesses caused by involvement in the production of tobacco (in Brazil)<sup>37</sup> and labour law violations including use of child labour (in England, United Kingdom, brought by Malawian tobacco farmers)<sup>38</sup> were also identified.
- 45. As for smoking and health-related civil liability actions, the most significant in terms of scale were health-care cost recovery litigation and class actions and related claims brought by victims of smoking-related disease. Brazil and the Republic of Korea have ongoing health-care cost recovery litigation against major global tobacco companies in those countries<sup>39</sup> and, in the case of Brazil, against their parent companies as well. These actions are particularly noteworthy, given that they are the first exclusively civil law countries<sup>40</sup> to bring health-care cost recovery claims against the tobacco industry. Additional actions considered by the Expert Group include the recent resolution of the decades-long litigation in Canada and the ongoing class action litigation in the United States.

#### **Brazil**

46. The Brazilian case, filed in 2019, is brought by the Attorney General's Office on behalf of Brazil's population, and seeks reimbursement for the health-care costs incurred by Brazil's public health system, Sistema Único de Saúde, <sup>41</sup> for treating 26 tobacco-related diseases. The case illustrates Brazil's proactive stance in addressing the societal and economic toll of tobacco consumption, not merely through regulation and public health campaigns but also by pursuing legal accountability including compensation for the costs of tobacco consumption and exposure to tobacco smoke. With a population exceeding 200 million and a universal health-care system that bears the brunt of tobacco-related harm, Brazil's lawsuit aims to relieve, in part, its tobacco economic burden. The lawsuit targets both national subsidiaries and international parent companies of BAT and Philip Morris International. Including the parent companies as defendants reflects the integrated nature of these corporate groups, where decision-making and profit allocation are centralized at headquarters level. By holding both local and global entities

37 Lídia Maria Bandacheski

<sup>&</sup>lt;sup>36</sup> See paragraph 63 below.

<sup>&</sup>lt;sup>37</sup> <u>Lídia Maria Bandacheski do Prado v. Alliance One (2015, Brazil); and Valdemar Santos v. Universal Leaf</u>
<u>Tabacos (2002, Brazil)</u> (accessed 27 May 2025). In both cases the claimants alleged they contracted serious illnesses as a result of exposure to toxic chemicals used in the production of tobacco crops. The Santos case was resolved in a confidential settlement and the Prado case is currently before the Common Court.

<sup>&</sup>lt;sup>38</sup> Milasi Josiya v British American Tobacco PLC (QB-2020-004542) (accessed 18 June 2025). The claim for negligence and unjust enrichment is brought by several thousand impoverished tenant tobacco farmers, their wives, children and other family members, who allege they were trafficked, and subject to forced labour, child labour and other dangerous and exploitative employment practices on Malawian tobacco farms. The action alleges violations of both the European Convention on the Human Rights and the Convention on the Rights of the Child. The claim is brought against BAT, Imperial Brands, their parent companies and subsidiaries. The case is currently before the High Court, with a trial scheduled for 2025.

<sup>&</sup>lt;sup>39</sup> The Expert Group notes that several Nigerian states also have health-care cost recovery actions pending in courts since 2007–2008.

<sup>&</sup>lt;sup>40</sup> Quebec, which commenced health-care cost recovery litigation in 2012, is both a common law and civil law jurisdiction.

<sup>&</sup>lt;sup>41</sup> Sistema Único de Saúde. Brasília: Ministério da Saúde; 2025 (accessed 27 May 2025).

accountable, the Attorney General's Office aims to address the coordinated actions that perpetuate harm across borders. By advancing the application of civil liability laws upon parent companies, Brazil seeks to address the global challenges posed by transnational corporations that profit from harmful products while externalizing health costs to societies, particularly in low- and middle-income countries.

- 47. A feature of the Brazilian action is that it relies on existing procedural and substantive laws rather than enabling legislation. This includes its collective redress procedures, which allow the Attorney General's Office to bring a claim on behalf of all the people of Brazil, and its strict liability laws, which ensure that persons who engage in inherently risky activities should bear the full costs of those activities. The Brazilian action also includes fault-based claims that are common to all tobacco litigation. This includes allegations concerning breach of duty to inform would-be smokers about the harmful consequences of smoking and the addictive nature of nicotine, manipulation of nicotine to make the product more addictive, marketing to children and adolescents, marketing of so-called light cigarettes as a less harmful product, and the destruction of documents detailing the industry's practices and knowledge.
- 48. The Brazilian litigation also seeks to establish causation and damage on a collective basis, using the concept of "diffuse damage". The Attorney General's Office argues that the economic burden of tobacco-related diseases on Sistema Único de Saúde constitutes a societal harm, borne by every Brazilian taxpayer smoker or non-smoker. By framing the damage as collective and systemic, the lawsuit seeks to avoid traditional barriers to proving causation in individual cases.

#### Canada

- 49. Court verdicts holding the tobacco industry civilly liable for the harm caused by tobacco consumption (2015) and settlements to provide compensation to health-care providers and victims of tobacco-related diseases, as well as funds for research into treatment of smoking-related diseases (2025), have been obtained in Canada.
- 50. The resolution of health-care cost recovery litigation and class actions in Canada in March 2025 represents a significant development in civil liability and compensation since the publication of the previous Expert Group's report in 2014. The procedural history of some of these lawsuits was discussed in that report (FCTC/COP/6/8), and the legislation used to facilitate such litigation is referred in the WHO FCTC Article 19 Civil Liability Toolkit<sup>42</sup> (FCTC/COP/7/13).
- 51. In May 2015 the Quebec Superior Court ruled in favour of the plaintiffs in two joined class actions which sought compensation for a number of smoking-related diseases and nicotine addiction. <sup>43</sup> The Court found that the tobacco companies had acted in breach of four Quebec laws by causing injury, failing to warn, misleading consumers, and interfering with the rights to life and security. The Court held that "In spite of overwhelming scientific acceptance of the causal link between smoking and disease, [the company] continued to preach the sermon of the scientific controversy well into the 1990s ...". <sup>44</sup> Referring to company statements casting doubt on the relationship between tobacco and disease, the judge stated that "[O]ne can only wonder whether the people making such comments were remarkably naïve, wilfully blind, dishonest or so used to

<sup>&</sup>lt;sup>42</sup> WHO FCTC Article 19 Civil Liability Toolkit (accessed 26 May 2025).

<sup>&</sup>lt;sup>43</sup> <u>Létourneau c. JTI-MacDonald Corp., 2015 QCCS 2382</u> (accessed 5 June 2025).

<sup>&</sup>lt;sup>44</sup> <u>Quebec Superior Court Justice Brian Riordan's judgment in Létourneau & Blais v. JTM, ITL & RBH, paragraph 1078</u> (accessed 30 May 2025). May 2025).

the industry's mantra that they actually came around to believe it. Their linguistic and intellectual pirouettes were elegant and malevolent at the same time. They were also brutally negligent."<sup>45</sup>

- 52. The judge ordered collective recovery of the maximum allowable compensation for moral damages to be given to each member of the CQTS/Blais class diagnosed with lung cancer or throat cancer (Can\$ 100 000 adjusted for inflation, which amounted to approximately Can\$ 350 000), and about one third as much to those diagnosed with severe emphysema. In respect of the 900 000 members of the Létourneau addiction case, he ordered the companies to pay Can\$ 131 million in punitive damages, but decided against awarding compensation to individuals because of the variability in the circumstances of the individuals in the context of collective recovery.
- 53. The judgment was unanimously upheld by the Quebec Court of Appeal in May 2019, with the Appeal Court reaffirming that the companies had systematically acted to trivialize the dangers of tobacco. Immediately after the appeal judgment was delivered, the tobacco companies filed for insolvency protection under the Companies Creditors' Arrangement Act on the basis that they did not have the ability to meet all their liabilities, including the amounts ordered in the CQTS/Blais and Létourneau actions. The companies used these insolvency proceedings as a mechanism to seek a global settlement to resolve all Canadian legal claims against them. These claims include reimbursement for tobacco-related health-care costs to Canadian provincial governments, class actions and lawsuits by individuals involving addiction and disease, and claims by farmers related to deceptive trade practices. The only two claims supported by a court ruling are the Quebec class actions.
- 54. Confidential negotiations towards a global settlement were managed by a court-ordered mediator. In September 2023 no draft agreement had emerged from this process, and the supervising judge ordered the mediator and other court officers to propose a draft settlement (referred to as a plan of compromise or arrangement) that could be the basis of a vote by the companies' creditors.<sup>47</sup> This is believed to be the first time in Canada that a proposed settlement has been drafted by court officials and not by the insolvent companies.
- 55. In October 2024, the mediator and court monitors filed a proposed plan for each company. Under this set of agreements, the companies would pay a total of Can\$ 32.5 billion, and would be released from all current and past liabilities. Of this sum, Can\$ 12.5 billion would be an immediate payment from the savings that had been amassed during the Companies Creditors' Arrangement Act process, during which time the companies had not been permitted to return the profits from Canadian cigarette sales to their multinational owners. Certain other nicotine and tobacco products like electronic nicotine delivery systems and heated tobacco products are excluded from all provisions of the proposed settlement.
- 56. Approximately Can\$ 6 billion would be used to compensate the Quebec victims whose court award had triggered the Companies Creditors' Arrangement Act process, and to provide similar compensation to injured smokers in other provinces. These are individuals whose lung cancer, throat cancer or emphysema was diagnosed during specific time periods, and who meet specific

<sup>&</sup>lt;sup>45</sup> <u>Quebec Superior Court Justice Brian Riordan's judgment in Létourneau & Blais v. JTM, ITL & RBH, paragraph 268</u> (accessed 30 May 2025).

<sup>&</sup>lt;sup>46</sup> Court File No. CV-19-616077-00CL. Imperial Tobacco Canada Limited and Imperial Tobacco Company Limited. <u>Twenty-second report of the Monitor</u>. Toronto: FTI Consulting Canada Inc.; 13 November 2024 (accessed 28 May 2025).

<sup>&</sup>lt;sup>47</sup> Court File No. CV-19-615862-00CL, CV-119-616077-00CL and CV-119-616779-00CL. Toronto: FTI Consulting Canada Inc.; 5 October 2023 (accessed 28 May 2025).

criteria in respect of their smoking history, based on certain liability findings of the Quebec Superior Court.<sup>48</sup> All other potential claims by smokers would be released, in return for which Can\$ 1 billion would be allocated to a new foundation which will fund research focused on improving treatment outcomes for victims of smoking-related disease.

- 57. Provincial governments would share in compensation of approximately Can\$ 25 billion, with the majority of this amount to be paid from future sales by the industry. It is estimated that it will take approximately 20 years for the companies to pay the compensation in full, but the timescale could be longer.<sup>49</sup>
- 58. All creditors unanimously voted in favour of the settlement plan.<sup>50</sup> After a court hearing, the Chief Justice of the Ontario Superior Court approved the settlement as being fair and reasonable.<sup>51</sup>
- 59. Features of the Canadian settlement which distinguish it from the 1998 Minnesota tobacco settlement and the Master Settlement Agreement between multiple United States state and territorial governments and tobacco companies are that it was not a negotiated agreement but a plan of arrangement drawn up by a court-appointed mediator, and that it did not include non-financial measures aimed at modifying industry behaviour, such as the restrictions on marketing that resulted from United States lawsuits. The mediator was appointed pursuant to the Companies Creditors' Arrangement Act legal framework, which is intended to allow debtors to pay off their debts while restructuring their business, and to return to profitability.

#### Republic of Korea

60. The health-care cost recovery claim in the Republic of Korea was brought by the National Health Insurance Service (NHIS), a public agency managing the Republic of Korea's health insurance programme. It filed a lawsuit in 2014 against major tobacco companies in the Republic of Korea, including KT&G, Philip Morris Korea and BAT Korea. The NHIS sought reimbursement for the insurance benefits it had paid to treat smoking-related illnesses – specifically lung cancers and laryngeal cancers. The claim was filed in relation to 3465 individuals with a history of over 20 pack-years of smoking, who developed the specified cancers after smoking for more than 30 years. The claim sought approximately US\$ 50 million, representing the insurance benefits paid by the NHIS for their treatment. The claim was brought to address widespread harm to Koreans caused by

<sup>&</sup>lt;sup>48</sup> Eligible smokers suffering must have smoked a minimum of 87 600 cigarettes prior to November 1998 and have been diagnosed with lung cancer, throat cancer and emphysema/chronic obstructive pulmonary disease prior to March 2012 for Quebec class action claimants or between March 2015 and March 2019 for smoking victims in other provinces. In the Quebec class action liability ruling, the Court had held that the public knew or should have known that smoking cigarettes could cause lung cancer, throat cancer and emphysema/chronic obstructive pulmonary disease *and* that smoking was addictive by 1 March 1996. This date was adjusted to November 1998 for the purposes of the settlement.

<sup>&</sup>lt;sup>49</sup> Court File No. CV-19-616077-00CL; CV-19-616779-00CL; CV-19-615862-00CL. Imperial Tobacco Canada Limited, 2025 Onsc 1358. Toronto: Superior Court of Justice – Ontario; 2025 (accessed 17 June 2025).

<sup>&</sup>lt;sup>50</sup> There were 289 906 votes in favour of the Imperial Tobacco plan, representing US\$ 96 382 202 265 in total value of voting claims, and zero against. Similar numbers approved the Japan Tobacco and Rothmans plans.

<sup>&</sup>lt;sup>51</sup> Court File No. CV-19-615862-00CL; CV-19-616077-00CL; CV-19-616779-00CL. Imperial Tobacco Canada Limited, 2025 Onsc 1358. Toronto: Superior Court of Justice – Ontario; 2025 (accessed 1 June 2025).

tobacco use<sup>52</sup> and the heavy financial burden caused by treating smoking-related illnesses.<sup>53</sup> Calls for legal accountability from the tobacco industry, in light of international precedents, and a desire to further raise public awareness of the health consequences of tobacco use, were also motivating factors for the lawsuit.

61. In 2020, the NHIS's claim was dismissed at first instance, with the court rejecting the international scientific consensus on the causal relationship between tobacco use and disease, and the industry's responsibility for the harm caused by tobacco use. The court also rejected the NHIS's standing to claim compensation on the grounds that meeting the costs of treating illnesses was part of its obligations as an insurer. The ruling faced severe criticism from the public health community<sup>54</sup> for not considering international precedents, and for its lack of detailed analysis of the strong – and universally scientifically accepted – causal relationship between tobacco use and the cancers that were the subject of the suit. The NHIS subsequently filed an appeal; at the time of writing this report, the appeal was ongoing, with 11 hearings held so far, and the final hearing in the appellate trial scheduled for 22 May 2025.

#### **United States**

- 62. The United States, which is not a Party to the WHO FCTC, remains a successful country in establishing the civil liability of the tobacco industry and securing compensation. Although it is not possible to provide exact figures for the compensation paid to victims of tobacco-related diseases, in 2024, corporate filings of the parent company of Philip Morris USA, Altria, reported that it paid over US\$ 1 billion in damages and interest since 2004, including payments to victims in the Engle class action progeny cases.<sup>55</sup>
- 63. The city of Baltimore in the United States has sought to recover past, present and future expenditures and losses from the tobacco industry<sup>56</sup> as a result of cigarette filter litter in the city pursuant to its policing powers to prevent and abate nuisances, including pollution. Baltimore is seeking damages, including punitive damages, equitable relief and criminal penalties, claiming that the defendants unlawfully littered, trespassed and caused a public nuisance, and that there were design defects in their products, giving rise to both strict liability due to the harm caused to the environment and absence of perceived benefit, and negligence liability, given that cigarettes with non-biodegradable filters were "unsafe to the environment as designed" at the time they left the defendants' control.<sup>57</sup>

<sup>&</sup>lt;sup>52</sup> As of 2019, the total number of deaths attributed to smoking was 58 036, including 50 942 men and 7094 women. This equates to an average of 159 deaths per day caused by smoking-related diseases.

<sup>&</sup>lt;sup>53</sup> Smoking-related insurance expenditure in the Republic of Korea (2019–2023), represented as total medical costs compared to **insurance benefits** (in billion Korean Republic won) per year was: 2019 (3365.1 versus **2824.0**); 2020 (2086.3 versus **2606.1**); 2021 (3473.8 versus **2929.6**); 2022 (2591.7 versus **3028.2**); and 2023 (3858.9 versus **3259.1**).

<sup>&</sup>lt;sup>54</sup> Goo MJ. <u>건보공단, 오늘 담배소송 항소이유서 제출…"쟁점별 심리 요청" [NHIS submits appeal in tobacco lawsuit – "Requests hearing by issue"]</u>. Newsis; 2 April 2021 (accessed 28 May 2025) (in Korean).

<sup>&</sup>lt;sup>55</sup> <u>United States Securities and Exchange Commission, Washington, D.C., Commission File Number 1-08940, Altria Group, Inc.</u> (accessed 12 June 2025).

<sup>&</sup>lt;sup>56</sup> Defendants are Philip Morris USA, Inc., Altria Group, R.J. Reynolds Tobacco Company, British American Tobacco Plc, Liggett Group LLC and The George J Falter Company.

<sup>&</sup>lt;sup>57</sup> Complaint, paragraph 118, Mayor And City Council of Baltimore City v. Philip Morris USA Inc, et al., No. 24-C-22-004904, Baltimore City Circuit Court, filed 21 November 2022 (accessed 28 May 2025).

### Administrative measures for establishing liability

64. The well-documented obstacles to establishing the civil and criminal liability of the tobacco industry have led to calls to examine administrative alternatives to court proceedings for determining liability for tobacco-related harms. This is also reflected in the COP10 decision reestablishing this Expert Group (FCTC/COP10(13)).

- 65. Administrative procedures provide an alternative means of establishing liability (civil or criminal). While administrative procedures can take a range of forms, they typically involve non-court-based determinations of liability, without the usual rules of procedure that apply to court proceedings, and that only limited, or no, appeals can be made to the administrative decision. The advantage of these less formal processes is that they provide the tobacco industry with far fewer opportunities to "out-litigate" their opponents by mounting constant procedural and evidentiary challenges. Administrative processes are designed to be resolved more quickly than court-based processes. As with court-based actions to establish liability of the tobacco industry, administrative filings and rulings can help in de-normalizing the tobacco industry and its products.
- 66. These administrative processes typically involve investigative processes and/or liability determinations by regulators and/or tribunals. For example, self-regulatory bodies can have the power to make declaratory orders of breach of an applicable code, and injunctive orders stopping further breaches. These orders are often final, with no appeal rights. Independent regulators, including ombudsmen or administrative agencies, can be given powers to carry out investigations including compelling documents from regulated persons. They can make declaratory and injunctive orders, impose fines or other regulatory sanctions (such as removal of licences), and in some cases have powers to provide (limited) remedies to affected victims, including compensation.
- 67. There are also administrative tribunals (with either specialist or general jurisdiction) that resolve contested legal disputes between regulator and regulated persons, or between private parties alleging breaches of civil law. The processes frequently involve modified rules of evidence and procedure. They have wide-ranging powers; they can make declaratory and injunctive orders, impose fines and other sanctions, and payment of compensation to affected parties. The purpose of specialist administrative tribunals some of which have been highlighted in the work of the previous Expert Group<sup>61</sup> is to provide a quicker and cheaper means of resolving legal disputes and to promote access to justice for individual claimants with limited means and limited life expectancies due to severe diseases, often caused by the defendants they are bringing claims against. There is also increasing use of administrative tribunals in other fora, such as environmental claims in accordance with international legal obligations and guidelines.<sup>62</sup>

<sup>&</sup>lt;sup>58</sup> Some countries, particularly in civil law jurisdictions, also have dedicated administrative courts for hearing administrative law related matters.

<sup>&</sup>lt;sup>59</sup> The Expert Group notes that some jurisdictions have administrative procedures and administrative courts where formal rules are not dissimilar to other court proceedings.

<sup>&</sup>lt;sup>60</sup> The United Kingdom's <u>Advertising Standards Authority</u> is one example (accessed 28 May 2025).

<sup>&</sup>lt;sup>61</sup> FCTC/COP/6/8, paragraphs 31 and 36.

<sup>&</sup>lt;sup>62</sup> Such as the Rio Declaration and United Nations Environment Programme guidelines, and the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters. See also Pring G, Pring C. Environmental courts and tribunals: a guide for policymakers. Nairobi: United Nations Environment Programme; 2016 (accessed 28 May 2025).

68. Administrative procedures generally lack the fair trial guarantees that apply to criminal proceedings, and are therefore rarely used to establish criminal liability. However, administrative agencies are sometimes given the power to make liability determinations for breaches of regulatory laws that can be characterized as "quasi-criminal". Such determinations can also be binding in any "follow-on" civil proceedings, where claimants seek compensation for losses caused by such breaches. Administrative procedures are frequently utilized to establish civil liability. This includes declaratory relief, injunctive relief, the imposition of non-criminal penalties such as fines and the removal of licences, and the awarding of compensation.

- 69. While most, but not all, administrative processes make allowance for some form of appeal to the court, those appeal rights are limited and, critically, the burden rests on the person challenging the administrative decision. Thus, for example, where the tobacco industry is found to have breached advertising laws by a regulator, the tobacco industry would then bear the burden of establishing that the decision was wrong in any appeal.
- 70. One significant advantage of these administrative processes, particularly for low- and middle-income countries, is that they are usually cheaper to fund and maintain than formal court systems.
- 71. While the Expert Group did not have the resources to conduct a systematic review of all cases in which administrative procedures have been used to determine liability for harms caused by tobacco, a number of examples were noted by the Expert Group, including administrative rulings related to advertising, packaging and environmental harms of tobacco and nicotine products.
- 72. The first example related to **misleading advertising in Colombia**. In response to a complaint brought by a child rights NGO in 2021, the Superintendency of Industry and Commerce in Colombia investigated and fined BAT's local subsidiary for failing to disclose product health risks related to nicotine and formaldehyde, and to clearly communicate nicotine concentration information in the marketing of its electronic cigarette brand Vuse, among other consumer protection violations. The Superintendency also ordered BAT to inform consumers of the harmful effects of its electronic cigarette brand in the company's advertising and product packaging. BAT appealed the decision to a higher administrative authority within the Superintendency. The agency upheld the decision and fine against the company in 2024, although it reduced the fine from approximately US\$ 290 000 to US\$ 260 000.<sup>63</sup>
- 73. The second example concerned **environmental levies in India**. The Central Pollution Control Board in India took administrative action against tobacco companies for using prohibited plastics to package their tobacco products, in violation of rules under an environmental protection law.<sup>64</sup> The Board issued show cause notices, and levied environmental compensation at approximately US\$ 60 per tonne of plastic used in packaging of tobacco products since the inception of the regulations in 2016. While companies contested the levies, a retesting of samples confirmed use

<sup>&</sup>lt;sup>63</sup> Superintendency of Industry and Commerce v. British American Tobacco Colombia, Resolution Number 51415 of 2024, File N° 21-75875. Bogotá: Directorate of Consumer Protection Investigations of the Superintendency of Industry and Commerce; 2024 (accessed 28 May 2025).

<sup>&</sup>lt;sup>64</sup> <u>Plastic Waste Management Rules, 2016, as amended, 2021 under the Environment Protection Act, 1986</u>. New Delhi: Ministry of Environment, Forest and Climate Change; 2021 (accessed 28 May 2025) – prohibits use of plastic for storing, packaging and selling of tobacco products.

of plastics, and the companies had to pay the levies determined by the Board plus interest for the delay and time period that they continued operations after the notice was issued.<sup>65</sup>

74. The third example involved **misleading advertising in Ukraine**. Based on a consumer complaint, <sup>66</sup> the Antimonopoly Committee of Ukraine initiated administrative proceedings against Philip Morris' local affiliate company for making advertising claims that its heated tobacco product system "emits 95% less harmful chemicals compared to cigarettes" and that "switching completely to IQOS" is "less risky to your health" than continuing to smoke conventional cigarettes. Following a three-year investigation, in 2024, the Antimonopoly Committee ordered Philip Morris to cease using these claims in its advertising, finding that the statements and variations of the statements were inaccurate and misleading, and in violation of Ukraine's consumer protection law. <sup>67</sup>

#### Work being done in relevant international fora

75. Work being done in international fora related to human rights, corporate accountability and the environment is increasingly applied to the tobacco industry and reflected in decisions adopted by the COP.

### Developments in human rights and tobacco control liability and/or litigation efforts

- 76. Over the past 10 years, the COP has adopted several decisions recognizing the connection between tobacco control and human rights, as highlighted in the Convention Secretariat report FCTC/COP10/15. Most recently, the COP reinforced these commitments by adopting decision FCTC/COP10(20), calling on Parties to integrate WHO FCTC principles into their engagement with United Nations human rights mechanisms, and requesting the Convention Secretariat to strengthen coordination with United Nations entities working on human rights.
- 77. Several international human rights bodies have long acknowledged the role of tobacco control in safeguarding fundamental rights particularly the right of everyone to the enjoyment of the highest attainable standard of physical and mental health<sup>68</sup> including those recognized in FCTC/COP/10/15. The Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health has recognized tobacco control as a critical human rights issue, and has urged States to implement WHO FCTC measures and hold the tobacco

<sup>&</sup>lt;sup>65</sup> <u>Direction issued under Section 5 EP Act</u>. New Delhi: Central Pollution Control Board; 2016 (accessed 28 May 2025).

<sup>&</sup>lt;sup>66</sup> Smoking is never safe. The AMCU has recognized reports about less harmful IQOS as misleading. Ukrinform; 7 February 2025 (accessed 28 May 2025).

<sup>&</sup>lt;sup>67</sup> <u>Antimonopoly Committee of Ukraine Recommendations regarding Philip Morris Sales and Distribution LLC, Recommendation 9-CR</u>. Kyiv: Antimonopoly Committee of Ukraine; 2024 (accessed 28 May 2025).

<sup>&</sup>lt;sup>68</sup> Committee on Economic, Social and Cultural Rights. <u>General Comment No. 14 (2000): The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)</u> (noting that governments must "actively discourage the use of tobacco" as part of their obligation to protect the right to health); Committee on the Rights of the Child. <u>General Comment No. 4. (2003)</u> (recommending that states restrict tobacco advertising and access, ensure public awareness, and promote tobacco prevention education to safeguard children's right to health); and Committee on the Rights of the Child. <u>General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24)</u> (recognizing the harms of tobacco to children, that states should protect children from tobacco harms and implement the WHO FCTC) (accessed 28 May 2025).

industry accountable for human rights violations.<sup>69</sup> Further, the Special Rapporteur has issued reports reinforcing the State obligation to adopt strong tobacco control policies in line with human rights commitments, and that States must take proactive measures to regulate and restrict tobacco industry influence in policy-making. These comments have related specifically to corporate accountability in health protection,<sup>70</sup> tobacco industry interference and misinformation,<sup>71</sup> and business' responsibility in human rights protection.<sup>72</sup> The Committee on the Elimination of Discrimination Against Women has also acknowledged the threat of tobacco use among women and girls.<sup>73</sup>

78. In addition to dedicated human rights tribunals, many States are currently under the jurisdiction of a regional human rights court, but the level of access and enforcement varies significantly. Human rights courts can hear cases related to harms caused by tobacco,<sup>74</sup> yet there has been no dedicated effort to explore or optimize the use of these fora for accountability.

<sup>&</sup>lt;sup>69</sup> Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover. New York: United Nations; 2014 (A/HRC/26/31); Right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Note by the Secretary-General. New York: United Nations; 2024 (A/79/177) (accessed 30 May 2025).

The Special Rapporteur urges States to: ... (e) When elements of a health sector are decentralized or handed over to the private sector, to ensure that there are sufficient checks and balances to ensure that this transition addresses corruption and, at the least, does not lead to more corruption. There must be adequate oversight, transparency and monitoring of private sector and decentralized provision")

<sup>&</sup>lt;sup>71</sup> Right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Note by the Secretary-General. New York: United Nations; 2017 (A/72/137), paragraph 39 (accessed 30 May 2025). ("The harmful effects of the tobacco industry ... [have] been covered up by manufacturers and industry lobbyists, including through sponsoring research to downplay links to health problems. Misinformation, pressure and bribery from ... [the tobacco industry] can interfere with the obligation of governments to ... protect public health.")

<sup>&</sup>lt;sup>72</sup> Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover. New York: United Nations; 2014 (A/HRC/26/31, paragraph 28 (accessed 30 May 2025). ("Although international human rights instruments refer to States as primary duty-bearers, non-State actors are also charged with the responsibility to respect the right to health. The International Covenant on Economic, Social and Cultural Rights prohibits the violation of human rights enshrined therein not only by States, but also by any "group or person", clearly implicating the responsibility of non-State actors in the realization of human rights (article 5).")

<sup>&</sup>lt;sup>73</sup> Concluding observations on the eighth periodic report of Luxembourg. New York: Convention on the Elimination of All Forms of Discrimination against Women; 2025 (CEDAW/C/LUX/CO/8), paragraphs 42(b) and 43(c) (accessed 30 May 2025).

<sup>&</sup>lt;sup>74</sup> See, for example, in the case of <u>Novoselov v. Russia</u> (Application no. 66460/01), the European Court of Human Rights finding that the government's admissions that a prisoner's cell windows were covered with metal shutters blocking access of fresh air, which led to a degradation of the health of the applicant, thereby violating Article 3 of the European Convention on Human Rights; and in the case of <u>Ostrovar v. Moldova</u> (Application no. 35207/03), the European Court of Human Rights finding that "... the Court considers that the Government did not fulfil their obligation to safeguard the applicant's health and instead allowed him to be exposed to cigarette smoke, which was dangerous in view of his medical condition..."; and in the case of <u>Elefteriades v. Romania</u> (Application no. 38427/05), the European Court of Human Rights finding that "The fact that the prison in question had been overcrowded at the relevant time in no way dispensed the authorities from their obligation to safeguard the applicant's health [...] circumstances, however positive, had not been sufficient to offset the harmful effects of the second-hand smoke to which he had been subjected" (accessed 30 May 2025).

79. Globally, courts have recognized that tobacco control measures are aimed at protecting human rights;<sup>75</sup> such arguments can be used by Parties in their enforcement of tobacco control measures, and by civil society acting to protect strong regulatory measures. For example, in Uruguay an NGO successfully challenged an executive decree that modified the plain packaging requirements in the country. In reaching its ruling, the court relied heavily on international human rights – particularly children's rights and the guiding principle of the best interest of the child as one of the four principles articulated in the Convention on the Rights of the Child. The court enjoined the implementation of the decree, and found in part that "the State has the obligation to especially protect children and adolescents from all forms of encouragement to tobacco consumption" (unofficial translation).<sup>76</sup>

80. The class action brought against the BAT and Imperial Brands Groups by Malawian tobacco farmers described in paragraph 44 expressly relies on human rights protections under the European Convention of Huma Rights and the Convention on the Rights of the Child.

### **Developments in business and human rights**

- 81. The United Nations Guiding Principles on Business and Human Rights also serve as a fundamental framework for corporate accountability in human rights violations.<sup>77</sup> They establish three key pillars: the State duty to protect human rights, the corporate responsibility to respect human rights and the right to access to remedy for those harmed. While these principles do not create direct legal obligations, they can significantly influence regulatory frameworks, national policies and corporate practices. In the context of tobacco control, the Guiding Principles reinforce the obligation of States to regulate the tobacco industry to prevent harm particularly to vulnerable populations and to limit industry interference in policy-making. The Special Rapporteurship on Economic, Social, Cultural and Environment Rights of the Inter-American Commission on Human Rights has recognized the Guiding Principles as a minimum means of global governance in this area, also recognizing the harms of tobacco industry interference with policy-making, among other corporate behaviours.<sup>78</sup>
- 82. Complementary to and mutually reinforcing the Guiding Principles, in 2024 the Human Rights Council decided to establish an open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights with the mandate "to elaborate an international legally binding instrument to regulate, in international

<sup>&</sup>lt;sup>75</sup> See, for example, the cases of <u>Nueva Walmart de Mexico v. Mexico</u>; <u>Aunestraja v. State of Tamil Nadu</u>; <u>Planta Tabak-Manufaktur Dr. Manfred Obermann GmbH & Co. KG v. Land Berlin</u>; <u>Grisciuc, Simion v. Republic of Moldova</u>; <u>Philip Morris GmbH v. Land of Bavaria</u>; and Quebec Superior Court Justice Brian Riordan's judgment in <u>Létourneau & Blais v. JTM, ITL & RBH</u>, paragraphs 479–88 (finding that, because they had intentionally failed to warn consumers about the safety defects in their products, tobacco companies had infringed the protected human rights of Quebecers to life and personal security) (all accessed 30 May 2025).

<sup>&</sup>lt;sup>76</sup> <u>Sociedad Uruguaya de Tabacología v. Executive Branch of the Uruguayan State</u>, AMPARO, IUE 2-54452/2022 (accessed 30 May 2025).

<sup>&</sup>lt;sup>77</sup> <u>Guiding principles on business and human rights</u>. Geneva: Office of the High Commissioner for Human Rights; 2011 (accessed 30 May 2025).

<sup>&</sup>lt;sup>78</sup> <u>Business and Human Rights: Inter-American Standards</u>. Washington, DC: Inter-American Commission on Human Rights; 2020 (OEA/Ser.L/V/II CIDH/REDESCA/INF.1/19) (accessed 30 May 2025).

human rights law, the activities of transnational corporations and other business enterprises". The draft instrument contains a provision on liability.<sup>79</sup>

### Developments on the intersection between environment and tobacco industry liability

- 83. In furthering its commitments under Article 18, the COP recently adopted decision FCTC/COP10(14) inviting Parties to hold the tobacco industry accountable under Article 19 for the damage it causes to the environment and the adverse health effects on workers involved in the cultivation and manufacture of tobacco products, and for the disposal and treatment of waste resulting from their manufacture and consumption. In its decision, the COP also requested the Convention Secretariat to examine regulatory options regarding the prevention and management of waste generated by the tobacco industry and its products, including a ban on plastic cigarette filters and management of hazardous waste from cigarettes, based on scientific evidence. This report will be submitted to the Eleventh session of the COP.
- 84. Under the Human Rights Council special procedures, the Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes indicates several instances of tobacco-related human rights violations in the context of environment and occupational exposure (in respect of specific companies). Further, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health has recommended that States act to prevent health or environmental harms stemming from the use of tobacco products, among others. In the special Rapporteur on the Rapporteur on the special Rapporteur on the Rapporteur on the enjoyment of the highest attainable standard of physical and mental health has recommended that States act to prevent health or environmental harms stemming from the use of tobacco products, among others.
- 85. The United Nations Environment Programme Intergovernmental Negotiating Committee is developing an international legally binding instrument on plastic pollution, including in the marine environment. The first part of the last negotiations, held in November 2024, did not produce a draft instrument for final negotiation, and it is unclear whether a list of plastics to be eliminated which could potentially include cigarette filters will be a part of any final legally binding instrument.<sup>82</sup>

### Options for technical support, international cooperation and the exchange of information for the effective implementation of Article 19

86. The previous Expert Group set out options and approaches for technical support, international cooperation and the exchange of information for effective implementation of Article 19 in its first report (FCTC/COP/6/8). Specifically, it noted the critical importance of international

<sup>&</sup>lt;sup>79</sup> Open-ended intergovernmental working group on transnational corporations and other business enterprises with respect to human rights and <u>Updated draft legally binding instrument to regulate, in international human rights law, the activities of transnational corporations and other business enterprises</u>. Geneva: Office of the High Commissioner for Human Rights; 2025 (both accessed 30 May 2025).

<sup>&</sup>lt;sup>80</sup> Report of the Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes. New York: United Nations; 2018 (A/HRC/39/48) (accessed 30 May 2025).

<sup>&</sup>lt;sup>81</sup> Right of everyone to the enjoyment of the highest attainable standard of physical and mental health: Note by the Secretary-General. New York: United Nations; 2024 (A/79/177), paragraph X(c) (accessed 30 May 2025).

<sup>&</sup>lt;sup>82</sup> Draft report of the intergovernmental negotiating committee to develop an international legally binding instrument on plastic pollution, including in the marine environment, on the work of the first part of its fifth session. Nairobi: United Nations Environment Programme; 2025 (UNEP/PP/INC.5/8) (accessed 30 May 2025).

cooperation and exchange of information to Article 19 implementation, given the trans-boundary nature of multinational tobacco companies and liability options for consideration in tobacco-consuming countries that may not have a domestic tobacco manufacturing industry.<sup>83</sup>

- 87. In relation to offering guidance to Parties for Article 19 implementation, the previous Expert Group noted the possible approaches through which the COP could support Parties discussed in the Convention Secretariat's report FCTC/COP/5/11. It also recognized that, owing to differing legal systems, providing general legal and procedural principles on guidance as opposed to model laws would be more adaptable for implementation by Parties.<sup>84</sup> In addition to the development of the WHO FCTC Article 19 Civil Liability Toolkit and Article 19 Expert Database (discussed in paragraph 12), the previous Expert Group also noted that joint litigation agreements, and communication plans and strategies to highlight tobacco liability litigation, were additional means of exchanging information.<sup>85</sup>
- 88. The previous Expert Group also recognized that it may be appropriate for the Convention Secretariat, on behalf of the COP, to provide assistance in relation to legal disputes as a means to uphold the WHO FCTC and its principles. It further noted that WHO may be able to offer additional support to Parties in this context.<sup>86</sup> Accordingly, between the Sixth and Seventh sessions of the COP, the Convention Secretariat supported Uruguay during the course of a multiyear international lawsuit brought by Philip Morris against Uruguay, challenging two of Uruguay's tobacco control laws. A joint amicus curiae brief by the WHO and the Convention Secretariat was filed in January 2015 to provide evidence in support of Uruguay's tobacco control measures and information about the WHO FCTC.<sup>87</sup> The Pan American Health Organization also filed a separate amicus curiae brief, which focused on tobacco control efforts and information in the Regions of the Americas. The tribunal dismissed all claims brought by Philip Morris,<sup>88</sup> and referenced these important amicus briefs throughout its decision.

Approaches to technical support, exchange of information and international cooperation identified in the survey on implementation of Article 19

#### **Technical support**

89. Survey respondents suggested several additional approaches to technical support, particularly from the Convention Secretariat. These included raising Parties' awareness of existing resources concerning Article 19, potentially through a dedicated online platform; continuing monitoring and collecting experiences of litigation cases to share with Parties on an ongoing basis; providing support in the implementation of Article 19, particularly for low- and middle-income countries; providing support on establishing how or whether extraterritorial claims can be satisfied; building Parties' capacity to implement and update legislation, including financial resources; strengthening the capacity of the judiciary and its awareness of Articles 5.3 and 19; and

<sup>83</sup> FCTC/COP/6/8, paragraph 26.

<sup>84</sup> FCTC/COP/6/8, paragraph 28.

<sup>&</sup>lt;sup>85</sup> FCTC/COP/6/8, paragraphs 34–35.

<sup>&</sup>lt;sup>86</sup> FCTC/COP/6/8, paragraph 36.

<sup>&</sup>lt;sup>87</sup> Amicus Curiae Brief by the World Health Organization and WHO Framework Convention on Tobacco Control Secretariat (ICSID Case No. ARB/10/7) (accessed 30 May 2025).

<sup>&</sup>lt;sup>88</sup> <u>Award</u> (ICSID Case No. ARB/10/7); and <u>Decision on rectification</u> (ICSID Case No. ARB/10/7) (accessed 30 May 2025).

maintaining a confidential forum where Parties can reach experts directly, including lawyers engaged in relevant litigation. Some of these suggested forms of support are covered by existing activities and resources provided by the Convention Secretariat, as described below.

90. The Expert Group also used the survey to gather insights into Article 19 resources, including those identified by the Convention Secretariat in its report FCTC/COP/10/12, which could assist Parties in implementing Article 19. Survey respondents indicated that it would be helpful to have information on how each specific resource could be used to implement Article 19. Accordingly, the Expert Group has developed a non-exhaustive list of existing annotated Article 19 resources (contained in Annex 1 to the present report).

#### Exchange of information and international cooperation

91. Survey respondents indicated a need for increased cooperation among Parties by strengthening regular reporting on Article 19 implementation and experience sharing, perhaps through reporting on the progress and status of Article 19 implementation. One Party also indicated that encouraging more dialogue among Parties, international organizations and civil society regarding environmental liability of the tobacco industry would be helpful in furthering Article 19 implementation.

### Additional approaches for the exchange of information and international cooperation

### Mutual legal assistance mechanisms and long-arm statutes to facilitate cross-border jurisdictional reach

- 92. Article 19.2 obligates Parties to cooperate with each other in exchanging information, including information on legislation and regulations in force, as well as pertinent jurisprudence. Article 19.3 requires that Parties provide one another with assistance in legal proceedings relating to civil and criminal liability, as appropriate and mutually agreed. The Expert Group reviewed several possible mechanisms for Parties engaged in or anticipating tobacco-related civil liability litigation and/or criminal investigations to consider what could provide cross-border assistance such as ordering documents to be produced, ordering witnesses to be questioned and, in some situations regarding criminal liability, extradition of persons to face criminal prosecutions.
- 93. The Expert Group also noted the importance of Parties' ability to access foreign courts to sue parent tobacco companies in their place of domicile, or to sue the parent company in the jurisdiction where the harm occurred, and their ability to enforce judgments across borders including against parent tobacco companies. The Expert Group further recognized the importance of Parties facilitating these extraterritorial aspects of litigation as part of fulfilling their obligations under Article 19.

94. Regarding criminal liability, bilateral treaties such as mutual legal assistance treaties can assist in extraterritorial criminal prosecutions. <sup>89</sup> These legal mechanisms can serve as powerful tools for Parties where tobacco companies hold relevant information outside a Party's jurisdiction, and would otherwise be out of reach in domestic civil and/or criminal proceedings. Additionally, national laws allowing for long-arm jurisdiction and foreign direct liability could create pathways for holding transnational corporations accountable for corrupt practice violations, such as the United Kingdom's Bribery Act (discussed in paragraph 40) or the Foreign Corrupt Practices Act in the United States.

95. In respect of civil matters, the Convention on the taking of evidence abroad in civil or commercial matters (Hague Evidence Convention)<sup>90</sup> and existing domestic legislation were noted as instruments that may allow Parties engaged in litigation to request support in obtaining evidence located in other jurisdictions. For example, a law in the United States (State non-Party) permits a foreign tribunal or an interested person in non-United States-based litigation to obtain discovery from inside the United States for use in the proceeding outside the United States.<sup>91</sup>

### Tobacco industry reporting and disclosures and Parties' exchange of such information

- 96. Establishing tobacco industry reporting and disclosure requirements in legislation is critical to enabling effective enforcement of certain provisions of tobacco control legislation. However, many jurisdictions lack comprehensive provisions specifying the range of information that tobacco industry-related individuals or entities should disclose, and the specific agencies authorized to collect and use the information. Failure to require transparency and disclosures from the tobacco industry could also lead to a lack of accurate information regarding the extent of harm caused by the tobacco industry, which significantly impairs the ability to legally recover such costs from the tobacco industry.
- 97. Several WHO FCTC guidelines for implementation include required tobacco industry disclosures and recommendations for public access to certain information which are particularly important for Parties' exchange of information and international cooperation related to liability including Guidelines for implementation of Articles 5.3, 6, 9, 10 (in part) and 13. Such disclosures include a requirement for tobacco industry submissions to the appropriate authority of certain information on registration of business entities, tobacco production, manufacture, market share, marketing expenditures, revenues, and activities such as lobbying, corporate social responsibility efforts (if any) and political contributions. The Expert Group noted that enacting measures to include required disclosures of tobacco industry-related financial flows, sanctions against a company, and corporate structures and investments would further assist Parties to detect and

<sup>89</sup> The Expert Group noted a 2001 case where Canada successfully sought subpoenas to acquire testimony from two United States residents in a tobacco smuggling investigation pursuant to the Mutual Legal Assistance Treaty between the United States and Canada: In re: Request from Canada pursuant to the treaty between the United States of America and Canada on Mutual Legal Assistance in Criminal Matters, 155 F. Supp. 2d 515, (2001) (accessed 30 May 2025), where in response to Canada's subpoena requests, United States residents brought a motion to quash the subpoenas arguing that the requested discovery would not be permitted under Canadian discovery laws. The appointed Commissioner (on behalf of the United States, and, by virtue, Canada) argued that underlying Canadian discovery laws were irrelevant. The United States District Court, M.D. North Carolina denied the motion to quash, noting that the bilateral treaty was meant to support mutual legal assistance, while a Canadian court could determine the admissibility of the acquired information at a later stage, in the context of future Canadian proceedings.

<sup>&</sup>lt;sup>90</sup> Convention on the taking of evidence abroad in civil or commercial matters. New York: United Nations; 1970 (accessed 30 May 2025).

<sup>&</sup>lt;sup>91</sup> 28 U.S. Code § 1782 – Assistance to foreign and international tribunals and to litigants before such tribunals (accessed 30 May 2025).

counter tobacco industry efforts to evade applicable liability regimes or to undermine tobacco control. Officers or directors could also be required to submit the reporting and, under a penalty of perjury, to verify and attest to the accuracy of the information reported.

98. Despite clear guidance on the various types of disclosures, including the guidelines for implementation, legislation mandating tobacco industry disclosures to government authorities remains limited. The Expert Group also noted that only a handful of Parties have implemented lobbyist registration legislation, and even fewer require political contribution reporting. Example legislation requiring tobacco industry disclosures from Chile, France and Thailand was considered by the Expert Group.

# Development of options for Parties to detect and counter tobacco industry efforts to evade applicable liability regimes or to undermine tobacco control

99. The Expert Group acknowledges that there is a considerable degree of overlap between tobacco industry efforts to evade liability and the obstacles to establishing liability that were reviewed by the previous Expert Group report (FCTC/COP/6/8). Unsurprisingly, tobacco litigation tactics to delay and protract litigation, bringing jurisdictional, constitutional and procedural challenges and appeals, all have the effect of making litigation take longer, draining the resources of governments or regulators or private parties bringing claims or prosecutions against the industry, and increasing the likelihood that the litigation is withdrawn or resolved on technical grounds without consideration of whether the industry is civilly or criminally liable for its conduct. Those tactics will not be rehearsed here. However, it is helpful to consider the obstacles to establishing criminal and civil liability as reported by survey respondents.

### Summary of survey responses on Article 19 implementation related to obstacles to establishing criminal and civil liability

100. Survey respondents identified several obstacles specific to establishing criminal liability involving the tobacco industry. Regarding tobacco control legislation, weaknesses in enforcement of relevant existing measures, the long process to enact new legislation, and the extraterritorial application of legislation were identified as challenges. Obstacles relating to criminal liability actions also included the lack of commitment on the part of public prosecutors to bring criminal actions, and that large backlogs and delays in resolving existing cases may be a major barrier to litigants obtaining decisions on the merits.

<sup>&</sup>lt;sup>92</sup> Resource Database on Tobacco Industry Interference (accessed 30 May 2025).

<sup>&</sup>lt;sup>93</sup> <u>Handbook on the implementation of WHO FCTC Article 5.3: policies and practices that protect against tobacco industry interference</u>. Bangkok: Global Center for Good Governance in Tobacco Control; 2021 (accessed 30 May 2025).

<sup>&</sup>lt;sup>94</sup> Ley núm. 20.730 Regula el Lobby y las Gestiones que Representen Intereses Particulares Ante las Autoridades y Funcionarios [Law No. 20730 Regulates Lobbying and Actions Representing Private Interests Before Authorities and Officials of March 2014] (accessed 30 May 2025).

<sup>&</sup>lt;sup>95</sup> France Ordinance No. 2016-623 of 19 May 2016 transposing Directive 2014/40 / EU on manufacturing, presentation and sale of tobacco products and related products 2016 (unofficial translation) (accessed 30 May 2025).

<sup>&</sup>lt;sup>96</sup> The Tobacco Products Control Act of A.D. 2017 of 5 April 2017 (accessed 30 May 2025).

101. Survey responses indicated a range of reasons for limited implementation of Article 19 in relation to civil liability and lack of successful, or any, civil litigation against the industry. Reasons proffered included:

- (a) lack of awareness about Article 19 and the tools for implementing it;
- (b) that implementation is resource intensive and requires multi-agency cooperation, and that this is not a priority particularly for government health departments, which often take the lead on tobacco control measures;
- (c) difficulties accessing the courts in many countries, since it is hard to obtain funding/legal representation for litigation, which is very costly, requiring detailed factual and expert evidence and it is difficult to have cases dealt with quickly due to procedural requirements and court backlogs; and
- (d) the power and influence of the tobacco industry, which means that it can use the courts to slow down litigation, raise technicalities to avoid determinations of the merits, and even use litigation to thwart tobacco control policies; further, that the power and influence of the tobacco industry may also reduce public support for litigation in some countries and colour judicial attitudes towards the industry and smokers or ex-smokers seeking compensation.

### Tobacco industry efforts to evade liability or undermine tobacco control and approaches to counter those efforts

- 102. In accordance with its mandate, the Expert Group also considered tobacco industry tactics outside litigation aimed at evading liability. These include use of other legal processes designed to restrict the amount of compensation any company must pay, even if it is found liable, through corporate restructuring and debt restructuring, including through use of insolvency procedures. They also include lobbying and litigation efforts designed to prevent future or undermine existing tobacco control measures and, more fundamentally, corrupt business practices intended to reduce the risk of courts holding them liable and/or regulators taking action against them.
- 103. One of the ironies of these liability-evading tactics is that litigation against the tobacco industry (of the kind Article 19 is designed to promote) has historically been an effective mechanism for exposing these fraudulent practices. The landmark judgment and findings of the U.S. District Court of Columbia in United States v Philip Morris et al.<sup>97</sup> based on extensive discovery of internal documents from the tobacco industry and important whistleblower testimony from individuals within the tobacco industry outline excoriating details of the decades-long fraud by the tobacco industry to undermine the scientific consensus about the adverse health consequences of tobacco use; to conceal and confuse the public about the health risks; to dissuade governments from introducing stronger tobacco control measures; and, perhaps most remarkably of all, to aggressively market a highly deadly and addictive product as a glamorous lifestyle choice to adolescents and young people. Similarly, findings by the Quebec Superior Court regarding the conduct of the tobacco companies, which were upheld on appeal, exposed the deceit of the Canadian tobacco defendants. As stated by the Court:

By choosing not to inform either the public health authorities or the public directly of what they knew, the Companies chose profits over the health of their customers. Whatever else can be said about that

<sup>97</sup> United States v. Philip Morris USA Inc. (9F. Supp. 2d 1, 2006 U.S. Dist. LEXIS 57759) (accessed 30 May 2025).

choice, it is clear that it represent[s] a fault of the most egregious nature and one that must be considered in the context of punitive damages. 98

104. The Expert Group considers that greater transparency and other actions are urgently needed to protect government tobacco control policy from tobacco industry interference, in accordance with Article 5.3 and its Guidelines for implementation. Ways to achieve this are set out in the recommendations section in paragraph 155.

105. It is not possible in this report to discuss all the different ways in which the tobacco industry seeks to undermine tobacco control efforts. Such efforts include direct and indirect lobbying through front groups and allies, including through diplomatic channels; threatening legal actions against governments to thwart prospective tobacco control measures, such as the Uruguay case discussed in paragraph 88; intimidating tobacco control advocates; attempting to influence judges; engaging in corporate social responsibility initiatives, including environmental, social and governance initiatives; and investing in tobacco and nicotine products and businesses outside of its cigarette business, including pharmaceutical or wellness companies, to garner political support and to create the false public perception that it is no longer in the cigarette business but now part of the solution to the global epidemic it caused. These tactics have been well documented in the cases cited above, by WHO, <sup>99</sup> and by peer-reviewed publications <sup>100</sup> and platforms monitoring tobacco industry activities. <sup>101</sup>

106. A broad definition of tactics to evade liability could include anything designed to prevent legal action being taken against the tobacco industry and, if it is taken, to prevent such actions from succeeding, or reduce its liability if an action is successful. This report cannot address all such tactics. Instead, it focuses on the commonly used legal and dictionary definition of evading – namely escaping in a way that is dishonest or otherwise improper – in examining tobacco industry tactics for evading liability.

#### **Evidence destruction to avoid liability**

107. It is well known – largely as a result of liability actions – that for decades the tobacco industry has destroyed sensitive internal documents which showed their knowledge of the adverse health consequences of smoking and the addictive nature of nicotine, and their marketing strategies, including marketing tobacco products to young people. Such destruction was designed to avoid the disclosure of such evidence in future legal proceedings against the tobacco industry. The previous Expert Group report suggested that Parties could create criminal offences for destruction of documents and other evidence by the tobacco industry during, or in anticipation of,

<sup>&</sup>lt;sup>98</sup> Quebec Superior Court Justice Brian Riordan's judgment in <u>Létourneau & Blais v. JTM, ITL & RBH</u>, paragraph 239 (accessed 30 May 2025).

<sup>&</sup>lt;sup>99</sup> WHO, WHO Tobacco Free Initiative, Conference of the Parties to the WHO Framework Convention on Tobacco Control. <u>Tobacco industry interference with tobacco control</u>. Geneva: World Health Organization; 2008 (accessed 1 June 2025).

<sup>&</sup>lt;sup>100</sup> Alebshehy R, Silver K, Chamberlain P. <u>A "willingness to be orchestrated": why are UK diplomats working with tobacco companies?</u> Front Public Health. 2023;11:977713; Matthes BK, Alebshehy R, Gilmore AB. <u>"They try to suppress us, but we should be louder": a qualitative exploration of intimidation in tobacco control</u>. Global Health. 2023;19:88 (accessed 1 June 2025).

<sup>&</sup>lt;sup>101</sup> <u>Tobacco Tactics</u>. University of Bath; 2025; Hendlin YH, Le Han E, Ling PM. <u>Pharmaceuticalisation as the tobacco industry's endgame</u>. BMJ Glob Health. 2024;9:e013866; <u>WHO FCTC Knowledge Hub on Article 5.3</u>. WHO FCTC; 2025; Friedman LC. <u>Tobacco industry use of judicial seminars to influence rulings in products liability litigation</u>. Tob Control. 2006;15(2):120–4 (accessed 1 June 2025).

legal proceedings. <sup>102</sup> Such laws should also require the persons who engaged in evidence destruction to compensate anyone whose claims, or causes of action, are adversely affected by the destruction.

#### Putting assets beyond the reach of national courts

108. In the Canadian litigation described in paragraphs 49–59, each of the tobacco companies adopted corporate structures and financial practices which had the effect of putting cash and other financial assets beyond the reach of Canadian courts. Prior to the insolvency proceedings, all three major tobacco defendants had transferred Canadian earnings to affiliated companies in other countries during the decades-long litigation against them. <sup>103</sup> The Quebec Court of Appeal upheld the punitive damages awarded against Japan Tobacco for their financial transactions, which were described as a form of "creditor proofing". <sup>104</sup>

- 109. The parent entities of their wholly owned Canadian operations had been joined as defendants in the provincial health-care cost recovery claims, and the settlement of these claims involved undertakings by the parent companies. A key outcome of the lawsuits was the loss of revenue to the parent companies from their Canadian operations. No profits had been remitted during the six years of insolvency protection, and it is the diversion of their profits to governments that will be used to finance the compensation. However, the parent entities were not required to contribute additional funds to the Canadian settlement, confining the value of the settlement to the revenue generated from Canadian sales.
- 110. Brazil's health-care cost recovery action, outlined in paragraphs 46–48, targets both national subsidiaries and international parent companies of the BAT and Philip Morris corporate groups. Including the parent companies as defendants reflects the integrated nature of these corporate groups, where decision-making and profit allocation are centralized at the headquarters level. By holding both local and global entities accountable, the Brazilian action aims to address the coordinated actions that perpetuate harm across borders. By advancing the application of civil liability laws upon parent companies, Brazil seeks to address the global challenges posed by transnational corporations that profit from harmful products while externalizing health costs to societies.
- 111. The Expert Group considers that the measures on jurisdiction and enforcement of judgments identified in paragraph 93 in the section on mutual cooperation can be an effective method of preventing the tobacco industry from evading liability by adopting corporate structures that put assets beyond the reach of national courts.
- 112. Seeking compensation from parent companies is an entirely appropriate litigation strategy for low- and middle-income countries, and Parties should consider exercising extraterritorial

<sup>&</sup>lt;sup>102</sup> FCTC/COP/6/8, Annex 3, paragraphs 44–7.

<sup>&</sup>lt;sup>103</sup> Imperial Tobacco Canada Ltd. c. Conseil québécois sur le tabac et la santé. 2015 QCCA 1737, paragraph 52 (stating that "Continuing the practice of distributing earnings out-of-jurisdiction at this point is at best disingenuous and at worst, bad faith") (accessed 3 July 2025).

<sup>&</sup>lt;sup>104</sup> Imperial Tobacco Canada Itée c. Conseil québécois sur le tabac et la santé. 2019 QCCA 358, paragraphs 1156–1163 (accessed 3 July 2025).

jurisdiction where appropriate.<sup>105</sup> In addition, increased cooperation among Parties in implementing Article 19 could help tackle the tobacco industry's strategy of asset shifting, including by ensuring the coordination of Article 19 litigation so that there are no safe havens for the tobacco industry to hide its assets.

### Using insolvency procedures to reduce the amount of compensation the tobacco industry pays

- 113. Invoking insolvency procedures could be described as both an acceptance of liability and an attempt to limit it. The process of invoking insolvency procedures involves a petitioner acknowledging that they are already liable to pay debts including through liability actions which they are unable to pay. It is an acceptance by the debtor petitioner that they must meet some of their liabilities or go into bankruptcy and relinquish at least some control of the company and/or its finances for the duration of the insolvency process. This is what happened during the Canadian litigation. Revenues built up by the tobacco companies during the Companies Creditors' Arrangement Act process were frozen for the duration until the settlement plans for compensating the creditor claimants in the tobacco litigation were approved.
- 114. On the other hand, invoking insolvency processes allows tobacco companies to take advantage of laws that are intended to allow companies to negotiate their way back to profitability by reducing their liability to their creditors. The fact that the survival of the company is one of the objectives of the insolvency laws was confirmed by the Ontario Superior Court when it approved the Canadian settlement. The Court concluded that the plans: "(a) Provide meaningful recovery to Affected Creditors, including the individual Claimants, as well as the Provinces and Territories; (b) Require the creation and funding of the Cy-prés Foundation, a US\$ 1 billion public charitable foundation designed to provide indirect benefits to a diverse group of [Claimant victims] and the general public; and (c) Allow the Tobacco Companies to continue as going concerns, which will benefit their employees, suppliers and other stakeholders". 106
- 115. Ensuring that tobacco companies are able to continue trading as a going concern is not one of the objectives of Article 19, or any part of the WHO FCTC. There are two main ways of preventing the industry utilizing insolvency processes designed to allow companies to trade back to profitability, and which would give weight to the interests of tobacco companies as going concerns. First, those involved in the manufacture, marketing or supply of tobacco products could be prohibited from using insolvency procedures altogether. Alternatively, where tobacco companies are permitted to use these insolvency procedures, the court could be given express powers to ensure that any schemes of arrangement are compatible with public health objectives specifically the prevention or reduction in tobacco consumption, nicotine addiction and exposure to tobacco smoke and could be given the power to provide non-monetary remedies that are consistent with these objectives. While the Expert Group recognizes that this would amount to exceptional treatment for tobacco, the exceptional nature of tobacco products warrants different treatment in insolvency processes. For the avoidance of doubt, these recommendations would not

<sup>&</sup>lt;sup>105</sup> The Expert Group also notes that the inclusion of BAT parent companies as defendants in the state health-care cost recovery in the State of Minnesota, United States, and later in the United States federal racketeering litigation resulted in public access, for the first time, to information about the company's global operations and their efforts to deceive consumers and the public, and to aggressively undermine tobacco control efforts in low- and middle-income countries.

<sup>&</sup>lt;sup>106</sup> Court File No. CV-19-615862-00cl; CV-19-616077-00cl; CV-19-616779-00cl. Imperial Tobacco Canada Limited, 2025 Onsc 1358. Toronto: Superior Court of Justice – Ontario; 2025, paragraph 194 (accessed 1 June 2025).

extend to bankruptcy proceedings designed to manage the distribution of the company's assets to its creditors as part of its liquidation and winding up.

- 116. Article 19 recognizes the value of both litigation that is designed to reduce tobacco consumption and exposure to tobacco smoke, and litigation intended to provide compensation to the victims of such consumption and exposure. In the recent Canadian settlement, for example, continued trading by the companies is part of the settlement plan so that the defendants are able to pay Can\$ 32.5 billion over an estimated 20-year period, or even longer if tobacco prevalence and consumption rates and therefore revenue decline faster than projected. Because there is no set end-point for payment of the compensation due, the settlement does not mandate a particular level of tobacco sales by the tobacco industry into the future, but the fact remains that the settlement is partly funded by future sales, which will cause further harm to people using tobacco products and people exposed to the smoke from such products, while health-care providers will continue to be burdened. The Canadian Court acknowledged that the alternative to the mediated settlement would be the liquidation or bankruptcy of the companies. The result is that many more of the tobacco industry's victims would go without any compensation. By approving the settlement plan, the creditors of the tobacco companies accepted the continued operations of the companies.
- 117. Compensation payments sourced from tobacco sales may affect efforts to reduce tobacco consumption and exposure to tobacco smoke. However, it is possible to obtain from the industry meaningful compensation for some victims of the harm caused by tobacco, and to use litigation for or ensure that litigation does not prevent further reductions in tobacco consumption and exposure to tobacco smoke.
- 118. One way of ensuring that the tobacco industry has sufficient assets to meet its liabilities without having to continue selling tobacco products and causing further harm could be through the use of freezing orders. <sup>107</sup> These are orders that can be made at any time before or during litigation, including after judgment, to prevent defendants from disposing of assets which would have the effect of making it harder for the claimant to enforce any judgment in its favour. These orders operate in different ways in countries with different legal traditions, but they share the common underlying objective of protecting the integrity of the court's processes and a claimant's ability to enforce their right to compensation against the defendant. Given that there is now a documented history of the tobacco industry routinely transferring assets outside the jurisdiction even while litigation is being brought against it, with the result that it could not meet its liabilities as determined by a court (as the Canada experience demonstrates), there is a sound case for making the use of freezing orders standard in all litigation related to the harm caused by tobacco.

### Additional solutions to counter efforts to undermine tobacco control and evade liability

119. One further measure that Parties could introduce to tackle corrupt business practices by tobacco companies undermining tobacco control and evading liability is the introduction of robust bribery laws which have extraterritorial application. Bribery laws in the United Kingdom could serve as a model. They make it in an offence to bribe a foreign public official, and in so doing apply the law of the country where the company is registered, not the laws of the country where the company is engaging in corrupt practices (where the legal systems are often weak). Accordingly,

<sup>&</sup>lt;sup>107</sup> Sometimes known as asset preservation orders or, in common law countries, Mareva Injunctions after the English case which recognized them: Mareva v International Bulk Carriers SA [1980] 1 All ER 213 (accessed 1 June 2025).

this is one practical measure that high-income countries in particular, where tobacco companies often have their headquarters, can introduce to assist low- and middle-income countries combat corruption generally, corruption by the tobacco industry in particular. The section on criminal liability practice considers cases investigated under the United Kingdom's Bribery Act (discussed in paragraph 40).

# Exploring the possible development of a methodology that estimates or quantifies the health-care costs borne due to tobacco use

120. The causal relationship between tobacco use and death and disease is not scientifically in doubt, <sup>108</sup> and is one of the cornerstones of the WHO FCTC. <sup>109</sup> Establishing legal causation, however, has long been a significant obstacle to holding the tobacco industry civilly or criminally liable for the harm it causes. <sup>110</sup> During the negotiations of the WHO FCTC, the Intergovernmental Negotiating Body addressed the inherent challenges regarding liability and compensation, including critical aspects regarding evidence, causation and epidemiological challenges in tobacco liability cases. <sup>111</sup> The discussions emphasized that proving causation in tobacco-related diseases presents considerable complexities, particularly due to the multiple factors that may contribute to these illnesses, <sup>112</sup> arguing for "the possibility of using statistical evidence as to damage caused by smoking". <sup>113</sup>

121. The previous Expert Group reasoned that compensation to governments and other health-care providers or funders should be determined using statistical, epidemiological or other scientific evidence without the necessity of establishing causation for each individual health-care recipient. The Group noted challenges common to several jurisdictions regarding proof of causation in civil liability actions, including a reluctance among judicial bodies to admit and/or allow parties to rely on evidence of the population level [...] to establish causation", and recommended adopting enabling legislation for Parties to bring health-care cost recovery litigation, with provisions to allow causation and damage to be established using statistical and sociological evidence without reference to individual patients. Moreover, the Group advised adopting "rules of evidence and preclusion that allow claimants to rely on findings made, or evidence given, in previous tobacco cases including in other jurisdictions". 117

122. Building on these findings and focusing on the mandate of this Expert Group, the present report provides an evaluation of the methodologies used to quantify health-care costs borne due

<sup>&</sup>lt;sup>108</sup> The health consequences of smoking: 50 years of progress. A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention; 2014 (accessed 1 June 2025).

<sup>&</sup>lt;sup>109</sup> WHO FCTC, Preamble, Article 8.

<sup>&</sup>lt;sup>110</sup> Max W, Tsoukalas T. <u>Economics on trial: the use and abuse of economic methods in third party tobacco litigation</u>. Tob Control. 2006; 15(Suppl 4):iv77–83 (accessed 1 June 2025).

<sup>&</sup>lt;sup>111</sup> See the Secretariat update on the WHO consultation on potential liability and compensation provisions for the framework convention on tobacco control (document A/FCTC/INB2/5 Rev.1).

<sup>&</sup>lt;sup>112</sup> See paragraph 16 of document A/FCTC/INB2/5 Rev.1.

<sup>&</sup>lt;sup>113</sup> See paragraph 24 of document A/FCTC/INB2/5 Rev.1.

<sup>&</sup>lt;sup>114</sup> See paragraph 18 of Annex 3 of document FCTC/COP/6/8.

<sup>&</sup>lt;sup>115</sup> See paragraph 12 of document FCTC/COP/7/13

<sup>&</sup>lt;sup>116</sup> See paragraph 17 of document FCTC/COP/7/13.

<sup>&</sup>lt;sup>117</sup> See paragraph 21 of document FCTC/COP/7/13.

to tobacco use, and seeks to narrow the knowledge gaps<sup>118</sup> that may prevent courts from using and giving due weight to available scientific knowledge as a basis for quantifying the health-care costs caused by tobacco use.

### Summary of the survey responses regarding the use of epidemiology and statistics in liability cases to establish causation

- 123. Survey respondents identified several studies assessing the economic burden of tobacco use on health-care systems and societies. Several methodologies were included in the studies identified the majority of them using a cost-of-illness approach<sup>119</sup> and an attributable fraction method,<sup>120</sup> or other econometric statistical modelling approaches.<sup>121</sup>
- 124. Survey participants were also asked whether judicial systems or relevant legislation allowed for the use of statistics or epidemiology to establish causation in health-care cost recovery cases or other liability cases. Despite the number of responses confirming the existence of legislation or legal practice that allow for the use of statistics or epidemiology to establish causation, there were only few concrete examples of the use of statistics and epidemiology in courts in litigation involving the tobacco industry.
- 125. The qualitative assessment of the responses demonstrated that health-care costs from tobacco consumption are a well-researched theme worldwide, and several methodologies could provide evidence to be used in litigation regarding health-care costs. The Expert Group noted that the overwhelming majority of studies are not used in tobacco-related litigation, according to survey responses. There are several possible explanations for such underuse, including: 123
  - (a) the fact that some epidemiological and statistical studies are not particularly designed for tobacco litigation;
  - (b) the specialized and technical language used by the studies that could be difficult to explain to judges and other legal practitioners;
  - (c) ambiguity regarding legal system allowance for the use of epidemiology or statistics to establish causation in liability cases;<sup>124</sup> and

<sup>&</sup>lt;sup>118</sup> Mainly providing explanations designed to bring the concepts of causation in epidemiology, statistics and law closer, and to demonstrate the potential use of scientific knowledge in tobacco cost recovery cases.

<sup>&</sup>lt;sup>119</sup> Onukwugha E, McRae J, Kravetz A, Varga S, Khairnar R, Mullins, C. <u>Cost-of-illness studies: an updated review of current methods</u>. *PharmacoEconomics*. 2015; 34:43–58 (accessed 1 June 2025).

<sup>&</sup>lt;sup>120</sup> Mansournia M, Altman D. <u>Population attributable fraction</u>. *BMJ*. 2018; 360:k757 (accessed 1 June 2025).

<sup>&</sup>lt;sup>121</sup> Poirier D. <u>Reviewed Work: Econometric models, techniques, and applications. M. D. Intriligator</u>. J Am Stat Assoc. 1979;74(368):938–9 (accessed 1 June 2025).

<sup>&</sup>lt;sup>122</sup> It is worth mentioning that several studies cited by respondents have other objectives and could not be used in litigation. However, even those that could serve as evidence were rarely used to support cost recovery cases.

<sup>&</sup>lt;sup>123</sup> Note that these possible explanations are based on the survey responses and the experts' previous experiences and knowledge.

<sup>&</sup>lt;sup>124</sup> Several survey respondents were unclear about the difference between the use of epidemiology and statistics as a general form of evidence admitted by their laws, as opposed to its use as evidence to establish causation in tobacco-related litigation

(d) technical and resource limitation to using existing methods to produce data of health-care costs due to tobacco use.

### The methodologies that estimate and quantify the health-care costs borne due to tobacco use and their application in tobacco-related litigation

126. The Expert Group surveyed the relevant studies and analysed methodologies for estimating health-care costs from tobacco use. The scope of work was divided into three main components. The first was to build a summary of principal methodologies for estimating health-care costs from tobacco use, encompassing both direct and indirect costs. The second was to review the elements of the different methodologies. The third was an assessment of the methodologies, including their strengths and limitations, with the objective of evaluating the existing methodologies and their suitability for use in civil liability litigation.

### Review of the principal methodologies

127. The principal methodologies for estimating health-care costs from smoking include the cost-of-illness approach, the willingness-to-pay approach, regression-based growth models, computable general equilibrium models and dynamic simulation models. These methods address direct costs (such as hospitalizations and medications) and indirect costs (such as travel costs for treatments and lost productivity) linked to smoking-related diseases, and can be used, in different ways, in health-care cost recovery litigation.

### Cost-of-illness approach

128. The cost-of-illness approach calculates health-care costs caused by tobacco use by determining how much of a disease's financial burden can be directly linked to smoking. This method starts by identifying diseases scientifically proven to be caused by smoking, such as lung cancer, chronic obstructive pulmonary disease and heart disease. These connections are established through decades of epidemiological research, including landmark studies like those cited by the United States Surgeon-General, which list over 26 smoking-related health conditions. The core of the cost-of-illness method lies in calculating the smoking-attributable fraction — a measure that quantifies the proportion of a health outcome (for example, disease incidence, mortality or health-care costs) directly linked to smoking. It is a cornerstone of estimating tobacco's societal burden, and is calculated through epidemiological or econometric approaches, each with distinct methodologies and data requirements.

129. The epidemiological approach calculates the smoking-attributable fraction using population-level smoking prevalence and relative risk data, and a mathematical formula that combines current and former smoker prevalence with their respective relative risks compared to never-smokers. The econometric approach estimates the smoking-attributable fraction using individual-level data (such as health claims and surveys) to model excess health-care costs for smokers. By statistically comparing smoking status on expenditures while controlling for confounders (income, comorbidities), it calculates the difference between smokers' costs and a hypothetical non-smoking population.

<sup>125</sup> The health consequences of smoking: 50 years of progress. A Report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention; 2014 (accessed 1 June 2025).

130. The epidemiological method is the usual approach, where researchers gather three critical pieces of data: smoking prevalence (the percentage of current and former smokers in a population), relative risk (how much more likely smokers are to develop a disease compared to non-smokers that have similar characteristics regarding age, sex, consumption habits and so on) and the total health-care costs for treating each smoking-related disease. Once the smoking-attributable fraction is determined, it is multiplied by the total health-care costs for each disease, and the result is the health-care cost of tobacco consumption of such disease at the population level. These calculations are repeated for all smoking-related diseases, and the results are summed to estimate the total health-care burden.

131. The cost-of-illness methodology can be applied using a prevalence approach that estimates the economic costs of smoking within a single year, capturing all health-care expenditures, productivity losses and deaths attributable to smoking-related diseases during that period, regardless of when smoking began or ceased; or an incidence approach that calculates the total lifetime costs for a cohort of smokers, projecting future health-care expenses, productivity losses and mortality impacts over their lifespan.

### Willingness-to-pay approach 126

132. The willingness-to-pay approach is an econometric model that estimates the value people place on health improvements or avoiding health risks, which proceed in several steps. First, the health outcome or risk to be valued (such as reducing lung cancer risk by 10%) is determined. Next, a choice between revealed preferences (observing real-world behaviour like job choices with different health risks) or stated preferences (using surveys with hypothetical scenarios) is made. For surveys, questions are designed that ask respondents how much they would pay for the defined health benefit. The survey is then conducted across a representative sample of the population, and responses are analysed, calculating average willingness-to-pay amounts and adjusting for factors like income or age. Finally, individual valuations are aggregated to estimate the total economic value of the health outcome for the entire population. This approach captures both tangible and intangible costs, providing a comprehensive measure of health's economic impact that can inform policy decisions.

### Regression-based growth models<sup>127</sup>

133. Regression-based growth models are econometric models that rely on the statistical analysis of data to test relationships between variables. They study how health issues (such as smoking-related diseases) affect a country's economic growth. They use statistics to link factors like disease rates to changes in gross domestic product, showing how sick workers might reduce productivity. For example, a 10% rise in lung cancer could correlate with a 0.5% drop in gross domestic product. By applying these regression-based approaches, the health impacts of smoking can be quantified to inform policy decisions and evaluate the effectiveness of programmes.

<sup>&</sup>lt;sup>126</sup> O'Brien B, Viramontes JL. <u>Willingness to pay: a valid and reliable measure of health state preference</u>? Med Decis Making. 1994;14(3):289–97 (accessed 1 June 2025).

<sup>&</sup>lt;sup>127</sup> Wacker KM, Beyer RCM, Moller LC. <u>Leveraging growth regressions for country analysis</u>. Policy Research Working Paper; 10751. Washington, DC: World Bank; 2024 (accessed 1 June 2025).

<sup>&</sup>lt;sup>128</sup> Nargis N, Hussain AKMG, Asare S, Xue Z, Majmundar A, Bandi P et al. <u>Economic loss attributable to cigarette</u> smoking in the USA: an economic modelling study. Lancet Public Health. 2022; 7(10):e834–43 (accessed 1 June 2025).

### Computable general equilibrium models<sup>129</sup>

134. Computable general equilibrium models are macroeconomic simulations that evaluate interactions across all economic sectors and offer a way to analysing the economic impact of smoking including on gross domestic product, employment, labour productivity and mortality-related losses. They simulate how a health policy (such as tobacco taxes) affects the entire economy – including jobs, prices and government budgets. These models are widely used by organizations like the European Commission, World Bank, Organisation for Economic Co-operation and Development, and government bodies to evaluate potential impacts of policy decisions before they are implemented.

### Dynamic simulation models<sup>130</sup>

135. Dynamic simulation models are macroeconomic simulations that project large-scale, long-term economic and demographic trends. They predict long-term impacts of health trends, like smoking rates over 50 years. They track how diseases spread, populations age, and costs accumulate. For instance, they might forecast rising health-care bills as smokers develop chronic illnesses.

### Assessment of the principal methodologies

136. The description of the methodologies above demonstrates that existing methodologies are used for a range of different purposes, and use concepts and data that greatly differ from one another. All the described methodologies are based on scientific evidence. However, when considering their suitability, it must be borne in mind that they are designed for specific purposes and goals, since the choice of modelling framework is guided by the question that is being asked. Therefore, the Expert Group assessed the methodologies based upon its mandate in the context of Article 19, here related to civil liability.

137. The focus was to evaluate the methodologies based on their purposes, strengths and limitations, and evaluate whether all of those components are still relevant and valid in a legal context where cost reimbursement is being claimed through civil liability. What is sometimes identified as a weakness in a methodology could become – in the legal context – a strength, and vice versa. For example, some methodologies are criticized for not encompassing all the direct and indirect cost due to tobacco use, because they do not quantify intangible costs like pain and suffering or the impact on welfare and leisure time. Others are deemed more comprehensive and accurate for encompassing the possible costs – tangible and intangible – of tobacco

<sup>&</sup>lt;sup>129</sup> Cicowiez M, Cruces G, Falcone G, Puig J. On the impacts of higher tobacco taxes in Argentina: a computable general equilibrium approach. Tob Control. 2024; 33(Suppl 2):s115–21 (accessed 1 June 2025).

<sup>&</sup>lt;sup>130</sup> Vugrin ED, Rostron BL, Verzi SJ, Brodsky NS, Brown TJ, Choiniere CJ et al. <u>Modeling the potential effects of new tobacco products and policies: a dynamic population model for multiple product use and harm</u>. PLoS One. 2015; 10(3): e0121008 (accessed 1 June 2025).

<sup>&</sup>lt;sup>131</sup> WHO guide to identifying the economic consequences of disease and injury. Geneva: World Health Organization; 2009:17 ("One of the first principles of any costing study is to define the viewpoint of the analysis, because the way costs should be measured depends crucially on the reason for measuring them, i.e., on the question being asked") (accessed 1 June 2025).

<sup>&</sup>lt;sup>132</sup> Economics of tobacco toolkit: assessment of the economic costs of smoking. Geneva: World Health Organization; 2011:13 (accessed on 1 June 2025).

consumption.<sup>133</sup> From different angles, these methodologies seek to address the direct and indirect costs of tobacco, although it seems impossible to address all the damage caused by its consumption.

138. Moreover, the use of this kind of evidence in courts must recognize that most civil liability actions brought to date in different parts of the world have focused on the financial costs to health care. Therefore, epidemiological models to establish causation, as well as the statistical evidence that quantifies the associated costs, must be consistent with liability rules that specify the categories of loss that are recoverable and by whom. Hence, despite the substantial number of studies evaluating the health-care costs of smoking in populations, there appear to be few studies with methodologies designed for the specific purposes of establishing causation in civil liability actions, where a study that provides a comprehensive but delimited estimate of the macroeconomic burden of disease is likely to represent the most favourable approach.

## Rejection by courts of the tobacco industry's arguments against health-care cost estimations

139. The tobacco industry has systematically criticized all methodologies used to estimate health-care costs from tobacco consumption in judicial settings, primarily disputing causation by arguing that epidemiological studies rely on observational data rather than randomized trials, and do not definitively link smoking to individual illnesses because they ignore confounders like alcohol use or genetics. The tobacco industry has contested aggregate data approaches (such as cost-of-illness models using the smoking-attributable fraction), claiming they lack individual-level specificity and overstate costs by not isolating tobacco's unique contribution. In addition, the tobacco industry has often relied on the so-called death benefit argument, <sup>136</sup> asserting that premature smoker deaths reduce long-term pension and social and health-care costs for elderly people. Additionally, it has criticized economic models as overly complex "black boxes" prone to manipulation.

140. Courts have consistently dismissed tobacco industry challenges to health-care cost recovery methodologies by prioritizing scientific validity, ethical principles and legal practicality. Tobacco industry arguments disputing causation – such as claims that observational epidemiological studies cannot definitively link smoking to individual illnesses or that legal causation cannot be established with epidemiological and statistical data – are usually rejected on the grounds of established scientific consensus.

141. Judges recognize that population-level evidence, like the smoking-attributable fraction derived from cohort studies, are reliable and sufficient for proving causation in mass liability, as

<sup>&</sup>lt;sup>133</sup> WHO guide to identifying the economic consequences of disease and injury. Geneva: World Health Organization; 2009:96 (accessed 1 June 2025).

<sup>&</sup>lt;sup>134</sup> Wright R. Causation in tort law. California Law Review. 1985;73(6):1735 (accessed 1 June 2025).

<sup>&</sup>lt;sup>135</sup> Parascandola M, Weed DL. <u>Causation in epidemiology</u>. *J Epidemiol Community Health*. 2001; 55:905–12 (accessed 1 June 2025).

<sup>&</sup>lt;sup>136</sup> A claim that while smokers incur health-care costs, they also generate savings for society by dying prematurely, thereby reducing pension payouts and long-term care expenditures. See Zeger SL, Wyant T, Miller LS, Samet J. <u>Statistical testimony on damages in Minnesota v. Tobacco Industry</u>. In: Gastwirth JL, editor. *Statistical science in the courtroom. Statistics for Social Science and Public Policy*. New York, NY: Springer; 2000 (accessed 1 June 2025).

<sup>&</sup>lt;sup>137</sup> Max W, Tsoukalas T. Economics on trial: the use and abuse of economic methods in third party tobacco litigation. Tob Control. 2006;15(Suppl 4):iv77–83; Zeger SL, Wyant T, Miller LS, Samet J. Statistical testimony on damages in Minnesota v. Tobacco Industry. In: Gastwirth JL, editor. Statistical science in the courtroom. Statistics for Social Science and Public Policy. New York, NY: Springer; 2000 (accessed 1 June 2025).

seen in cases like Blue Cross and Blue Shield of New Jersey v. Philip Morris, Inc., et. al. (2000–2001)<sup>138</sup> and British Columbia v. Imperial Tobacco Canada, Ltd. (2005).<sup>139</sup> Courts also categorically reject the tobacco industry's "death benefit" argument (that premature smoker deaths reduce pension or health costs) as ethically indefensible, emphasizing that human life cannot be monetized as a cost-saving measure.<sup>140</sup> Challenges to aggregate data models, such as claims of overestimating costs or unreliable "black box" methodologies, are rejected by courts that recognize the scientific and legal validity of using "reasonable approximations" in large-scale cases, where tracking individual smokers is deemed impractical, disproportionate and sometimes unreliable.<sup>141</sup>

142. Court rulings have also dismissed tobacco industry assertions about tobacco's economic benefits (such as health-care spending boosting gross domestic product) by highlighting opportunity costs – resources diverted to treat preventable diseases could otherwise fund productive investments like education. A feature of these rulings is recognition of the value of peer-reviewed methodologies, adherence to public health ethics and the practical necessity of aggregate evidence in mass litigation. By upholding rigorous epidemiological and econometric models while dismissing tobacco defendant critiques as scientifically and morally flawed, courts have helped ensure that tobacco-related health-care cost recovery claims align with societal welfare and legal standards.<sup>142</sup>

# Cost-of-illness methodology approach as a straightforward way to quantify health-care costs in health-care cost recovery litigation

143. After assessing all principal methodologies, the Expert Group found the cost-of-illness methodology, using an epidemiological framework and a prevalence approach, to be a suitable approach for quantifying damages in health-care cost recovery litigation, especially if designed to compensate for direct costs. It uses the epidemiological framework and prevalence-based analysis to estimate health-care costs linked to tobacco use by determining what proportion of diseases — and their associated expenses — are caused by smoking, providing a straightforward, step-by-step and transparent way to quantify damages in a format suitable for a legal context.

144. In applying such methodology, first, researchers identify diseases scientifically proven to be caused by smoking, which connections are supported by decades of epidemiological studies. Next, the smoking-attributable fraction is calculated to find the percentage of a disease's total costs attributable to smoking. Then, the prevalence approach applies this smoking-attributable fraction to annual health-care costs for each smoking-related disease, obtained using medical records or

<sup>&</sup>lt;sup>138</sup> Blue Cross & Blue Shield of New Jersey, Inc. v. Philip Morris, Inc., 178 F. Supp. 2d 198, 208 (E.D.N.Y. 2001) (stating "Statistical proof combined with other evidence is a necessary and pragmatic evidentiary approach to this and other massive tort cases. It is consistent with the defendants' Constitutional rights and legally sufficient to support plaintiff's state law claims") (accessed 1 June 2025).

<sup>&</sup>lt;sup>139</sup> British Columbia v. Imperial Tobacco Canada Ltd. 2005 SCC 49 (accessed 1 June 2025).

<sup>&</sup>lt;sup>140</sup> Zeger SL, Wyant T, Miller LS, Samet J. <u>Statistical testimony on damages in Minnesota v. Tobacco Industry</u>. In: Gastwirth JL, editor. *Statistical science in the courtroom. Statistics for Social Science and Public Policy*. New York, NY: Springer; 2000 (accessed 1 June 2025).

<sup>&</sup>lt;sup>141</sup> Max W, Tsoukalas T. <u>Economics on trial: the use and abuse of economic methods in third party tobacco</u> litigation. Tob Control. 2006;15(Suppl 4):iv77–83 (accessed 1 June 2025).

<sup>&</sup>lt;sup>142</sup> Max W, Tsoukalas T. <u>Economics on trial: the use and abuse of economic methods in third party tobacco litigation</u>. Tob Control. 2006;15(Suppl 4):iv77–83; Jung M. <u>A legal and epidemiological consideration of the causal relationship between tobacco and lung cancer</u>. Asian Pac J Cancer Prev. 2021;22(9):2723–7 (accessed 1 June 2025).

other forms of measuring health expenditures. For example, if the smoking-attributable fraction demonstrates that 83% of lung cancer costs in that population are caused by smoking, and a country spends US\$ 1 billion yearly on lung cancer treatment, smoking accounts for US\$ 830 million of those costs. This process is repeated for all the tobacco-linked diseases evaluated, and the results are added together to estimate the annual health-care burden of smoking of such diseases. Unlike more complex lifetime models, the prevalence approach focuses on costs incurred in a single year, using usually available data like hospital records, medication expenses or other valid sources, multiplying them by the percentage of costs caused by tobacco use.

- 145. The cost-of-illness methodology with these parameters aligns with the legal standards for proving legal causation in more than one way. First, it establishes general causation by demonstrating smoking's proven role in increasing disease risk (such as through relative risk values that can be adapted from research conducted in other countries or regions)<sup>143</sup> in a form that has been deemed valuable in litigation. As an example, courts have accepted this population-level evidence, as seen in cases like Blue Cross and Blue Shield of New Jersey v. Philip Morris Inc., et. al., where aggregate smoking-attributable fraction models were deemed sufficient proof.<sup>144</sup> Also, some of Canada's provincial health cost recovery laws permit provinces to use population-level models that use statistics or epidemiology without identifying specific patients, recognizing the impracticality of proof through individual patients on a case-by-case basis;<sup>145</sup> further, smokingattributable fraction models were used in the recently approved global settlement approved by the Ontario Superior Court. 146 Second, it presents a clear causal path that can be understood by judges (and jurors where relevant) who may not have specialized knowledge in epidemiology or statistics, and need to understand how tobacco use directly leads to increased health-care costs. Third, its transparency ensures replicability and scientific credibility by relying on peer-reviewed epidemiological data and publicly available health expenditure estimates.
- 146. The method's simplicity, objectivity and alignment with public health research make it readily aligned with the general idea of legal causation for quantifying tobacco-related health-care costs in legal settings. It could be applied, depending on the legal system, through either the enactment of specific legislation or a favourable interpretation of general causation understandings.
- 147. This does not mean that other recognized methodologies should be disregarded when implementing Article 19 or that any methodology could be deemed unsuitable for its use in tobacco-related litigation. Despite being a straightforward, easily understandable and data-driven methodology, the cost-of-illness approach could underestimate other aspects of health-care cost

<sup>143</sup> Sharma R, Rakshit B. <u>Global burden of cancers attributable to tobacco smoking, 1990–2019: an ecological study</u>. EPMA J. 2022;14(1):167–82 (accessed 1 June 2025).

<sup>&</sup>lt;sup>144</sup> <u>Blue Cross and Blue Shield of New Jersey, Inc. v. Philip Morris, Inc., 178 F. Supp. 2d 198, 208 (E.D.N.Y. 2001)</u> (accessed 1 June 2025).

<sup>&</sup>lt;sup>145</sup> Chapter R-2.2.0.0.1 – Tobacco-related Damages and Health Care Costs Recovery Act (accessed 2 June 2025). ("In an action brought on a collective basis, proof of causation between alleged facts, in particular between the defendant's wrong or failure and the health care costs whose recovery is being sought, or between exposure to a tobacco product and the disease suffered by, or the general deterioration of health of, the recipients of that health care, may be established on the sole basis of statistical information or information derived from epidemiological, sociological or any other relevant studies, including information derived from a sampling. The same applies to proof of the health care costs whose recovery is being sought in such an action.")

<sup>&</sup>lt;sup>146</sup> First amended and restated court-appointed mediator's and monitor's CCAA Plan Of Compromise And Arrangement, Schedule "G" (accessed 2 June 2025).

recovery, such as intangible costs like pain and suffering. Also, where the litigation is not limited to health-care (such as costs of fires caused by cigarettes or environmental clean-up), the cost-of-illness approach could underestimate damages calculations. As mentioned above, the choice of suitable methodology is based on the measure of interest and the purpose of the litigation. If the purpose is to encompass other costs not evaluated by the cost-of-illness approach, then other methodologies should be considered, accompanied by considerations about their acceptance by the legal system as a valid measure of legal causation.

## **Conclusions on methodologies**

- 148. The WHO FCTC was built upon a scientific consensus about the harms of tobacco, and such consensus is achieved by epidemiology and statistics. Therefore, such consensus is grounded on a collective approach, and it is important to conclude that it is entirely appropriate to use statistical evidence to establish legal causation in health-care cost recovery cases. The use of epidemiology and statistics in such cases is not only compatible with Article 19 but also represents the best evidence of the loss and damage caused by tobacco use that science can provide.
- 149. Regarding the possible development of a methodology, the conclusion is that there are existing methods that can measure health-care costs of tobacco use in different forms, using different data sources and with several goals. Also, such methodologies reflect decades of scientific reasoning, peer review and criticism, and have been accepted as the best available scientific reasoning for the evaluation of health-care costs due to tobacco use.
- 150. It is advisable to choose and tailor such methodologies carefully for their use in a civil liability action. This Expert Group concludes that there are established methods for the parties to adopt, depending on the aim of litigation and availability of data. The cost-of-illness methodology, using an epidemiological method and a prevalence approach, is an easy path to providing solid evidence for use in civil liability since it constitutes the more direct, established and used methodology to assess tobacco health-care costs and, despite being less comprehensive than other methods, provides the clearer path for judicial appreciation. It is a rather transparent methodology that enhances persuasiveness for non-expert decision-makers, ensuring that the argument remains accessible and compelling. Therefore, such methodology is scientifically sound and could be accepted and used by courts when evaluating collective claims related to health-care costs due to tobacco use.
- 151. Other methodologies like the econometric models (the willingness-to-pay approach and regression-based growth models) and the macroeconomic simulations (computable general equilibrium models and dynamic simulation models) could also be used, when feasible and in situations where a more comprehensive evaluation of health-care costs due to tobacco use is sought, taking into account that legal systems must be able to comprehend the methodologies, and that legal causation requires proof of a damage that has clear boundaries and clear and cohesive causation path. Hence, it is advised that before using econometric models and macroeconomic simulations, the legal system should be evaluated beforehand to analyse how claims could be built, what harms could be vindicated, and how epidemiological, econometric and statistical evidence produced by those methodologies could be used in those claims.

## **Recommendations for Article 19 implementation**

152. The following recommendations are designed to help Parties fulfil their obligations under Article 19. The list of recommendations outlines legislative actions that Parties can consider taking

to deal with civil and criminal liability, including compensation where appropriate, for the harm caused by tobacco. This includes facilitating criminal and civil legal proceedings, but also administrative procedures for establishing liability, where appropriate. Recommendations are also made as to how Parties can cooperate in the implementation of Article 19, and provide mutual assistance in relation to legal proceedings. These recommendations take account of all the practices, including relevant developments in relevant international fora, set out in this report and reports of the previous Expert Group (FCTC/COP/6/8 (Annex 3) and FCTC/COP/7/13).

153. Not all the recommendations will be suitable for all countries. Parties should assess these recommendations in light of their current laws and legal systems, and their experience to date in establishing liability and securing compensation for the harm caused by tobacco.

## **General principles**

- 154. These recommendations are guided by the following principles.
  - (a) Actions related to liability for the harms caused by tobacco are an important part of comprehensive tobacco control. Compensation should not impede reductions in the harm caused by tobacco, and should not prejudice low- and middle-income countries' ability to obtain compensation for the harm caused by tobacco.
  - (b) Reforms to civil liability should facilitate effective access to justice for harms caused by tobacco.
  - (c) Reforms to criminal liability should be based on the need for effective enforcement of all tobacco control laws or general laws applicable to the production, manufacture, marketing, supply and disposal of tobacco products, with the aim of preventing future violations.
  - (d) Any interactions between Parties and the tobacco industry in the context of civil and criminal proceedings or administrative procedures for determining liability should be consistent with Article 5.3 and its Guidelines for implementation.
  - (e) Cooperation and information exchange between Parties is needed to ensure effective information transfer and to ensure that the tobacco industry cannot exploit jurisdictional boundaries to evade liability.

## Recommendations related to liability actions

- 155. Having regard to these principles, the following list of options related to civil and criminal liability and administrative measures to establish liability is recommended by the Expert Group. Parties should consider adopting legislation or other measures which ensure the following:
  - (i) The whole of government, including judges and prosecutors, are aware of the WHO FCTC and obligations under Articles 5.3 and 19, as well as recommendations in the Guidelines for implementation of Article 5.3, including by increasing the capacity and resources of relevant government ministries to proactively address tobacco industry liability.
  - (ii) Class action procedures are available for any civil liability actions against the tobacco industry related to the harm caused by tobacco.

(iii) Health-care providers have a direct and distinct cause of action entitling them to recover health-care costs attributable to wrongs committed by the tobacco industry, regardless of when the wrong was committed.

- (iv) Causation in civil liability actions related to the harms caused by tobacco can be established solely through the use of epidemiological, statistical or other sociological evidence.
- (v) Evidentiary disclosure is available against the tobacco industry in any civil liability actions related to the harms caused by tobacco.
- (vi) In any civil liability actions against the tobacco industry related to the harms caused by tobacco, the industry bears the burden of proving: (a) that it complied with all relevant civil laws; or (b) that any breach of those laws was not the cause of the injuries or losses of the claimant/s; or both (a) and (b) in appropriate cases.
- (vii) Tobacco control laws or general laws applicable to the production, manufacture, marketing, supply and disposal of tobacco products impose strict liability, where appropriate.
- (viii) Voluntary assumption of risk is not an available defence in civil liability actions for any time period before the defendant publicly and clearly acknowledged the harms caused by tobacco.
- (ix) Time limits for victims of harm caused by tobacco to bring civil liability actions are abolished or can be extended.
- (x) Claimants in civil liability actions can rely on evidence submitted and findings made in other civil liability actions, and courts take note of liability findings against the tobacco industry in other jurisdictions.
- (xi) Civil liability actions against the tobacco industry for the harm caused by tobacco can be funded through "contingency" or "success" fees. Any adverse cost liability for claimants is abolished.
- (xii) Settlements of class actions and health-care cost recovery claims related to harms caused by tobacco are subject to court approval. In furthering this recommendation, Parties should ensure that courts must be satisfied that the settlement is fair and reasonable and would not impede further prevention or reduction in tobacco use, nicotine addiction and exposure to tobacco smoke. Additionally, civil society organizations not directly or indirectly affiliated with the tobacco industry or those working to further its interests should have standing to address the court on whether a settlement meets these criteria, subject to court discretion.
- (xiii) Where the tobacco industry is permitted to use insolvency procedures, the court has powers to ensure that any schemes of arrangement are compatible with public health objectives specifically the prevention or reduction in tobacco use, nicotine addiction and exposure to tobacco smoke and can order non-monetary remedies that are consistent with these objectives.
- (xiv) Destruction of documents for the purpose of avoiding their disclosure in future litigation is a criminal offence. Further, Parties should ensure that a person whose civil claim is prejudiced by the destruction of such evidence should be entitled to compensation from the person responsible for the destruction established to a civil standard of proof.

(xv) Fines for liability for the breach of tobacco control laws provide for effective deterrence by adopting a range of criminal penalties that are proportionate to the seriousness of the violation and the degree of responsibility of the violator, including increased penalties for repeat offenders. Where appropriate, Parties should ensure that this includes fines proportionate to the annual turnover of the defendant from their production, manufacturing, marketing, supply or disposal of tobacco products.

- (xvi) Where companies are found criminally liable for breaches of tobacco control laws, directors are personally liable for the breaches if they were found to be intentional, reckless or negligent. This recommendation does not preclude any individual from being found directly liable for breaches of tobacco control laws.
- (xvii) Qualified civil society organizations not directly or indirectly affiliated with the tobacco industry or those working to further its interests are given the power to prosecute breaches of tobacco control laws or general laws applicable to the manufacture, marketing and supply of tobacco products, and a percentage of any criminal fine imposed should be payable to the civil society organization that brought the prosecution. Parties should also ensure that such civil society organizations have secure funding to bring legal actions to enforce tobacco control measures.
- (xviii) Effective protections are established for whistleblowers who make disclosures of tobacco industry practices relating to harm caused by tobacco and for victims of tobacco industry intimidation.
- (xix) Legislation provides administrative agencies and tribunals, including existing tribunals, with authority to determine liability for harms caused by tobacco where appropriate and that such determinations are subject to limited appeals.
- (xx) Streamlined procedures exist for responding to requests for the production of documents and the giving of evidence for proceedings in other jurisdictions related to harm caused by tobacco.
- (xxi) Jurisdictional rules allow claimants to sue persons engaged in the production, manufacture, marketing, supply and disposal of tobacco products in the place of domicile of the defendant or the place where a claimant suffered harm caused by tobacco.
- (xxii) Procedures exist that allow for the efficient enforcement of judgments from courts outside the jurisdiction in cases related to the harms caused by tobacco.
- (xxiii) Freezing orders, which are also known as asset preservation orders and prevent the dissipation of assets that could be used to satisfy liability determinations, are routinely available against persons involved in the production, manufacturing, marketing, supply and disposal of tobacco products.
- (xxiv) Anti-bribery laws have extraterritorial application so that they apply to all actions of persons involved in the production, manufacturing, marketing, supply and disposal of tobacco products.

#### Recommendations related to information exchange and monitoring

(xxv) Required tobacco industry reporting to the appropriate government authority includes information on registration of business entities; tobacco production, manufacture, supply and disposal; market share; revenues; sanctions against the entity; where legally allowed, marketing expenditures, corporate social responsibility efforts, lobbying activities, political contributions; mergers and acquisitions; and pertinent

- jurisprudence, including liability outcomes (such as injunctive relief, compensation, sanctions as ordered or agreed) and relevant developments in international fora.
- (xxvi) Information gathered from tobacco industry reporting in recommendation xxv and/or with the support of civil society is routinely shared between Parties.

## Recommendations related to methodologies for estimating health-care costs caused by tobacco use

- (xxvii) Epidemiological and statistical studies, which are suitable for use in health-care cost recovery litigation, are resourced and developed.
- (xxviii) The use of data from other countries and regions is encouraged, while making the necessary adjustments, where Parties cannot produce their own data, including relative risks and health-care cost estimations.
- (xxix) Judges and legal practitioners are encouraged to understand epidemiology, statistics and causation studies from these scientific disciplines because they represent the best evidence of the loss and damage caused by tobacco use that science can provide, and they are reliable evidence for establishing civil liability.
- (xxx) Parties share information and cooperate with matters related to epidemiology and statistics to foster the collection of data and the production of knowledge regarding scientific evidence to be used in civil liability actions.

## **Action by the Conference of the Parties**

156. The COP is invited to note the report of the Expert Group and to consider adopting the draft decision contained in Annex 2 of the present report.

#### Annex 1

## Non-exhaustive list of existing annotated Article 19 resources

- (a) The WHO FCTC Article 19 Civil Liability Toolkit¹ serves as a step-by-step guide for Parties on how to design, implement and enforce civil liability measures against the tobacco industry. It includes resources to assist policy-makers and legal practitioners in holding the tobacco industry accountable for the harms caused by their products. It is particularly useful for jurisdictions seeking to strengthen their legal framework under Article 19 and to sue the tobacco industry. A multi-language version of the Civil Liability Toolkit is available online in the six official languages of the United Nations.
- (b) The Article 19 Expert Database,<sup>2</sup> maintained by the Convention Secretariat, is a database of experts and institutions for implementation of Article 19 (Liability) of the WHO FCTC pursuant to decision FCTC/COP7(11).<sup>3</sup> It provides access to experts and institutions that can provide Parties, upon request, with technical assistance related to tobacco industry liability. Parties can use this resource to connect with legal professionals, academics and practitioners who have experience in developing and implementing liability strategies. It facilitates technical support and capacity-building for Parties implementing Article 19.
- (c) The WHO FCTC Knowledge Hub on Legal Challenges McCabe Centre for Law and Cancer<sup>4</sup> provides resources on legal trade law, investment law, and domestic and information on legal challenges to WHO FCTC implementation in domestic and regional courts. It equips Parties with tools to anticipate and counter legal challenges from the tobacco industry when implementing liability measures, ensuring a strong defence for national tobacco control policies. The Convention Secretariat continues to support the WHO FCTC Knowledge Hub on Legal Challenges in maintaining its website, which features updates on legal challenges to WHO FCTC implementation in relation to trade and investment law and in domestic and regional courts, pursuant to decision FCTC/COP6(18).<sup>5</sup>
- (d) The WHO FCTC Knowledge Hub on Article 5.3 Thammasat University and Mahidol University<sup>6</sup> focuses on tobacco industry interference and can assist Parties to identify, address and prevent industry interference that may obstruct efforts to implement Article 19. The Knowledge Hub provides case studies and tools to strengthen governance and minimize conflicts of interest,

<sup>&</sup>lt;sup>1</sup> WHO FCTC Article 19 Civil Liability Toolkit (accessed 27 May 2025).

<sup>&</sup>lt;sup>2</sup> Article 19 Expert Database (accessed 27 May 2025).

<sup>&</sup>lt;sup>3</sup> In decision FCTC/COP7(11), further recalled in decision FCTC/COP8(18), the COP requested the Convention Secretariat, in accordance with its mandate as described in decision FCTC/COP6(7), to develop a database of experts and institutions that can provide Parties, upon request, with technical assistance related to tobacco industry liability, create a digital platform for international cooperation, and make available and regularly update related resources.

<sup>&</sup>lt;sup>4</sup> WHO FCTC Knowledge Hub on Legal Challenges (accessed 2 June 2025).

<sup>&</sup>lt;sup>5</sup> In decision FCTC/COP6(18), the COP requested the Convention Secretariat, in coordination with the WHO Secretariat and the relevant knowledge hubs, to continue facilitating information sharing and cooperation among the Parties with regard to legal challenges against their tobacco control measures in domestic courts or through international dispute settlement mechanisms.

<sup>&</sup>lt;sup>6</sup> WHO FCTC Knowledge Hub on Article 5.3 (accessed 1 June 2025).

including the Resource Database Tobacco Industry Interference. Developed pursuant to FCTC/COP8(18), this Database is maintained by the Knowledge Hub for Article 5.3 in collaboration with Global Center for Good Governance in Tobacco Control, with support from the Convention Secretariat. The Database compiles available information posted by governments and observers including "position papers, statements, reports, correspondences, minutes of meetings with tobacco industry representatives, submissions on product ingredients, contracts and agreements, and other relevant documents, including from entities that could be categorized as the tobacco industry, and funded groups, inter alia, organizations and individuals that work to further the interests of the tobacco industry".

- (e) The **Truth Tobacco Industry Documents Library**<sup>8</sup> contains over 14 million internal documents from the tobacco industry, revealing evidence of their harmful practices, including marketing strategies and interference in public health policies. Parties can use these documents as evidence in litigation, supporting claims of liability and strengthening legal arguments against the industry. It was built to house and provide permanent access to the once-secret tobacco industry internal corporate documents produced during United States litigation and made public through United States litigation settlements.
- (f) **Tobacco Control Laws**<sup>9</sup> provides access to tobacco control laws from around the world, as well as summaries, analyses and policy fact sheets to assess how tobacco control measures align with the Convention and some of its guidelines. It also provides access to full text and summaries of tobacco control decisions from courts around the world. Parties can analyse successful legal precedents and strategies to inform their own approaches to liability measures under Article 19, including judicial and legislative considerations. The website is managed by the International Legal Consortium at the Campaign for Tobacco-Free Kids.
- (g) **Tobacco Tactics**<sup>10</sup> provides rigorous academic research and findings in an accessible format. Tobacco Tactics details key issues in tobacco control, focusing on the global tobacco industry and those connected to or interacting with it. Developed by the Tobacco Control Research Group at the University of Bath, Parties can use this platform to counter industry arguments and misinformation when pursuing liability measures under Article 19.
- (h) The Global Center for Good Governance in Tobacco Control (GGTC)<sup>11</sup> provides technical resources and strategic support to help Parties implement Article 19 of the WHO FCTC to advance tobacco industry liability. Its Liability Resources Package compiles key materials on implementing Article 19, with a focus on approaches beyond litigation. GGTC develops tools to assess the industry's economic, environmental and social impacts including the Environmental Cost Calculator and convenes movements which call for holding the tobacco industry fully accountable for its harms, such as Global Youth Voices and the Stop Tobacco Pollution Alliance. It also facilitates screening and identification of tobacco industry actors, including through its work on the Article 5.3 Knowledge Hub's Global Resource Database, while its Global Tobacco Industry Interference Index systematically tracks government responses to tobacco industry tactics.

<sup>&</sup>lt;sup>7</sup> Resource Database on Tobacco Industry Interference (accessed 2 June 2025).

<sup>&</sup>lt;sup>8</sup> Truth Tobacco Industry Documents (accessed 2 June 2025).

<sup>&</sup>lt;sup>9</sup> Tobacco Control Laws (accessed 2 June 2025).

<sup>&</sup>lt;sup>10</sup> Tobacco Tactics (accessed 2 June 2025).

<sup>&</sup>lt;sup>11</sup> <u>Global Center for Good Governance in Tobacco Control</u>; see also <u>How can the tobacco industry be held accountable?</u> (accessed 2 June 2025).

- (i) Stopping Tobacco Organizations and Products (STOP)<sup>12</sup> is a network of academic and public health organizations operating globally as part of the Bloomberg Initiative to Reduce Tobacco Use. STOP connects experts in all aspects of the tobacco industry's business to expose and counter its relentless efforts to sell harmful, addictive products. It monitors and exposes the tobacco industry's tactics to interfere with public health policies. Parties can leverage STOP's research and analysis to strengthen their legal cases and counter arguments by the industry when implementing civil liability measures under Article 19.
- (j) The **Right to Health Policy Hub**<sup>13</sup> provides human rights-based legal arguments and international treaty body documents that support public health policies, including tobacco control. Parties can use this Hub to incorporate a human rights framework into Article 19 implementation, strengthening their legal rationale for holding the tobacco industry accountable. This resource highlights the growing connections between these health policies and human rights obligations, as presented by official documents issued by human rights bodies. The website is managed by the International Legal Consortium at the Campaign for Tobacco-Free Kids and the Global Health Advocacy Incubator legal team.
- (k) The **Tobacco and Human Rights Hub**<sup>14</sup> provides resources for advocacy tools addressing tobacco control through a human rights-based approach including information from international and regional human rights bodies, academic articles, litigation, treaty body reporting and more. Parties can use this resource to find examples of how to incorporate tobacco into human rights reporting, find templates for reporting, and find documents that illustrate tobacco control topics for human rights advocates and human rights topics for tobacco control advocates. The website is managed by Action on Smoking and Health.
- (I) Make Big Tobacco Pay<sup>15</sup> provides tools, technical resources and strategic advice to address industry tactics that undermine liability measures and other tobacco control efforts. The website is managed by Corporate Accountability.

<sup>&</sup>lt;sup>12</sup> STOP (accessed 2 June 2025).

<sup>&</sup>lt;sup>13</sup> Right to Health Policy Hub (accessed 2 June 2025).

<sup>&</sup>lt;sup>14</sup> Tobacco and Human Rights Hub (accessed 2 June 2025).

<sup>&</sup>lt;sup>15</sup> Make Big Tobacco Pay (accessed 2 June 2025).

## Annex 2

#### **Draft decision:**

## Implementation of Article 19 of the WHO FCTC on Liability

The Conference of the Parties (COP),

Acknowledging that issues relating to liability, as determined by each Party within its jurisdiction, are an important part of comprehensive tobacco control;

Reminding Parties of their obligations under Article 19 of the WHO FCTC;

Recalling decisions FCTC/COP4(15), FCTC/COP5(9), FCTC/COP6(7), FCTC/COP7(11) and FCTC/COP10(13) in relation to implementation of Article 19 of the WHO FCTC on liability;

Recalling also decision FCTC/COP8(18), which encouraged Parties to promote national and international cooperation to enhance implementation of Article 5.3 of the WHO FCTC in relation to Article 19 of the WHO FCTC;

Further recalling that in decision FCTC/COP10(13) the COP re-established an expert group on liability, taking into account the work completed by the expert group on liability established pursuant to decision FCTC/COP5(9) and whose mandate was extended in decision FCTC/COP6(7);

Welcoming the report contained in document FCTC/COP/11/6 and noting with satisfaction the outcome of the work of the Expert Group on Implementation of Article 19 of the WHO FCTC on Liability,

## 1. CALLS ON the Parties:

- (a) to apply the recommendations and options provided by the Expert Group in their report FCTC/COP/11/6, as appropriate, to strengthen their implementation of Article 19 of the WHO FCTC;
- (b) to use the tools and resources available for Parties to strengthen their implementation of Article 19, including those contained in Annex 1 of the report FCTC/COP/11/6;
- (c) to share updated information including practice, challenges, lessons learned and expertise in relation to implementation of Article 19, between the Parties and through the Convention Secretariat, using, among others, the reporting system of the WHO FCTC and the database of experts and institutions for implementation of Article 19;

#### 2. REQUESTS the Convention Secretariat:

- (a) to disseminate the findings of the work of the Expert Group and to continue to raise awareness about Article 19 of the WHO FCTC, as well as the resources, expertise and tools available for Parties to strengthen its implementation;
- (b) to continue efforts to provide support to Parties in implementation of Article 19 of the WHO FCTC, including through facilitating information and experience sharing among Parties

and with the participation of civil society not directly or indirectly affiliated with the tobacco industry or those furthering its interests;

(c) to continue to update the COP on progress with implementation of Article 19 of the WHO FCTC by the Parties, as necessary.

(XX plenary meeting, xx November 2025)

---