Establish document development and retention

It is important that a comprehensive document development and retention policy, in line with government practice, is in place so that the policy development processes can be fully demonstrated if the measure is legally challenged.

Each step of the policy development and drafting process should be recorded and documented. This means keeping a careful record of:

- Key Ministry of Health meetings where the policy is discussed or decisions are taken on aspects of the policy;
- The reasons for policy decisions taken about any aspect of the policy (see for instance the key initial policy development decisions outlined in **Guide 3.1**);
- Communications or meetings with other government departments (see Guide 4.1)
- Communications or meetings with external public health bodies, experts or civil society organisations with documentation of attendees;

- Interactions with industry or industry representatives outside of public consultations with documentation of attendees*;
- All the evidence that has been considered as part of the evidence review, when it was considered and by whom;
- **7.** Any external written submissions received from organisations or industry whether as part of the a consultation or otherwise;
- **8.** Both internal and external correspondence including emails relating to the policy.

*Meetings with the tobacco industry or industry representatives should only take place, and be conducted, in line with the WHO FCTC Article 5.3 and the FCTC Article 5.3 guidelines so as to protect tobacco control polices from commercial and other vested interests¹.

Internal government discussions between different departments are an important part of the policy development process so demonstrating that they took place can show proper due process. Records of meetings should include agendas and minutes. A regulatory impact analysis (see **Guide 2.2**) can act as a useful part of the record of policy development.

LEGAL CHALLENGES to a tobacco control policy, in both national courts and international tribunals, can often include a claim that due process has not been adhered to or that effective consideration of all the relevant evidence and issues was not had before a final decision was made. It is important that a government can demonstrate the steps it has taken.

IN THE INTERNATIONAL INVESTMENT ARBITRATION claim brought by Philip Morris International against two of Uruguay's tobacco control laws², the arbitrator appointed by Philip Morris, Gary Born, gave a dissenting opinion on certain issues where he disagreed with the outcome of the tribunal award (*see* **Guide 4.2**). Gary Born's dissenting opinion was that Uruguay's Single Presentation Requirement (that only

permits each brand to have a single variant) was adopted without due process or proper consideration of the evidence and was therefore arbitrary and in breach of Uruguay's Bilateral Investment Treaty with Switzerland:

"In my view, **the record does not support** a conclusion that the single presentation requirement ... was preceded by any meaningful internal study, discussions or deliberations at the Ministry of Public Health, or by other Uruguayan authorities...

It is significant that the evidentiary record contains no minutes, agendas, protocols, preparatory materials, memoranda, letters, emails or other documentary evidence suggesting that any meetings, conference calls or other interactions concerning the single presentation requirement ever occurred." [\P 108 - 109] (emphasis added)

The position of the Uruguayan Government was that the policy was properly considered before being adopted and the majority of the tribunal agreed, but the fact that one of the three arbitrators was prepared to find a breach of the Investment Treaty that could have led to huge damages being awarded is a reminder to Governments of the need to follow due process and **keep a record of that process.**

Freedom of information requests

In addition, governments need to be aware that tobacco companies have lodged a significant number of freedom-of-information requests in countries considering plain packaging. These requests can be designed to tie up government resources and to be 'fishing' exercises in preparation for legal challenges. Governments should consider strategies to prepare themselves to respond to such requests, by developing an approach to document management from the outset.

The International Union Against Tuberculosis and Lung Disease have produced a Toolkit with Guides on how to implement the FCTC Article 5.3 and prevent tobacco industry interference: www.theunion.org/what-we-do/publications/english/pubtc Guides-set.pdf

Philip Morris Brand Sàrl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v. Oriental Republic of Uruguay (ICSID Case No. ARB/10/7). The award and dissenting opinion can be found here: www.italaw.com/cases/460