ROTATION OF HEALTH WARNING LABELS:

Research-Based Recommendations for Implementation

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

Institute for
Global Tobacco Control

CONTENTS

Explore multilingual
resources to support
the implementation of
health warning label
rotation, including a
video, policy brief,
and more.

1. Introduction

From top: Examples of plain and standardized packaging on cigarette packs sold in France, New Zealand, and Uruguay, from the TPackSS (Tobacco Pack Surveillance System) special collection.

Search the TPackSS online database.

Health warning labels (HWLs) are highly effective in conveying the health risks associated with tobacco use. For their effectiveness to be maintained, evidence indicates that the periodic rotation of these labels is crucial. Without rotation, HWLs have a diminishing impact over time, known as "wear-out," which can result from general habituation to warnings or specific fatigue with the content.[1] Besides providing novel messaging, rotation can enable more tailored messaging for specific population subgroups.[2] Therefore, regular rotation is essential for maintaining their relevance and impact.

In order to analyze compliance with rotation, we previously examined 24 countries within the WHO Region of the Americas to assess their implementation of the rotation of HWLs, as set out in Article 11 of the WHO Framework Convention on Tobacco Control (FCTC). Our analysis[3] revealed that the majority of these countries have incorporated the key elements recommended by FCTC Guidelines into their national legislation. However, despite the presence of HWLs with pictograms and rotation in these countries, significant challenges persist. The primary challenge lies in the continuous need to update these warnings. Passing new HWLs to prevent message fatigue and maintain their efficacy over time necessitates more than just passing an initial tobacco control law; each new set or round of HWLs requires the introduction of a new legal measure, typically in the form of a ministerial resolution or decree.

Our initial analysis did not enable us to ascertain whether new iterations and rounds were consistently being adopted and if all the other elements outlined in these countries' laws were being effectively implemented on the ground. To gain a deeper understanding of HWL implementation in practice, we conducted interviews with policymakers and tobacco control advocates in six countries. This research aimed to observe and analyze the challenges associated with the practical implementation of rotation of HWLs and provide recommendations for policymakers and international organizations.

2. Methods

We conducted **19 in-depth interviews** in January–March 2023 with government officials and tobacco control advocates from civil society organizations and academia from **six countries:** Chile, Guyana, Indonesia, Jamaica, Mexico, and Vietnam. Each interview had an approximate duration of 30 minutes. The interview guide aimed to explore the effectiveness of HWL regulations, detail the processes involved in their execution, and identify any challenges encountered along the way.

These six countries were chosen as they all meet the basic criteria set out in the Guidelines for the implementation of Article 11 of the FCTC. They all require rotation, set out rotation periods, and number of pictograms per set. Additionally, they all have information available online that allowed us to do the necessary preliminary research before interviewing local key informants. Moreover, given that the original project was based in the Region of the Americas, we wanted the opportunity to look at the three Pan American Health Organization (PAHO) subregions in more depth, with one country in North/Central America, one in South America, and two in the Caribbean. To look at experiences outside of

that Region, we also wanted to focus on two Bloomberg Initiative to Reduce Tobacco Use priority countries in order to have more examples from low- and middle-income countries where at least one iteration of HWLs had taken place.

The six countries analyzed provide a wide range in the number of HWLs, rotation times, and enforcement mechanisms, allowing us to look at different rotation options and mechanisms. Additionally, they find themselves in varying situations regarding the implementation of HWL regulations. Vietnam, Indonesia, Jamaica, and Guyana passed the initial law and have introduced the first iteration of HWLs but have not made subsequent changes since then (although countries in the Caribbean Community and Common Market, or CARICOM, have two rotating sets). In contrast, Mexico and Chile have embarked on multiple iterations, navigating through the entire process several times. This allowed us to explore the different challenges found in the different stages of implementation. Overall, **the overarching objective of these interviews was to compile valuable insights into HWL rotation practices to inform best practices and address potential issues.** Below we will explore the key challenges described by stakeholders and set out recommendations for countries and international organizations.
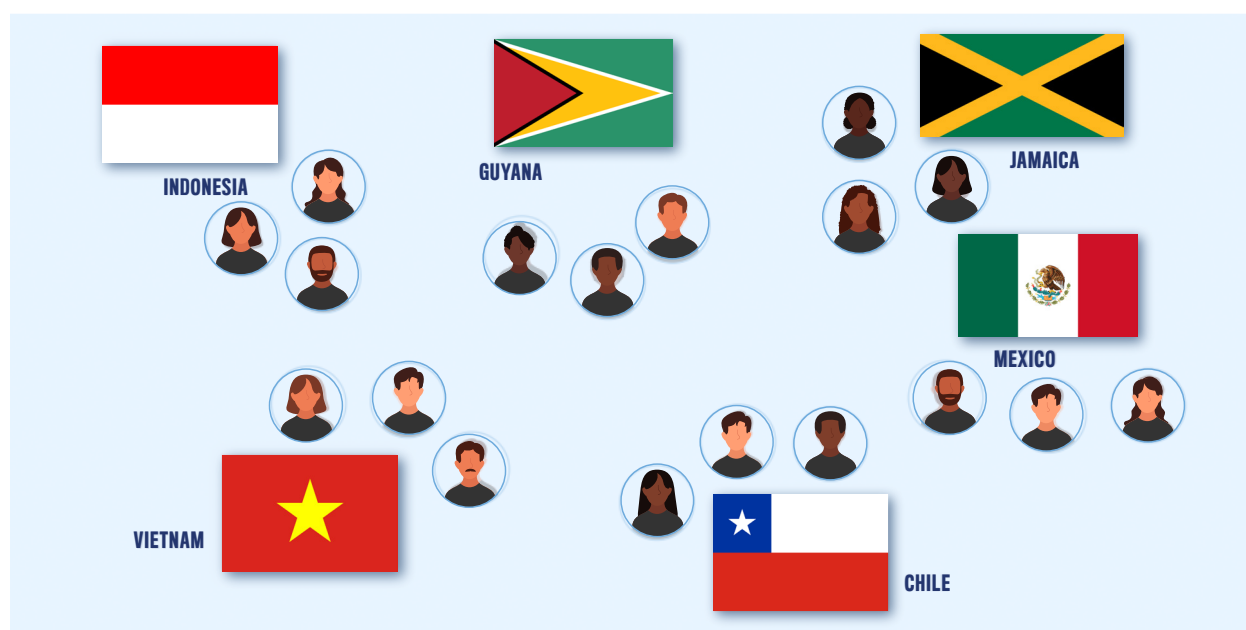
3. Challenges

There are two types of challenges gleaned from the interviews:
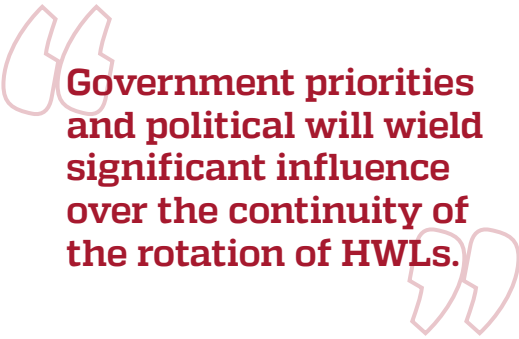
- The first group is those challenges tied directly to the specific nature of HWLs, primarily the need to continue to pass new iterations through a complex legal process.

- The second includes challenges of a broader nature, encompassing issues within the broader domain of tobacco control implementation.

3.1 HWL-specific challenges

3.1.1 Political elements

The introduction of new rounds of HWLs necessitates substantial government involvement. It extends beyond the administration that initially supported and enacted tobacco control laws. As a result, government priorities and political will wield significant influence over the continuity of the rotation of HWLs. Furthermore, transitions in government can introduce additional obstacles that negatively impact rotation.

> "Government priorities and political will wield significant influence over the continuity of the rotation of HWLs."

GOVERNMENT PRIORITIES AND POLITICAL WILL

Tobacco control often receives limited attention within the government and Ministry/Department of Health, partly due to the absence of dedicated resources or personnel specifically responsible for tobacco related matters. Government officials interviewed described being part of larger health teams (e.g., noncommunicable disease departments) or having only one or two people in charge of all tobacco control matters. They added that when working on tobacco control, governments are more focused on issues like regulating smoke-free spaces, advertising restrictions, and taxation and perceive HWL rotation as a complex, costly, and time-consuming endeavor with uncertain immediate benefits. **Even when packaging and labeling are prioritized, the rotation of HWLs tends to rank low in the hierarchy of concerns,** overshadowed by other initiatives such as plain packaging or altering HWL dimensions. Individuals mention that they often do not want to push for new rotation since this might take the focus away from more pressing issues. Others describe that they are currently waiting for bigger changes to their tobacco control laws before working on anything in relation to rotation. Overall, this dilemma of prioritization, coupled with evolving government agendas, limited awareness, and apprehension about complicating legislative processes, creates hurdles in rotating to new HWLs.

CHANGES IN GOVERNMENT

Transitions in government present a unique challenge, necessitating engagement with new leadership that extends beyond the administration where buy-in and knowledge around HWLs were present. Political shifts, including periodic presidential elections, can significantly affect the advancement of HWL implementation due to substantial changes and personnel turnover within Ministries of Health or other relevant offices. During transitions, there may be new personnel lacking prior experience in HWLs or tobacco control more broadly. Moreover, **resource allocation for tobacco control can vary widely from one administration to the next.**

In some cases, **government decision makers may lack a comprehensive understanding of HWL rotation,** resulting in decisions misaligned with the evolving efficacy of warning labels. For instance, in one country, officials reused an image from a previous round, unaware of its diminishing impact due to normalization. Educating and sensitizing new governments on the importance of HWLs and tobacco control measures demands considerable time, which may overlap with the deadlines for rotation. Even if rotation has been successful in previous iterations, the introduction of new administrations may stop all processes.

One interviewee mentioned having iterations last more than 28 and 30 months instead of the established 12 because they could not get the new authority to support a new round.

3.1.2 Time and Bureaucracy

The process of passing new iterations of HWLs is complex and time-consuming. So even though original tobacco control laws may specify a rotation period (normally between 6–24 months), the practical implementation often extends beyond this timeframe. This is due to significant time, financial, and resource commitments required. The bureaucratic process includes various stages, which can include complex bidding processes involving research institutions, the establishment of committees for topic selection, the evaluation of warnings and pictograms including focus groups and other qualitative research, and multistep government approvals by different government offices and departments.

BIDDING

TOPIC SELECTION

COMMITTEE INVOLVEMENT

EVALUATIONS & QUALITATIVE RESEARCH

MULTISTEP GOVERNMENT APPROVALS
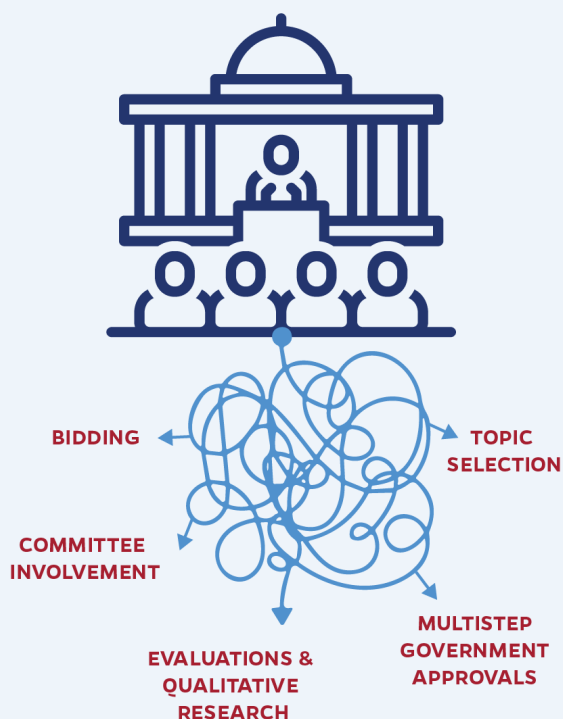
Complex administrative processes can result in extended HWL durations beyond what is legally mandated.

For example, in Mexico, the original law says that HWLs need to be rotated every two years at most. However, individuals mentioned that the whole process of passing a new ministerial resolution may take more than two years. Initially, the government office needs to set up a council of experts to decide the new topics to be explored, the text messages, and the quantity of HWLs. They then must partner with a university or research center to conduct preliminary testing with potential messages and images. This can include focus groups and qualitative interviews to assess messages, images, placement of labels, colors, fonts, etc. After reaching an internal consensus, the Secretary of Health, specifically the National Tobacco Control Office, along with the Office of the Attorney General of Health, proceed to create a Secretarial Agreement. This agreement requires approval from the Secretary of Health, the Deputy Secretary of Health, the National Commissioner against Addictions, and the Commissioner of the Federal Commission for the Protection against Sanitary Risk. This agreement is then submitted to the National Regulatory Improvement Commission. Once approved, it is published in the Official Gazette of the Federation. This whole process can take multiple years. As soon as a round is published, the team in charge must start the whole process again immediately.

With the way the laws are set up and without automated processes, it is almost impossible to have new iterations passed before the deadlines. This is made even more difficult by the lack of an image bank, an issue we explore later. Additionally, as mentioned above, the transition of governments can further affect the rotation schedule, necessitating longer intervals to accommodate the new administration's learning curve. For example, officials in one country mentioned that in a year when a new administration came into power, they needed an extra 12 months to get the new government up to speed. This meant that a new round took 24 months to be passed instead of the legally established 12 months. This complex administrative process can result in extended HWL durations beyond what is legally mandated.

3.1.3 Legal loopholes and lack of clarity

One major issue is the ambiguity in the wording of laws, which leads to varying interpretations by government authorities and tobacco companies regarding the frequency and scope of HWL rotation.

Ambiguity in the wording of laws can lead to varying interpretations by government authorities and tobacco companies regarding the frequency and scope of HWL rotation.

For instance, in Vietnam, the law stipulates that six HWLs should be rotated every two years, but there is a lack of clarity on whether this means all six images must be displayed and rotated within those two years concurrently or continuously or even if each of the six individual images can be rotated once every two years. This ambiguity has resulted in Vietnam using the same HWLs for nearly a decade. Similar issues arise in Indonesia, where the law states that rotation should occur "24 months at the soonest" but lacks clarity regarding a maximum time.

Additionally, during transition periods when new HWLs are introduced, **companies can exploit these ambiguities to delay compliance.** Efforts to change regulations or laws to make them clearer face significant hurdles, including lobbying by the tobacco industry and lengthy legislative procedures.

3.1.4 Finding images

One of the most significant challenges is the difficulty in finding or creating suitable images. This is a costly and time-consuming process that starts with expert groups/committees and government officials deciding on which themes and diseases to focus on and which target groups to prioritize. After these decisions are made, governments must source appropriate images, which is a daunting task. Individuals mention that **it is easy to come up with content and the text portion of HWLs, but it is a lot harder to find images.**

Existing national, regional, and international image banks may not always provide relevant or high-resolution images, and copyright issues can complicate their use. Even large databases (like those of the WHO) and regional databases (like PAHO's) are hindered by copyright and usage restrictions. Individuals mention that many images on these organization's sites are often of low quality and unusable due to low resolution. Even when they are of high quality, legal barriers may prevent national governments from using them. Additionally, these banks are rarely updated, are often repetitive, and lack variety. There are a lot of images in regional or WHO banks that stop being available because decisionmakers in the countries that originally provided the images change and incoming officials decide to stop making them publicly available.
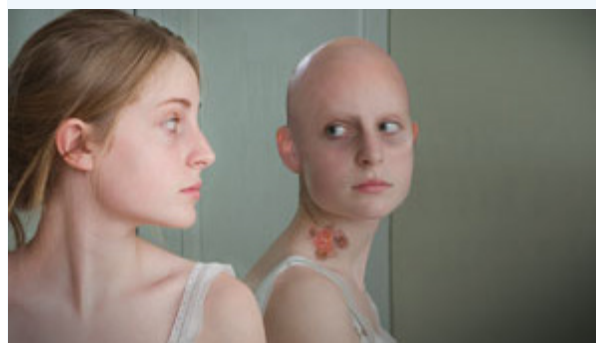
From top: Select images from the WHO Pictorial Health Warnings on Tobacco Products Database, from Bangladesh (2016–2017), Costa Rica (2014), and Indonesia (2017). Rights to images from this database are typically owned by their respective national governments and/or agencies/ministries. Requests for use are fielded by the secretariat of the WHO FCTC.

Sourcing or creating relevant, high-quality images is a daunting process—costly, time-consuming, and complicated by a variety of factors.

Generating their own images is also a complex endeavor. **Creating visuals that effectively convey the severity of health consequences poses logistical, financial, and emotional challenges.** Some individuals described the need to collaborate with local hospitals, academic institutions, or morgues to produce these images. In some countries, efforts were initially made to capture real-life cases, but sensitive issues like the mental health of volunteers and the input of family members made it challenging to find individuals willing to share their experiences. The difficulties in obtaining image donations or the necessary body parts and organs for image creation further compound the challenge. Consequently, **a shift towards crafting fictional yet realistic scenarios has occurred.** Current approaches involve procuring images and enhancing them through software tools like Photoshop or graphic design software.

Despite subpar image quality in existing banks, some countries opt to use available images due to the time and effort needed to find alternatives. In some cases, images can be modified or digitally enhanced to incorporate specific health conditions. Other times, countries cannot find images for the health topic/disease priorities, having to go with less effective solutions or use images that are less impactful.

Additionally, cultural and ethnic relevance is crucial, requiring images that resonate with the local population. Individuals mention that **sometimes images available in international banks do not have diversity,** which would lower their effectiveness. Certain images may not resonate with the local population, making it necessary to create region-specific images. This has worked well in regions like CARICOM, where Guyana officials describe obtaining their images from Jamaica and Suriname.

Apart from budget constraints, interviewees mention that the number of images that a round will have often also depends on the number of available images. Rounds in one country, for example, have varied between 2–6 images, adjusting to the reality of obtaining images that are good enough. Others further describe the extensive effort needed to achieve even three or four images every year or two.

3.1.5 Proper Evaluation

The evaluation of HWLs is critical for assessing and maximizing their effectiveness and impact on specific population groups, but it presents challenges due to its cost and the varying rigor of evaluations.

There are two stages of evaluation: pre-implementation evaluation, when images are being chosen for a new round, and post-implementation evaluation to measure their effectiveness once they have been deployed.

PRE-IMPLEMENTATION EVALUATION

Pre-implementation evaluations involve designing labels that resonate with different population groups, considering factors like gender, age, and health issues. Ideally, evaluations should encompass diverse groups and be conducted before choosing specific images to maximize effectiveness. **Targeting different priority groups, such as youth and women, with relevant images is essential,** potentially necessitating a larger matrix of diverse themes and groups to accommodate varying perspectives and sensitivities. For example, studies suggest that body image is important to teenagers, and explicit images related to severe health consequences like tumors and fetuses are perceived as more effective deterrents for young people. Moreover, there are certain health topics or diseases that differ between population groups. One interviewee mentioned the importance of emphasizing the significant cardiovascular risks associated with smoking and use of oral contraceptives, as it can be a powerful message for women but is often overlooked.

To maximize effectiveness, pre-implementation evaluations should encompass diverse groups and be conducted before choosing specific images.

Explicit images related to severe health consequences are perceived as effective deterrents, as suggested by this pack obtained during TPackSS data collection in India.

It is also important to be aware that different groups may react differently to images and to include this in research and evaluations. For instance, in Chile, a controversial HWL image depicting a fetus with the message "smoking kills your baby" offended various groups, particularly women, and raised concerns about its alignment with broader public policies related to sexual and reproductive health, women's rights, and minority rights.

Overall, research including focus groups, and qualitative studies are valuable tools for assessing the potential impact of warning labels before implementation. However, the rigor and extent of these evaluations vary, with some countries lacking comprehensive assessments and others not carrying them out altogether. **Individuals mentioned that evaluations only take place when the budget allows for it.** Others added

that evaluations were done through universities or public health centers for the first iterations until resources were no longer available.

POST-IMPLEMENTATION EVALUATION

Post-implementation evaluation is vital for understanding how well HWLs are working and whether they are achieving their intended goals. However, it is generally limited or absent in many countries. When conducted, it tends to be at a general level, often assessing the overall effectiveness of HWLs in large surveys rather than evaluating specific rounds or images. This lack of comprehensive post-implementation evaluation can hinder efforts to refine and improve warning labels based on real-world outcomes.

> "
> **A lack of comprehensive post-implementation evaluation can hinder efforts to refine and improve HWLs based on real-world outcomes.**
> "

POLITICAL INFLUENCE ON IMAGE SELECTION

Even when research is available, political actors exercise significant influence in HWL image selection, sometimes overriding evidence-based recommendations. **Government discretion allows political considerations to impact decisions, potentially diverging from public health priorities or research findings.**

3.1.6 Economic and human resources

As mentioned above, the process for HWL rotation is not only time-consuming but also costly in terms of both finances and human resources. While the FCTC sets guidelines for the number of images and the frequency of changes, the practical implementation often depends on budgetary constraints. The majority of interviewees described that apart from political will, the subjective nature of the number and length of rounds ultimately comes down to funding and resources. **A lack**

of financial and human resources often leads to the extension of existing warnings or the reuse of past images, without the novelty and effectiveness of new warnings. For example, interviewees from CARICOM countries, Guyana, and Jamaica, mentioned that they have struggled to pass a new round of HWLs due to limited resources, leading to the prolonged use of the same warnings for almost a decade despite the intention to introduce new ones. The COVID-19 pandemic further exacerbated budgetary issues, causing delays or suspensions in the rotation process.

Creating, testing, and evaluating new images requires financial resources. Inadequate resources hinder the evaluation of new images, making it challenging to determine their effectiveness.

3.2 Broad tobacco control implementation challenges

3.2.1 Tobacco industry interference

Tobacco industry interference is not specific to the rotation of HWLs, but it is also a pervasive challenge in this context. One challenge discussed is the extent of tobacco companies' influence over the selection of images—and while less common today, concerns persist where such practices may endure. Individuals in Indonesia and Vietnam mentioned that civil society organizations still perceive that ministries consult with the tobacco industry when making these decisions, raising concerns about undue influence. Some individuals mentioned that after consulting with the tobacco industry, Ministries of Industry or Trade have picked lower-ranked warnings or weakened versions of the images. This is aggravated by **conflicting interests** that may exist among various ministries involved in the legal process. For example, Ministries of Industry and Trade may have different goals than the Ministry of Health.

> **Lobbying, influence, and tactics by the tobacco industry to minimize HWL impact pose pervasive challenges.**

Industry lobbying practices also come into play, with tobacco companies arguing that HWL images are overly aggressive or damaging. Legal challenges have arisen in several countries, where individuals have filed lawsuits against specific HWL images, causing delays and resource expenditure. Tobacco companies' insistence on using locally sourced images further complicates the process, as they claim foreign images may not be directly applicable to the local context. While this is not based on science or evidence, **some countries prefer to find local images to avoid industry's arguments** to receptive government offices, leading to demands for locally sourced images and further delaying the process.

In some instances, tobacco companies also have discretion in selecting HWLs for specific products or store locations (e.g., rural vs urban) to make them less impactful. For example, they will use an image targeted for older adults with a product aimed primarily at youth. Moreover, to minimize the impact of the images, the industry employs tactics to make them less visible or distracting, including varying images or modifying design elements to draw consumer attention away from the warnings.

3.2.2 Enforcement

Both the FCTC and national laws outline specific enforcement requirements, primarily concerning equal distribution of HWLs on retail packages and the transition period between rounds. Individuals mentioned varied levels of enforcement by country. In cases where there has only been one iteration of HWLs, enforcement focuses on ensuring the required warning is displayed on packs, a relatively straightforward task. Additionally, in countries where all tobacco products are imported, like in the CARICOM region, it is easier to conduct random checks at the point of entry to ensure an equal distribution of HWLs in each pack and the proper placement of new labels. **The broad challenges in enforcement stem from limited resources,** including a shortage of enforcement agents and competing priorities within government agencies. Some countries or regions lack specialized health inspectors dedicated solely to tobacco-related issues, meaning they often must prioritize broader health inspection duties that extend beyond tobacco control. Even when doing tobacco-related inspections, they often have more pressing responsibilities, such as enforcing smoke-free spaces.

Interviewees mentioned that it would be very easy for tobacco companies to not comply with this rule as it is not being checked for in any of the countries analyzed. This would mean that if a round had four HWLs, it would be easy to have the "worse" or most "damaging" image only on 5–10% of products versus the required 25%.

> **While regulations stipulate that HWLs should be equally distributed among products and brands, it is nearly impossible to monitor and enforce this requirement effectively.**

TRANSITION PERIODS

Overall, individuals mentioned that larger cities and urban areas quickly see changes in rounds, although old products can usually still be found months after in more rural areas. Individuals mentioned that there are no ways to supervise this phenomenon.

Inspections occur both at the manufacturing facilities and at the country's entry points for imported tobacco products to ensure that old HWLs are no longer being produced or in rotation. However, **the tobacco industry sometimes inundates the market with products featuring old warning labels before new regulations take effect,** posing challenges to effective enforcement.

Verification processes, though sporadic, are primarily conducted at the factory level, especially during the initial days of a new round of regulations. Health inspectors visiting production facilities must ensure that the printing plates are producing the new pictograms and not the old ones. However, in theory, as mentioned by both government employees and civil society members, manufacturers could produce significant quantities with old plates on the last day of their validity and flood the market with products featuring outdated warning labels for several months. **Because legally the industry is not currently responsible for getting old stock off the shelves at the point of sale, old HWLs can remain for a long time.**

Tobacco companies employ a variety of tactics to make HWLs less visible or distracting, as revealed by multiple compliance studies conducted by the Institute for Global Tobacco Control (IGTC).

Browse IGTC fact sheets and resources.

EQUAL DISTRIBUTION OF HWLs

Individuals mention that while regulations stipulate that HWLs should be equally distributed among products and brands, it is nearly impossible to monitor and enforce this requirement effectively. To check compliance, one would have to visit both individual factories and points of sale, take samples, and inspect the cartons. **This approach is highly impractical and made impossible by constraints in human and financial resources.**
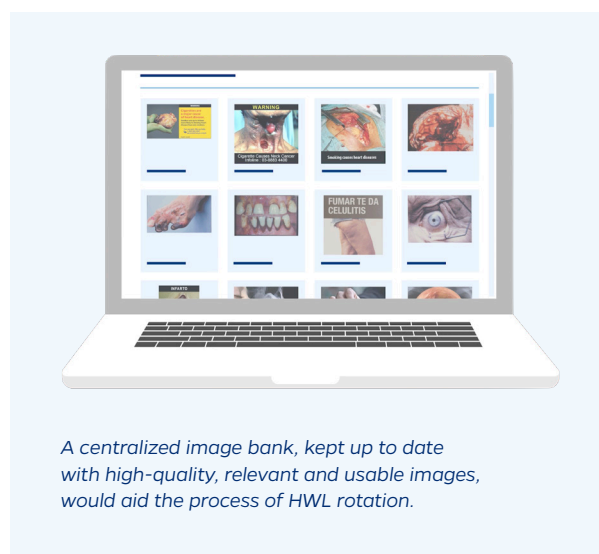
4. Recommendations

Having every country do all the necessary work for the successful implementation of HWL rotation is not realistic, especially given the financial and logistic hurdles described above. However, there are a few **significant things that can be done at the international (e.g., WHO) or regional level** to assist all countries and make a substantial impact.

4.1 Image banks

The biggest challenge mentioned by all participants is the lack of usable image banks. **To improve this, and in keeping with FCTC/COP3(10),[4] it should be the responsibility of the WHO and, in the cases of existing regional image banks, that of the respective regional offices to:**

- **Invest in comprehensive international and existing regional image banks:** Develop a comprehensive repository of images that represent diverse populations and have demonstrated effectiveness across various countries. Images in these banks should have formal qualitative evaluations prior to them being uploaded and should tackle a variety of health topics addressing diverse groups and populations (e.g., youth, women). This will allow for countries to shift the focus from using whatever images are available to selecting those that have had proven impact. The repository should include images with the necessary permissions, ideally without copyright constraints, and allow countries to adapt images to suit their specific contexts.

- **Have ethnically and culturally relevant images:** Images in the WHO and existing regional banks should be sourced and evaluated in countries within the region and reflect the different ethnicities and cultural components present. If an international WHO image bank is prioritized, it needs to contain a large variety of images that have been evaluated and created from multiple regions. This is especially relevant for regions that do not have their own image banks.

- **Keep databases up to date:** Ensure images are still publicly available and of high quality.

A centralized image bank, kept up to date with high-quality, relevant and usable images, would aid the process of HWL rotation.

- **Ask countries to eliminate restrictions in their national databases:** This includes creating agreements allowing countries to access and use images from other nations freely. Moreover, regional bodies should simplify the process of obtaining permissions for image usage, especially when images are owned by private companies. Further, make the process to rescind approval for existing images cumbersome so that incoming administrations do not prevent others from using their images.

- **Provide support:** Provide resources to countries for creating local images when needed.

- **Explore artificial intelligence:** Research the possibility of using the growing AI space to develop images.

With an image bank in place at an international and/or regional level, there are two areas where countries should focus their national efforts: institutionalizing the process and setting out several future rounds.

With centralized support in key areas, countries can overcome financial and logistical barriers to successful implementation of HWL rotation.

4.2 Institutionalizing the process of HWL rotation

Ensuring the continuity and success of HWL rotation necessitates minimizing their reliance on political will and available resources. This is especially crucial considering that changes in government can potentially disrupt the progress made. To address this challenge, several strategic approaches can be implemented.

In the legal arena, exploring avenues for making regulatory changes related to laws without the need for issuing new warnings through a cumbersome legal instrument can streamline the process. Additionally, the formal creation of an expert group dedicated to streamlining the selection of images and themes for HWLs can significantly cut down on delays and uncertainties. Members of the expert group should not have any ties to the tobacco industry and related industries. Regarding the overall structure of the HWL rotation process, **the goal should be to reduce the dependency on political will and available resources.**

Countries should focus their efforts on streamlining their processes: minimizing dependency on political will and available resources, clarifying details around rotation frequency and number of variants, and working ahead to ensure continuity of the HWL rotation process.

This can be achieved by delegating responsibilities to stable government institutions, or those with established processes, such as decentralized and autonomous bodies like Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS). Decentralized bodies may have a stronger institutional memory and be more stable during political changes compared to government agencies controlled by the executive branch, thereby mitigating vulnerability to external factors.

Furthermore, securing adequate financial and human resources through legislative or executive actions for the rotation process is essential. This includes developing fixed funding plans and transparent strategies for resource allocation, addressing the constant competition for resources. Allocating budget resources for the regular determination of health topics and pictograms, evaluation and committing to consistent processes—rather than leaving them to discretion—enhances institutionalization and ensures greater consistency.

4.2.1 Closing legal loopholes

As part of the institutionalizing process, governments should aim to close legal loopholes, including:

- Addressing ambiguities in the wording of regulations, such as clarifying when and how image rotation occur. For example, ensure that the language specifies whether "rotate five" means (a) having five images at once and then bringing in five new ones to rotate or (b) rotating one of those five at a time.

- Avoid vague terms like "at the soonest." Instead, replace them with phrases like "at the latest" to hold the government and tobacco companies accountable and empower civil society to advocate for timely image rotation.

4.2.2 Setting out several rounds within one legal instrument

Countries should set out multiple rounds of health warning images within a single regulation or legal instrument to maximize resources. For example, Mexico's newest approach is having a total of 12 images, rotating four images every six months for a total duration of 18 months. This strategy allows for some flexibility and breathing room in implementing new images, like CARICOM's two-schedule approach, where each schedule of images is in place for 12 months (plus the transition period), providing a 24–month period before new images need to be put in place. By doing the heavy lifting of the rotation process, including research and evaluation and the administrative approvals all in one go, governments can spend more time ensuring the images are as effective as possible and having a larger break before having to start the process again. With a regional/international image bank available, countries could set out even more rounds within one

legal instrument. **We recommend that countries pass enough sets of warnings to rotate for a 10–year commitment,** following FCTC Guidelines and research (between 12–36 months and 8–12 warnings per set). If countries are unable to produce a new cycle of HWLs at the end of ten years, countries could potentially start at the beginning of the cycle.

Multiple rounds of health warning messages and pictograms are included in the Mexico Ministry of Health Agreement on Health Messages and Information to Appear on Packaging and Labeling (March 1, 2023 to August 31, 2024).

4.3 Additional recommendations

For countries that may have the budget or resource capabilities or for those that wish to prioritize HWLs rotation before an image bank is in place, we have set out the following additional recommendations.

4.3.1 Establishing Partnerships

Establishing strategic partnerships can significantly enhance various aspects of the HWL process, from image sourcing to research and evaluation. Countries should consider the following approaches:

- **Establishment of a permanent expert group/council:** Creating a permanent council that includes representatives from civil society, academia, government, and

other relevant stakeholders can provide institutionalized oversight across different stages of the HWL process, including pre- and post-implementation evaluation.

- **Collaboration with academic institutions and health centers:** Partnering with academic institutions can enable countries to tap into the expertise of researchers and scholars and lower costs. Collaborating with hospitals and other relevant institutions can provide access to a broader range of impactful visuals for images. This diversity in image sourcing can enhance the ability of HWLs to convey critical health messages effectively and resonate with a wider audience.

- **Requesting international support:** Countries should secure budgets for HWL rotation in their own budget allocations. However, for countries that do not have the budget or resource capabilities, we recommend seeking technical support from international organizations, like the WHO and regional bodies, to support the HWL process—primarily, research and evaluation. This technical support can be instrumental in conducting comprehensive and insightful assessments of HWL effectiveness.

4.3.2 Country-to-country coordination or use of regional bodies

Promoting country-to-country coordination and leveraging regional bodies like WHO regional offices or trade blocs (e.g., MERCOSUR, CARICOM, ASEAN) offers several benefits, including the sharing of best practices, resources, and images among neighboring countries within a region.

- **Establish regional designated roles:** One option is having regional networks where countries share similar populations and designate specific roles for participating countries, allowing them to learn from one another's experiences and streamline the HWL implementation process. For instance, one country could focus on conducting evaluations, while another could specialize in creating the actual images, facilitating the sharing of these images among all the participating countries. In the Caribbean region, for example, CARICOM already serves as a mechanism that enables countries to collaborate effectively on tobacco prevention and control and has allowed lower-

income CARICOM members to use images from other member states, which they would not have been able to obtain on their own.

- **Utilizing existing resources:** Newer countries starting rotation efforts are advised not to reinvent the wheel but to use existing resources and collaborate with other countries in the region to streamline their process.

4.3.3 Improving enforcement

To address the enforcement issues during and after transition periods, governments should consider shifting the verification process from the manufacturing point to the point of sale in countries where manufacturing occurs in the country. This change aims to improve control and prevent older warning labels from circulating for an extended period after new regulations come into effect.

Countries should add legal obligations for the tobacco industry—to make them responsible for getting rid of product with old HWLs from stores and points of sale.

4.3.4 Allow for flexibility

Flexibility in selecting and updating warning images helps ensure that the warnings remain relevant and impactful, especially

when addressing evolving public health issues. For example, Mexico was very successful in incorporating timely issues such as the COVID-19 epidemic into their warning labels. Therefore, **it is important to be able to have the ability to introduce new images if they are timely.**

Introducing timely images and messaging requires flexibility and bolsters HWL impact and relevancy, as demonstrated by this COVID-related health warning mock-up from Mexico.

4.3.5 Improving evaluation

A critical aspect of rotation involves conducting evaluations at different stages of the process and sharing this data within networks. By systematically evaluating the impact of specific images on different populations and making this information publicly accessible, countries can gain valuable insights into the effectiveness of HWLs. Until this is done at an international or regional level for an evaluated image bank, countries should try to conduct as much evaluation as possible and share it with other countries.

At all points of evaluation, **countries should aim to reduce political and industry interference.** First and foremost, it is imperative to completely exclude the tobacco industry and related industries from any involvement or interference in the HWL selection process, as well as in any legislative or regulatory process. Additionally, Ministries outside of the Ministry of Health should also be kept out of this process to prevent undue influence.

Secondly, countries could create a dedicated working group responsible for HWL evaluation. This group should consist of representatives from civil society, government institutions, academia, and other relevant entities. The selection of HWL images and messages should rely on two main criteria: input from focus groups and other qualitative research and assessment by a panel of national experts, including health institutes, academic institutions, and international organizations.

PRE-IMPLEMENTATION EVALUATION

Specific recommendations for different parts of the evaluation process are as follows:

- Incorporate research and focus groups into an institutionalized evaluation process.

- Evaluate images with consideration for diverse population groups, including youth, different genders, and rural vs. urban populations, to account for the possibility of people who do not currently smoke but who may do so in the future. For example, one of the significant successes in Chile was the introduction of a series of sequential messages, telling the story of a woman's journey from being diagnosed with cancer due to smoking through to her death. This was particularly significant because it marked the first time images tackled the impact of smoking on women's health other than pregnancy. Further, this addressed a significant issue in Chile where smoking among women was a growing concern.

Chile's 2022 HWL rotation included images aimed to discourage consumption among young people, a priority population group. (Photo credit: PAHO/WHO)

- Explore the possibility of conducting a large comprehensive image evaluation project that encompasses a diverse range of images. By doing so, a substantial image bank can be established that serves as a valuable resource for future label rotation. This approach minimizes the need for subsequent smaller evaluations and can benefit both that country and others by expanding the available image pool.

POST-IMPLEMENTATION EVALUATION

- Collect feedback through public polls periodically to gauge the effectiveness of specific warning labels on the public.

- Use evaluation data from the current iteration to inform the development of future health warning labels.

Limitations:

A potential limitation of this study was the sample size and selection. While the countries were selected to represent diverse conditions and systems, the relatively small number of interviews may limit the generalizability of the findings. Interviews from other WHO regions (e.g., EURO, AFRO, and EMRO), could strengthen the study and provide additional best practices.

References:

1. World Health Organization. Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products). 2008.

2. Hammond D. Health warning messages on tobacco products: a review. Tob Control. 2011 Sep;20(5):327–37.

3. Alonso F, Welding K, Cohen JE. Laws and regulations governing rotation of health warning labels on cigarette packs in the Region of the Americas. Washington, DC: Pan American Journal of Public Health; May 2022; Vol. 46: e123.

4. World Health Organization. Decisions: Conference of the Parties to the WHO Framework Convention on Tobacco Control, Third session, Durban, South Africa, 17-22 November 2008 [Internet]. FCTC/COP/3/DIV/3. Feb. 2009. Available from: https://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf

Accompanying Resources:

Explore multilingual resources to support the implementation of health warning label rotation, including a video, policy brief, and more.