Developing Regulatory Strategies

1. Overview

Significant regulatory developments will take place over the next few years in most of our markets, driven principally by the WHO's Framework Convention for Tobacco Control (FCTC).[1] While regulation poses challenges to our business, it also presents significant opportunities. Rational science-based and comprehensive regulations based on the principle of harm reduction can provide a solid basis for future growth, benefiting PMI by establishing clear rules governing the manufacture, marketing and sale of tobacco products and providing a platform for our investment in research and development and product innovation.

In light of the inevitability of regulation across all of our markets, its importance to public health and, its potential to drive our long-term business success, markets must develop and execute holistic regulatory strategies. Regulatory strategy is as important as portfolio management, sales strategy, consumer innovation and other core components of the markets' business plan. In the past, markets have relied heavily on functional "experts" in HQ (CA, R&D, Operations), particularly in the area of product regulation. HQ will continue to provide advice, guidance and training to assist the markets. However, regulatory strategy is a business strategy, and line management is responsible for understanding, developing and executing appropriate market plans for regulation. During market reviews in 2007, therefore, markets will be expected to present a detailed regulatory strategic plan. Plans must be proactive and must include clearly defined objectives, milestones, and specific actions.

In developing strategies, markets should take into account global and regional trends in regulation, as well as PMI's overall objectives. Even though all elements of the regulatory framework we seek may not be feasible in every country today, markets should consider how to move regulation towards our desired objectives, addressing both public health and our business goals.

Importantly, although PMI's goals are aligned in many respects with public health views, we do not and will not support regulations that would deprive us of our ability to compete fairly with other tobacco product manufacturers or deprive adults of the ability to buy and use tobacco products. Nor will we accept proposals that are likely to raise unintended consequences which are neither good for public health nor for the legitimate tobacco industry, such as increasing the demand for illicit products.

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[1] As of March 2007, 145 countries have ratified the Convention, including most of our major markets. Many governments have already introduced and/or enacted legislation that incorporates existing provisions of the FCTC. In that regard, although several provisions of the Convention are quite specific (e.g., health warning requirements and marketing bans), we expect the Conference of the Parties (the governing body of the FCTC) to elaborate further rules in specific areas of regulation in mid-2007 and in 2008. These rules (either in the form of guidelines or protocols/amendments to the Treaty), will likely be adopted in most of our markets. The second meeting of the Conference of the Parties will take place in Bangkok from June 30 to July 6, 2007. We now expect that "recommendations" rather than official guidelines will be issued in the area of product regulation, but formal guidelines are expected in other regulatory areas covered by the Treaty, such as illicit trade.

4) Pack size restrictions

Our objective is to support the implementation and enforcement of laws that mandate that cigarettes, regardless of pack size, are not accessible to minors and that consumers are adequately warned about the serious health effects of smoking. As long as adequate sales supervision and access controls are in place, the size of the pack should not be a material factor in preventing youth smoking.

Specific Actions to Consider

- Based on your market dynamics, including competition and ability of enforcement, consider proposing pack size limitations.[15]
- Propose that where stick sales are a large part of the market, governments:
    - mandate that retailers and street vendors provide sticks in pouches or cardboard folders that bear health warnings (such pouches and containers could be provided by manufacturers), and
    - implement and enforce youth access measures.
- Where bans on single sticks are proposed in markets with significant single stick SOM, work with government on implementation and enforcement.

[15] It is appropriate to note that the public health community supports pack size limitations, and that while we do not agree that the size of the pack alone determines youth smoking incidence (especially if youth access rules are rigorously enforced), we have decided to support size limitations.

5) Marketing restrictions

Our principal objective is to retain the ability to communicate at points-of-sale and through direct communications to our adult consumers. Bearing in mind that most countries, following the text of the FCTC, will seek to ban all forms of tobacco product advertising and marketing, markets should pursue a strategy of supporting significant restrictions on general communications, striking the right balance between restricting marketing and permitting direct communications to adult smokers. Markets should, however, consider whether retaining POSM, direct communications or other forms of marketing are essential for business objectives in light of local factors.

Specific Actions to Consider

- Propose health warning requirements in all tobacco advertisements.
    - As with health warnings on pack, the government, not manufacturers, should decide content, placement, size, colour, and font.
- Seek a ban on television, radio, cinema, print, out-of-home, and/or other forms of communication visible to the general public.
- Seek to preserve POSM in general access retail, such as kiosks, convenience stores. Where a POSM ban is proposed consider:
    - Restrictions, as opposed to a ban, which could include limitation of POSM to certain sizes and/or numbers per store, bans on outward facing POSM, and/or limiting POSM to the sections of the retail shop where tobacco products are sold.
    - A general exemption for tobacconists and/or points of sale where access is restricted to adults.
- Propose explicit legislation/regulation permitting direct communications (communications by the market to an adult consumer through internet, mail, electronic mail, telephone, in home, in LAMPs, etc.) subject to reasonable age-verification processes.
- Where measures to ban specific one-to-one communications are proposed, raise alternative measures, such as regulated access requirements, and educate regulators, raising awareness of the control mechanisms we have in place to restrict communications to adults.
- Propose regulations requiring (or permitting) communication of product information either through tobacco-specific regulation or regulation governing consumer goods in general.
- Seek to preserve "switch selling" and product trial to adult smokers.

- Obtain an exemption for communications for next generation products, subject to review by a competent regulator based on scientific data. (*see discussion on regulation of next generation products below*)

- Maintain the ability to communicate to the trade.

6) Point of sale display bans

Our objective is to maintain the right to display the product at retail.[16] The display of product at retail is the most basic way consumers learn about products, and it is a fundamental means of competition among manufacturers. Moreover, adult smokers should be able to learn about, see, select, and find the brand or brands they prefer in retail outlets. Markets should note, however, that excessive product display can trigger action to ban point of sale display entirely.

Specific Actions to Consider

- Seek to exclude product display from the definition of "marketing" or exempted from restrictions on tobacco marketing.[17]
- Where bans are proposed or likely to be proposed, markets should:
    - Consider the purpose of the proposed ban. If, as in some markets, the intent is to address youth access, propose alternative measures.[18]
    - Propose alternative measures, such as limiting the total size of product display and/or the number of pack facings permitted in each shop.[19]
    - Propose a provision permitting retailers to display tobacco price lists with images of pack, and defend the ability of retailers to communicate to adult consumers about products.
    - Propose an exemption for tobacconists/tobacco specialty stores and/or shops that limit entry to adults.
    - Propose an exemption (if necessary) permitting display of products on age-restricted internet sales sites.

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[16] Several Canadian provinces, Iceland, and Thailand have effectively banned display of tobacco products at retail. Turkey proposed placing product in closed cupboards (subsequently withdrawn), Norway has introduced a proposal to ban display, and Ireland is in the process of implementing a ban. More countries will follow this trend, which is being advocated by public health groups who view product display as an alternative form of advertising.

[17] For example, the Swedish Tobacco Act exempts from marketing restrictions "*marketing which consists only of offering tobacco products available for sale.*"

[18] In Turkey, proposed legislation to require tobacco products to be kept in closed cupboards in retail was intended to ensure that products were not visible to youth outside shops and not within reach of youth inside shops, either from open counter-top secondary pack displays or unattended carton displays on open shelving in hyper-markets. The market proposed an alternative that met the legislators' objectives while still allowing display: (1) a prohibition on self-service displays, and (2) a prohibition on displaying product in a way "likely to be seen from the outdoors." The amended legislation is still pending in Parliament.

[19] Appendix B is a presentation outlining PM Australia's approach to point of sale display bans raised in some Australian states.

- Consider the basis to oppose product display bans, working with the Law Department to develop legal arguments and, if necessary, pursue litigation to preserve the right to display products

7) **Generic packaging**

Our objective is to protect our ability to use trademarks/brand imagery and colours on our packaging.[20] Relegating tobacco product packaging to a black and white format would strip manufacturers of their trademarks and their property rights. If a market is faced with a proposal for generic packaging the market should work closely with the Law Department and HQ/Regional CA.

Specific Actions to Consider

- Support legislation that defines advertising in a manner that excludes packaging (and oppose definitions that explicitly include packaging as prohibited "advertising").[21]

- If generic packaging is proposed, develop defensive briefs using legal and policy arguments, incorporating IP, competition and trade arguments.

    - Consider alternative legislation that would ban picture packs/special editions, and grandfather trademarks/trade dress registered as of a specific date.

    - Markets that face proposals for generic packaging should consider limiting their use of special picture packs.

[20] Some groups are raising generic packaging, arguing that colours and pack designs are means of "advertising." See Framework Convention Alliance's proposal for generic packaging legislation, stating:

> "By making packaging unappealing to consumers, the objective of generic packaging is to 'denormalize' tobacco product use and prevent the tobacco package from being an alluring advertisement .... Packages should be required to be generic both inside and outside." *fctc.org/modelguide/lsection08.html*

[21] This approach was taken for example by Australia's Tobacco Advertising Prohibition Act 1992Tobacco Advertising Prohibition Act 1992, Art. 9.2.: "Words, signs or symbols that appear: (a) on a tobacco product; or (b) on the packaging of a tobacco product... do not, when so appearing, constitute a tobacco advertisement...."

8) Regulation of conventional products

Our objective is to obtain science-based regulations for conventional tobacco products that create an integrated and systematic evaluation of tobacco products, applying equally to all manufacturers and all products.[22] Regulation of conventional products can benefit public health, establish a level playing field by imposing strict standards for all manufacturers and products, and is an essential basis for regulation of next generation products with the potential to reduce exposure and/or risk

However, product regulation has the potential to significantly alter our conventional brand portfolio, and a crucial objective, therefore, is to protect our ability, within a public health-based regulatory framework, to continue to manufacture and market conventional products that are acceptable to adult consumers. Markets should consider taking action in each area of the following areas of conventional product regulation, recognizing the challenges involved, as well as the opportunities – and, importantly, the ability of local governments to implement and enforce complex product regulations, as well as your market's and PMI's capacity to comply with new regulatory requirements:

- Regulation of ingredients
  - Definition of ingredients
  - Ingredients reporting
  - Assessment and approval of ingredients
- Regulation of smoke constituents (T, N, CO and other smoke constituents)
  - Testing and reporting
  - Performance standards/ceilings
- Other aspects of conventional product regulation
  - By-brand testing of sidestream smoke constituents
  - By-brand smoke toxicity testing
  - Disclosure, testing and performance standards for tobacco blends
  - Regulation requiring disclosure of product design
  - Regulation governing packaging materials
  - Laboratory standards
  - Good manufacturing practices

[22] See PMI's TobReg Submission at pages 1-2 (discussing PMI's support of product regulation).

a) Regulation of ingredients

Our objective is to maintain the ability to use flavouring ingredients in our products, provide ingredient information in a manner that defuses the controversy surrounding the transparency of ingredient information, and to obtain science-based regulations for the assessment and approval of ingredient use.

Although we believe regulators should have the authority to ban ingredients, bans of ingredients must be based on objective scientific data.[23] A ban on ingredients could have a disproportionate impact on PMI's portfolio, given our reliance on American blended products, which use higher levels of ingredients than Virginia brands, notably sugars, cocoa and liquorice ("burley casing").

Markets should consider ingredients regulation in three distinct, but interrelated, parts: (1) the definition of "ingredients," (2) reporting requirements, and (3) assessment and approval.

Definition of ingredients

The definition of "ingredients" will determine our disclosure and assessment obligations and capabilities, and can significantly alter the complexity and burden of ingredient regulation without providing additional public health benefits. Our objective is to have ingredients defined as the term is commonly understood: substances added to tobacco and to NTMs. Other items and substances, such as tobacco blends, chemicals in packaging materials, and residues of crop protection agents, should be regulated separately.

Specific Actions for Consideration

- Seek a definition of ingredients similar to the one proposed in PMI's TobReg Submission. [24]
- If broader proposals are made, propose that other elements included in the definition (*e.g.*, tobacco blends, packaging materials, and CPA residues) are regulated through other provisions of tobacco regulation.[25]

Ingredients reporting

Our objective is to provide governments and consumers with detailed ingredients information, while protecting our valuable brand recipes. Ingredient disclosure has

[23] Public health officials, including WHO, continue to allege that certain ingredients increase the toxicity and addictiveness of tobacco products. Although we do not believe the data support these allegations, we expect regulators to attempt to ban certain ingredients. Indeed, some public health groups have proposed banning any ingredient that makes a product more palatable or contributes to taste, which they contend contradicts the public health goal of reducing tobacco consumption. A full discussion on ingredients regulation is provided in PMI's TobReg Submission at pages 29-42.

[24] See PMI's TobReg Submission at page 29-30.

[25] See PMI's TobReg Submission at page 29-30.

become a serious point of contention and is inhibiting our ability to engage on other product issues in the European Union.

Our strategy is to propose (and in many markets voluntarily provide) detailed and publicly available ingredients reports using a "three-list" format.[26] While many governments have accepted this format, governments in the EU, as well as the European Commission, have rejected it. As a result, we are planning to make full-by brand disclosures to EU governments and the Commission, using state-of-the-art digital rights management technology and negotiating, where appropriate, undertakings from governments to ensure maximum trade secret protection.

Specific Actions to Consider

- Consider voluntary ingredients reports to the government and to the public (via the internet) using the three list model prior to legislative action.
- Make certain that legislation contains a provision protecting trade secrets, especially ingredients used in innovative products.[27]
- Propose the three list model as part of the legislation or regulation.
- If the three list model is rejected *and* proper assurances of confidentiality can be obtained, support the EU-style disclosure. Check with the Law Department and HQ CA prior to making this suggestion.
- Maintain the ability to disclose NTM ingredients as a composite report, rather than by-brand, as we often use different suppliers (and therefore different ingredients) for the same brand sold in a single market.[28]

Assessment and approval of ingredients

Our objective is to obtain science-based standards for assessing and approving the use of ingredients. We agree that regulators should have the ability to ban the use of ingredients that *increase the inherent toxicity or addictiveness of tobacco products*. But we disagree that a ban can be based on palatability/taste or other subjective criteria.[29]

Specific Actions to Consider

- Pursue disclosure of ingredients as discussed above.
- Engage with local regulators, scientists and public health officials to explain how we assess ingredients and the reasons why we use ingredients, sharing

[26] The three list format provides by-brand information for high-use ingredients, a list of all ingredients for all brands (including low-use flavours (*e.g.*, aftercut flavourings)), and a list of all ingredients in NTMs. See PMI TobReg Submission at page 30-31.

[27] See PMI's TobReg Submission at page 31.
[28] See PMI's TobReg Submission at page 30.

[29] See PMI's TobReg Submission at pages 32-42.

our toxicological data that shows that ingredients at current use levels do not increase the overall toxicity of tobacco products.

- Recommend regulations that require science-based toxicity testing methods, based on the proposal in PMI's TobReg Submission.[30]
    - Specific requirements should be flexible, but at the same time meaningful, requiring all manufacturers for all products to follow the same high standards PMI uses today.
- Alternatively, suggest that regulators wait for the development of international standards or recommendations from the Conference of the Parties.[31]
- Secure a standard for approval and banning of ingredients that is based on whether an ingredient increases the inherent toxicity or addictiveness of tobacco smoke.[32]
    - A ban must be based on scientific data establishing that it will benefit public health.
    - Propose that regulators are not permitted to ban ingredients based on "addictiveness" until internationally accepted science-based methods for assessing "addictiveness" are adopted.[33]
    - Oppose standards that permit prohibitions based on palatability or taste.[34]
    - Seek alternative standards or specific exemptions for:
        - flavour ingredients in next generation products (subject to regulatory review by a regulator based on scientific data) [35]
        - ingredients necessary for the manufacturing of our products, such as humectants.[36]

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[30] See PMI's TobReg Submission at pages 34-40 ("A Model for Assessing Toxicity").

[31] This, however, has the potential of delaying meaningful regulation and/or risking non-scientific and prohibitive rules.

[32] See PMI's TobReg Submission at page 32 (quoting the U.S. Institute of Medicine's 2000 Report) (ingredient toxicology should be conducted "with the objective of identifying those ingredients that add no significant toxicity to tobacco products and therefore can be considered safe in the context of its use.")

[33] See PMI's TobReg Submission at pages 39-40.

[34] See PMI's TobReg Submission at 41-42. We are marshalling the best scientific and public policy arguments to support our positions, including, for example, data that show no significant differences in toxicity between brands with and without ingredients, and no differences in overall smoking incidence, youth smoking incidence, and cessation rates in markets dominated by American blended products as compared to Virginia markets, where the majority of brands have no or virtually no added flavour ingredients.

[35] Some public health experts have noted that in order to reduce harm, next generation products must be acceptable to adult smokers. Flavourings may play an essential role in consumer acceptability and thus harm reduction. See PMI's TobReg Submission at page 74.

2. PMI's Regulatory Objectives

PMI core regulatory objectives, listed below, should form the basis of each market's strategy.

- Maintaining our ability to manufacture and sell conventional products that meet our consumers' preferences (*e.g.*, ability to use ingredients and reasonable smoke constituent ceilings).
- Achieving equitable fiscal measures that are integrated with public health policy and do not result in excessive tax increases or merely drive consumers to lower taxed, therefore lower-priced, products.
- Maintaining our ability to communicate to adult smokers.
- Obtaining science-based product regulations based on the principle of harm reduction and establishing product standard and requirements for testing and reporting and thereby establishing a level playing field.
- Obtaining comprehensive and fully enforced measures to prevent youth smoking.
- Keeping the "door open" for tobacco next generation products with the potential to reduce exposure / risk (*i.e.*, regulators should have the authority to grant exemptions from regulatory restrictions on conventional products for next generation products).
- Establishing regulatory frameworks for the assessment, approval and marketing of next generation products.
- Restricting public smoking, while maintaining adult smokers' ability to enjoy our products in some public venues, and preserving the right of adults to smoke in private places and outdoors.
- Obtaining comprehensive and fully enforced measures to prevent illicit trade.

3. Market Specific Strategies

In addition to PMI's overall objectives, markets should take into account local factors including, public health objectives in the market, business objectives, product portfolio, and competitive factors. Local strategies must address the following issues:

- Government expertise and capacity – Is the existing governmental/regulatory infrastructure in the country sufficient to support comprehensive tobacco regulation? Is the government capable of understanding and implementing complex regulatory issues? If not, how can the needed expertise and capacity be developed?

- Standard must take into account the concept of commercial and technical feasibility – i.e., if the standard results in products that are not acceptable to adult consumers or are impossible to manufacture, it results in *de facto* prohibition.
- Interested parties, including manufacturers, should be provided with notice and comment on a ban and have the right to seek judicial review prior to the ban's implementation.
- Regulators should be required to consider the standard's impact on "countervailing measures" or unintended consequences such as an increase in illicit trade in the event of a total ban (in American blended markets).[37]
- Adequate time should be permitted to adapt to bans or limitations of ingredients use.

- Consider proposing alternative standards and restrictions:
  - Propose a ban on "distinctly confectionary flavours."
    - Recent Australian legislation provides for a two part test: the product is banned if it has a distinctly confectionary flavour *and* is marketed in a manner attractive to minors.
  - Propose a ban on "characterizing flavours" (a flavour that predominates the flavour of the smoke, as opposed to a flavour that merely contributes to the brand's distinct taste) that are attractive to minors.[38]
    - Note that tobacco types, menthol and clove should not be considered "characterizing flavours"
- In parallel to these strategies, markets should:
  - launch flavoured brands/brand extensions judiciously and using appropriate marketing terms and packaging.[39]

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[36] See The ASPECT Consortium, *Tobacco or Health in the European Union Past Present and Future* (October 2004) (prepared for the European Commission Directorate-General for Health and Consumer Protection) (suggesting a public health based test for ingredients approval, but stating that "exemptions should only be made for ingredients which are necessary for the manufacture and storage of tobacco products providing they are safe.")

[37] The FDA bill currently before the US Congress is a good example. See Section 907 TOBACCO PRODUCT STANDARDS and, in particular paragraph (b) ESTABLISHMENT OF STANDARDS, which requires the FDA to provide information in support of the standard, allows interested parties to comment prior to the adoption of the standard, and requires the FDA to take into consideration "countervailing effects" such as "the creation of a significant demand for contraband or other tobacco products."

[38] Under the draft FDA legislation, "[a] cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke."

[39] Controversy surrounding the adequacy of ingredients disclosure and the recent proliferation of 'flavoured' brands, particularly fruit flavours, has heightened the scrutiny and criticism of ingredients.

- pursue development of Virginia and/or "no flavouring" versions of significant brands
- include a disclaimer on the pack and in advertising of "all natural" or "additive free" products, that those terms do not mean the product is "safer" than products with ingredients; encourage the government to legislate the same.

b) Regulation of smoke constituents

Our objective is to obtain science-based testing, reporting and performance requirements and standards for smoke constituents that will establish a level playing field, create the basis for innovative products that reduce risk, and allow us to continue to manufacture and market products that adult consumers enjoy.

Markets should consider regulation of smoke constituents in two categories: (1) testing and reporting, and (2) performance standards (*e.g.*, ceilings).

Testing and reporting

Our long term objective is to obtain legislation/regulation requiring manufacturers to test for and report levels of harmful smoke constituents on a by-brand basis. While PMI supports such testing, which is a building block for the assessment of innovative products,[40] the cost of such testing on a by-brand basis is substantial, and currently there are a limited number of laboratories with the capacity to conduct such testing.

Most markets already require testing and reporting of tar, nicotine and carbon monoxide yields of cigarette brands under the ISO test method.[41] In addition, several countries (notably, Canada and Brazil) require manufacturers to provide by-brand yields of 40 to 50 other smoke constituents which have been identified by public health authorities as likely causes of tobacco related diseases.[42]

Specific Actions to Consider

- Where ISO testing and reporting of tar, nicotine and CO is required, propose amending the requirement to include the Health Canada test method.[43]
- Where no testing is required, propose ISO and Health Canada.
- Support/propose by-brand testing of other mainstream smoke constituents, following PMI's TobReg Submission, including the benchmarking method.[44]

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[40] R&D's strategy for research and development of innovative products is based on the principle, as stated in the IOM Report, that "[f]or many diseases attributable to tobacco use, reducing risk of disease by reducing exposure to tobacco toxicants is feasible." See PMI TobReg Submission at page 53. Regulation of smoke constituents in conventional products, therefore, is important to build government and consumer knowledge and to provide a baseline against which to measure innovative products.

[41] PMI supports testing of T/N/CO, although we have agreed with WHO that the current ISO (FTC) test method should be augmented with a more intensive method (the "Health Canada method"). See PMI TobReg Submission at pages 8-15. WHO has recently stated to ISO that it no longer supports its proposal and recommends that ISO delay any changes to its test method pending recommendations from the Conference of the Parties.

[42] See PMI's TobReg Submission at pages 16-24.

[43] See PMI's TobReg Submission at pages 8-15.

  - Specific requirements should be flexible, but at the same time meaningful, requiring all manufacturers for all products to follow the same high standards.
  - Educating regulators about the complexities of by-brand smoke constituent testing is essential in order to avoid unworkable and unnecessarily burdensome regulations.

- Support consumer communication of quantitative information on smoke constituent yields (based on ISO and an intensive test method such as Health Canada) through internet, pamphlets, package onserts.
  - This is a fundamental element of our strategy to build understanding of smoke constituents and to lay the groundwork for communications about innovative products.[45]

Performance standards/ceilings

Our strategy is to advocate science-based performance standards that will support harm reduction and, critically, take into account technical and commercial feasibility. Ceilings on smoke constituent may pose significant technological and consumer acceptability challenges, and we must be able to continue to manufacture conventional products that adult consumers prefer. While posing potential obstacles for our conventional brand portfolio, performance standards could benefit our investment in innovative products by establishing baselines against which new products would be assessed.

Markets should note that with respect to nicotine, there is controversy as to whether public health would be benefited by elimination, reduction or increase in nicotine yields.[46] For the same reasons that performance standards should consider consumer acceptability, we oppose granting regulators the ability to eliminate or substantially reduce nicotine yields.

Specific Actions to Consider

- Support legislation that grants a regulator the authority to impose smoke ceilings, but seek the following:
  - Standards must be based on scientific data establishing that the standard will benefit public health.

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[44] See PMI's TobReg Submission at pages 16-23. For a discussion of testing of sidestream smoke constituents, see discussion below.

[45] Consumer communication of by-brand smoke constituent yields is contemplated by the FDA legislation and recent legislation proposed in Uruguay. Markets should note, however, that WHO and other public health groups believe that only qualitative, not quantitative, information on smoke constituents should be provided to consumers.

[46] See PMI's TobReg Submission at 25(quoting WHO's Scientific Advisory Group: "[w]ith respect to nicotine, it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine per unit (*e.g.*, cigarette) and further study of this issue is required.")

- Standard must take into account the concept of commercial and technical feasibility – i.e., if the standard results in products that are not acceptable to adult consumers or are impossible to manufacture, it results in *de facto* prohibition.
- Legislation should provide interested parties, including manufacturers, with notice and comment and the right to seek judicial review before the standard takes effect.
- Regulators should be required to consider the standard's impact on "countervailing measures" or unintended consequences such as an increase in illicit trade.[47]
- Adequate time should be permitted to adapt to the new ceilings.[48]

- At this point in time, it is not recommended that markets proactively seek or support specific ceilings for individual or groups of smoke constituents. Such action should wait until we have further scientific data to support standards.

- On tar, nicotine and CO ceilings based on the current ISO test method, markets should consider accepting ceilings in line with the current EU requirements (10-1-10).
  - Adequate time must be provided to transition from current market preferences to 10-1-10.
  - Legislation should specify that the ceiling is based on current ISO test methods, and in the event new test methods are adopted, the ceilings should be adjusted accordingly.[49]
  - Legislation or regulations should specifically incorporate the ISO provision on tolerances, and enforcement agencies must take ISO tolerances into account.[50]

[47] See FDA bill section 907.

[48] The EU Tobacco Product Directive provided for a 2 year implementation period when the ceilings were reduced from 12 mg tar to 10 mg.

[49] See PMI's TobReg Submission at page 13.

[50] ISO 8243 provides for "confidence intervals" – permissible variations above or below the specified yield for tar, nicotine and CO. ISO 8243 provides for a tolerance of +/-15% for tar and nicotine and +/-20% for carbon monoxide in a series of tests, and greater tolerances for single tests. These tolerances are needed because of inherent variability in test methods, inherent sampling variability, and naturally occurring variations in the properties of different blends and crops of tobacco that impact T, N, and CO yields. In addition, variability inevitably occurs in testing conducted in different laboratories or in the same laboratories at different times. The EU Commission has released draft guidelines that suggest acting only when yields are found to be consistently at the upper range of the confidence interval over a period of time. That is consistent with our view.

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- Products manufactured for export should be exempt from these domestic ceilings, so as to maintain the domestic industry's ability to export.

- Where proposals are made to reduce ceilings on tar, nicotine and CO below 10-1-10, markets should consider opposing them.

  - Given the current debate over whether reducing machine-measured T/N/CO yields reduces risk of disease, regulations requiring further reductions are not prudent until more data, particularly from human exposure studies, are available.

  - Further reductions in nicotine are also questionable given the debate within the public health and scientific community as to whether increasing or deceasing nicotine is the best approach to address tobacco related diseases. (*see discussion above*).

c) Other conventional product regulation

Other elements of conventional product regulation, such as regulation of sidestream smoke testing, product packaging and product design, have either been adopted or proposed in some markets and are on the agenda of the WHO and the Conference of the Parties. In markets designated as "lead" or "key" regulatory markets, we may seek to proactively address these other areas of regulation. Proposing regulations that go beyond the basics can help build credibility and show that PMI is willing to take a leading role in developing comprehensive regulation. In other markets, focusing on the basic product regulatory issues – ingredients and smoke constituents – may be sufficient. Markets should consider whether to include regulation in these other areas in their regulatory action plan.

By-brand testing of sidestream smoke constituents

Several countries currently require manufacturers to report constituent levels in sidestream smoke (e.g., Canada and Brazil). It is likely that similar requirements will be proposed in other markets and by the Conference of the Parties. PMI opposes by-brand sidestream smoke constituent testing and reporting, except under the specific circumstances noted below.

Specific Actions to Consider

- Oppose sidestream smoke constituent testing on the grounds that composition of sidestream smoke does not differ meaningfully among brands, and by-brand testing is, therefore, not a useful application of governmental and manufacturer resources.[51]
- Consider, as an alternative, supporting by-brand sidestream smoke constituent testing on a one time basis to verify similar toxicity across conventional brands and to serve as a benchmark against which to measure new products.
- Propose requiring sidestream constituent testing where a claim is made that the product reduces sidestream smoke to substantiate the claim. [52]
- Where sidestream smoke constituent testing is required, work closely with R&D, Operations and CA to address specific requirements discussed in PMI's TobReg Submission.[53]

[51] See PMI's TobReg Submission at 23.

[52] See PMI's TobReg Submission at page 23.

[53] See PMI's TobReg Submission at page 24.

By-brand smoke toxicity testing

Health Canada requires by-brand toxicity testing (based on standard *in vitro* toxicity assays). WHO also has recommended that "*in vitro* and *in vivo* toxicology testing" be included as a component of tobacco product research and testing.[54] It is likely, therefore, that markets will need to address proposals for by-brand smoke toxicity testing. PMI opposes by-brand smoke toxicity testing for conventional products, except under the circumstances discussed below.

Specific Actions to Consider

- Oppose by-brand annual toxicity testing on the grounds discussed in PMI's TobReg Submission.[55]
- Consider supporting by-brand toxicity testing on a one time basis to verify similar toxicity across conventional brands and to serve as a benchmark against which to measure new products.
- Propose requiring by-brand smoke toxicity testing where:
    - a reduced exposure/reduced risk claim is made,
    - smoke constituent data for the brand suggest potential greater toxicity than conventional brands, or
    - a brand incorporates significant new technologies or design features not found in conventional products

Disclosure, testing and performance standards for tobacco blends

Regulations requiring disclosure of tobacco blends on a by-brand basis is required in a number of countries.[56] Similarly, several countries, including Canada, require manufacturers to test the tobacco blend for specific chemical compounds. Both requirements have been endorsed by WHO's TobReg. It is also possible that regulators will seek to impose performance standards (ceilings) on constituents in tobacco blends. PMI's objective is to focus regulators on mainstream smoke, which is directly relevant to consumers and health, but it is likely that markets will face regulation of the blend. PMI does not oppose disclosure of non-confidential blend information and would accept testing of tobacco blend constituents (although this is not a preferred option).

Specific Actions to Consider

- Obtain a provision in the legislation that provides for protection of trade secrets (e.g., disclosure of specific tobacco grades by brand)

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[54] See PMI's TobReg Submission at pages 27-28.

[55] See PMI's TobReg Submission at page 27 (all conventional products produce smoke of similar toxicity as measured by commonly-used in vitro assays and by-brand testing is therefore not a useful application of governmental and manufacturer resources).

[56] See PMI's TobReg Submission at page 43-46.

- Propose disclosure of tobacco types by brand (e.g., burley, Oriental, Virginia)
- If proprietary information is required (tobacco grade by brand), consider options discussed above regarding disclosure of full by-brand ingredient disclosure (e.g., disclosure to government that is protected, and a public disclosure).
- Consider proposing regulations as suggested in PMI's TobReg Submission.[57]
- If performance standards/ceilings are proposed for tobacco blend compounds, follow the same proposals as discussed above for smoke constituent performance standards.

Regulation requiring disclosure of product design

PMI's objective is to require manufacturers to disclose certain design features.[58] This has been proposed by WHO's TobReg, and is a reasonable requirement. Such requirements could prevent unfair competition by our competitors that seek to circumvent regulatory (and fiscal) requirements.

Specific Actions to Consider

- Support requirements for manufacturers to disclose certain product design characteristics (e.g., length of cigarette, length and weight of tobacco rod, filter design, ventilation type and level) as discussed in PMI's TobReg Submission.
- Provide for trade secret protection, where applicable, following the guidelines discussed above for ingredient disclosure.

Regulation governing packaging materials

WHO and several other public health groups have proposed tobacco ingredients regulation address chemicals that migrate from packaging into the product be included in. If faced with this issue, markets should consider the approach suggested by PMI in its submission to TobReg: a separate category of regulation on tobacco products packaging. [59]

Specific Actions to Consider

- Support regulations requiring manufacturers to report on an annual basis the type(s) of packaging materials used for each brand.
    - Include protection for proprietary information, if any.

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[57] See PMI TobReg Submission at pages 43-46.

[58] See PMI TobReg Submission at pages 50-51.

[59] See PMI TobReg Submission at page 51.

- Require reporting of potential migrants (chemicals that can transfer from the packaging into the product).
- Propose regulations requiring manufacturers to comply with standards set forth in European Directives governing packaging and other materials intended to come into contact with foods.[60]

Laboratory standards

PMI's objectives are to establish a requirement that all manufacturers conduct required testing and assessment of their products in accredited laboratories, and that government monitoring and verification of compliance is conducted at independent laboratories. We have also expressed our agreement with WHO that "testing and measuring tobacco products at the national or regional level are essential to monitor compliance" with product regulation.[61]

Specific Actions to Consider

- Include in proposed regulations requirements for laboratory standards both for manufacturers and for government verification, as proposed in PMI's TobReg Submission.[62]
    - Any laboratory that conducts testing required by regulations – including a laboratory owned or used by a manufacturer – should be required to be accredited to conduct that testing.
    - Laboratory standards should require that testing and data are "credible and consistent with the most rigorous of international standards."[63]
    - Any funding by manufacturers of independent laboratories should be fully transparent and should not affect the independence and integrity of laboratories.[64]
    - Government verification of test data submitted by manufacturers should be conducted only by government-approved laboratories.

Good manufacturing practices

Good Manufacturing Practices (GMPs) have existed for the pharmaceutical industry for a number of years and guidelines for that industry have been published by the

[60] Note that PMI currently applies these standards to its product packaging.
[61] WHO, Tobacco Free Initiative, http://www.who.int/tobacco/global_interaction/tobreg/laboratory/en/.

[62] See PMI's TobReg Submission at page 79.

[63] TobReg *Guiding Principles* at 7.

[64] *Id.* at 5.

- Consider recommending that the government establish national scientific and technical advisory bodies to handle the more complex issues related to tobacco product regulation.

- Consider whether regional or international public health and scientific organizations, such as WHO's TobLabNet can assist the government.[2]

- Regulatory authority – Is there an appropriate agency or department within the government to implement and supervise tobacco regulation?

  - Consider suggesting a single government agency (existing or new) that would have authority to regulate tobacco, coordinating closely with other relevant governmental bodies.[3]

  - Alternatively, suggest, as the FCTC recommends, establishing "a national coordinating mechanism or focal points for tobacco control."[4] This could be accomplished through the creation of an inter-governmental task force on tobacco.

- Enforcement/strength of the rule of law – Will regulations, if enacted, be effectively and rigorously enforced against all manufacturers and all tobacco products? What are the obstacles presented by existing deficiencies in enforcement authority or capabilities, and what options are available to address these obstacles?

  - Propose granting regulators with powers necessary for effective enforcement, such as the authority to audit and inspect, and the ability to exact penalties in the event of non-compliance.[5]

  - Consider mechanisms for monitoring enforcement by public health groups (e.g., WHO's Regional Offices or TobLabNet) and/or incentives to enforcement.

- Funding – What mechanisms are available today and what can be proposed to ensure that the government has the necessary funds to implement and enforce regulations?

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[2] Information about TobLabNet can be found on WHO's internet site at who.int/tobacco/global_interaction/tobreg/laboratory.

[3] See *Tobacco Regulation: A Framework Proposed by Philip Morris International*, submitted to WHO's Study Group on Tobacco Product Regulation (May 2006) ("PMI's TobReg Submission") at page 6. PMI's TobReg Submission is referenced throughout this document. Markets may share this submission with external stakeholders, but should not suggest in any way that TobReg requested or has endorsed the submission. PMI made the submission on its own initiative, and TobReg has not responded to it.

[4] FCTC Article 5(2)(a).

[5] See PMI's TobReg Submission at page 81.

European Commission, the U.S. Food and Drug Administration, and the WHO. PMI has suggested that GMPs be established for the tobacco industry, and should require manufacturers to maintain high standards in the manufacture and control of tobacco products and should provide a basis for the enforcement of product regulations.

As the issue of tobacco specific GMPs are not yet well developed, markets should work closely with Operations and HQ CA before proposing GMPs.

9) **Regulation of next generation products**

Our objective is to build momentum for legislation governing next generation products with the potential to reduce exposure or risk. Obtaining legislation is a central component of our strategy, both to support our new generation products and to limit the ability of other manufacturers to make unfounded claims.

While some public health officials have expressed a view that the development and marketing of next generation products will undermine the public health goal of achieving further reductions in tobacco use, a growing number of regulators and public health groups view product modification as a legitimate component of tobacco control. The growing support of snus as a safer alternative to cigarettes has further improved the chances of legislation on this important topic.

PMI is increasing its outreach to regulators and public health officials, sharing with them our product developments (e.g., THS), and our internal knowledge and progress on risk assessment. Our support of conventional product regulation will also provide impetus for the regulation of next generation products.

Regulatory strategy on innovative products with the potential to reduce risk should take three approaches, and must be closely coordinated with R&D, Law and HQ CA:

- First, we should seek across all categories of regulation to provide regulators with the authority to exempt innovative products from certain restrictions that apply to conventional products -- with the obvious caveat that restrictions intended to prevent youth smoking should apply both to conventional and next generation products. These include, as noted above, bans on public smoking, marketing restrictions, descriptor bans, and bans on the use of ingredients. Recent legislation in South Africa specifically allows such exemptions and should be used as a model.[65]

- Second, also noted above, we should advocate regulations for conventional products that will establish the foundation or baseline against which next generation products are measured. Specifically, these include requirements to measure, report and disclose to governments and consumers specific smoke constituents and, in certain cases, mainstream smoke toxicity and sidestream smoke testing.

- Third, we should obtain specific regulatory frameworks/requirements for next generation products. The recent FDA bill is a good example. The majority of work in this area will be driven by R&D's regulatory group working with HQ CA and several "key" or "leading" market teams such as Australia.

[65] The legislation states, "The Minister may … exempt any tobacco product from a provision of this Act … provided that, in the opinion of the Minister, it is in the public interest for the particular tobacco product to be so exempted, taking into consideration its harm reduction properties."

Specific Actions to Consider

Keeping the door open for next generation products

- Propose legislative or regulatory provisions that establish ability of regulators, based on a review of scientific data, to permit additional freedoms/exemptions for next generation products, including exemptions from marketing restrictions, bans on descriptors, and smoking bans.

- Consider proposing alternative fiscal requirements which would permit alternative (and lower tax rates) for products determined to have the potential to reduce exposure/risk.[66]

Establishing conventional product regulation as a foundation for innovative products

- Establish requirements to publish smoke constituent information on a by-brand basis.[67]

- Propose a ban on tobacco product health claims unless the product has been reviewed by a qualified regulator. [68]

Creating a specific regulatory framework for innovative products

- Establish PMI credibility on innovative product regulation by engaging with regulators, public health and the scientific community.
    - Sharing PMI's basic research on next generation products and methods to assess risk
    - Sharing data and experiences with THS

- Supporting the public health community's positions on snus, and, where applicable, legislation that would provide for claims for snus and preferential treatment of snus.[69]

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[66] PMI CA is preparing a memo on 'developing fiscal strategies' that will address this subject matter in detail.

[67] Communications to consumers that would allow a comparison between levels of smoke constituents from one brand to another should be made in a manner that will not mislead consumers into believing one brand is safer than another, if that is not the case.

[68] This is consistent with the FDA legislation pending in the US Congress. It is also consistent with the Framework Convention Alliance's position which calls for a ban on health claims, but states that legislation should "leave the door open to [the government], through the rule-making process, to allow health claims at a future time if there becomes sufficient evidence to support such claims for existing or newly developed products." *fctc.org/modelguide/1section10.html*

[69] Note that the public health community is divided on this issue.

- Raise awareness of government and public health officials of the need for regulatory supervision of claims, by bringing to their attention the proliferation of products with express and/or implied claims.[70]

- Propose a basic regulatory framework for next generation products that could be based on:

    - the FDA bill, which does not provide detailed requirements on data required to support a claim, but established a basic framework for regulation and requires the FDA to establish a procedure for approving "modified risk" tobacco products,

    - R&D's regulatory framework which is largely inspired from, and in line with regulations that govern the marketing of pharmaceutical products, medical devices and food.[71]

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[70] See PMI TobReg Submission at pages 54-57.

[71] See PMI TobReg Submission at pages 57-78, and R&D's forthcoming paper Science-based Framework for the Categorization and Regulation of Innovative Tobacco Products (available July 2007).

10. Regulation of alternative (non-tobacco) products

Our objective is to obtain regulatory oversight of non-tobacco products sold as alternatives to cigarettes. An increasing number of "alternative" products are being introduced, including (1) "herbal" and other non-tobacco cigarettes, and (2) products containing no tobacco but delivering nicotine (and flavourings), such as NicStic. These products are being marketed as pleasurable alternatives to cigarettes and, in some cases, also as cessation therapies.

Because these products do not contain tobacco, their regulatory and fiscal status is often unclear; regulators do not apply rules for either pharmaceutical or tobacco products. As a result, these products are sold without any regulatory oversight (no ingredients disclosure, no health warnings, no disclosure of adverse side-effects) and not subject to excise tax.

Some of these products may be effective cessation devices or may in fact be safer than tobacco products. Therefore, markets should ensure that actions taken are not misperceived as attempts to block effective products to reduce risk or facilitate cessation. Further, we must consider the impact of our actions on any efforts of PMI on next generation products that may not contain tobacco.

Specific Actions to Consider

- Provide products to R&D for assessment.
- Identify products to regulators as they are introduced into the market.
- For herbal cigarettes and other cigarettes not containing tobacco, advocate the same regulatory and fiscal requirements as tobacco-based cigarettes, until and unless a medical benefit is proven and certified by appropriate regulatory authorities.[72]
- For non-tobacco products that deliver nicotine, advocate appropriate regulatory oversight for the product either as a tobacco product or as a cessation therapy, depending on the marketing claims.
- Consider contacting regulatory agencies and/or taking legal action. Consult with HQ CA, R&D and the Law Department before doing so, and obtain the required approvals under G-119 before taking any legal action.

[72] Several countries already regulate herbal cigarettes in the same way as tobacco cigarettes. For example, finding that herbal cigarettes generate similar levels of harmful substances such as carbon monoxide and tar as conventional cigarettes, New Zealand includes herbal smoking products in smoking bans, and prohibits the sales of herbal cigarettes to minors. The European Union Tobacco Excise Directives provide that cigarette excise tax should be applied to non-tobacco cigarettes unless they are *"used exclusively for medical purposes."*

11) Reduced cigarette ignition propensity standards

Regulation of cigarette ignition propensity, which was first introduced in the State of New York, is gaining support outside of the US, having been adopted in Canada and raised in several other countries (most recently in the EU and Australia). Although we do not believe that regulation in this area is a crucial component of tobacco regulation, our cooperation in the development of RCIP regulations can help establish working relationships with public health groups and can serve as a basis for discussion on other areas of product regulation. Importantly, affiliates should clearly communicate that compliance with the New York standard does not mean that a cigarette is "fire safe." Whether regulated or not, a carelessly handled lit-end cigarette can cause fires.

Specific Actions to Consider

- Before proposing or supporting RCIP standards, determine whether the market and PMI has adequate capacity to produce and test product under the current standard used in New York.
- Support national (as opposed to state/municipal) standards, and, where applicable, such as in the EU, regional standards
- Leverage support of RCIP standards to seek other regulations, including regulation for next generation products
- Ensure that where regulations are adopted, the New York standard is used
    - Provide for periodic reviews of the standard and possibility of amendment in the event of new and better test methods.
- Provide for appropriate enforcement mechanisms to monitor compliance by the competition.
- Ensure that sufficient implementation time is allowed

12) Public smoking restrictions

Our objective is to obtain meaningful public smoking restrictions that (1) eliminate smoking in general public indoor spaces, (2) allow employers and HORECA to permit smoking for their customers and employees under specific rules, (3) provide for product-based exemptions to smoking bans, and (4) inform the public about the health effects of ETS to non-smokers.

Smoking restrictions should not lead to a situation where tobacco products can be bought but not consumed, i.e. *de-facto* prohibition. In that regard, PMI does not support the use of public smoking bans to reduce consumption or to prevent adult smokers from using tobacco products in private places such as in homes or in cars.

Specific Actions to Consider

- Seek prohibitions on smoking in general public indoor spaces, in schools, playgrounds, and other places that are frequented predominantly by minors, in hospitals, and on public transportation.

- Seek flexibility for employers and HORECA to provide for separate smoking areas for their employees and customers.[73]

    - Ventilation could be required in order to make the environment more comfortable but should not be suggested as a way to address public health concerns about ETS exposure.

    - Exemptions should be made (or a process for granting exemptions should be included) for tobacco companies and adult consumer testing.

- Seek requirements that where smoking is permitted, the public is informed about the health risks of ETS exposure to non-smokers.

- Seek legislation that would permit an exemption for products that do not burn and therefore do not produce smoke or eliminate all or produce significantly less smoke.[74]

    - Exemptions should be subject to review by a competent regulator based on scientific data.

    - Exemptions should be limited to appropriate venues such as workplaces and HORECA and, where relevant, outdoors and private places such as cars and homes.

[73] For example, Spain enacted legislation that bans smoking in most public places and in all workplaces, but permits smoking in bars, nightclubs and restaurants as follows: venues less than 100 square metres can choose to prohibit or permit smoking, and venues larger than 100 square meters can provide smoking areas which can be no larger than 30% of venue's total surface area.

[74] PM Switzerland recently raised this prospect. See Appendix C for the relevant excerpt from the market's position paper.

- Consider recommending Indoor Air Quality guidelines for ETS, such as established in Japan.

- In markets where smoking bans are under discussion or likely to arise, consider introducing THS in some HORECA venues to generate support for a product-based exemption to public smoking restrictions.

- Oppose bans on smoking in private places (such as cars) or in general outdoor areas.

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13) Youth smoking prevention

Our objective is to obtain regulations preventing the sales to and use by minors of tobacco products, including effective enforcement mechanisms. There are three core components of YSP regulation: (1) minimum age laws, (2) penalties for underage sales/purchase/supply, and (3) retail licensing.

PMI supports a comprehensive approach to YSP including regulation, enforcement, communication messages and education, involving parents, educators, the trade, the society, the manufacturers and the governments. As this memo focuses on regulatory strategy, it addresses only the regulatory aspect of YSP.

Specific Actions to Consider

- Propose legislation that would:
    - Establish a minimum age law, if none exists
    - Increase the minimum age to 18 if current minimum is under 18
    - Mandate age verification by retailers of customer appearing to be under the age of 25
        - Development of a national ID system, if none exists, for use at retail (e.g. age of majority national ID cards)
    - Impose strict penalties for underage sales
        - Monetary fines
        - Elimination of retailers' right to sell in case of repeated violations
        - Prohibit manufacturers, distributors and wholesalers from supplying retailers who are shown – and appropriately confirmed – to be knowingly selling to minors
    - Establish government monitoring systems, including government "mystery shopper" programs and other auditing systems
    - Require manufacturers to develop state of the art youth access programs, including retailer training and retail signage
    - Prohibit self-service display or require self-service display to be in line of sight of retailer
    - Restrict vending machine either to adult only venues or in line of sight of proprietor, or incorporate access mechanisms to prevent purchase by minors.

- Require notification of parents/guardians and/or schools when a minor is caught purchasing or using tobacco products
- Makes it a crime for an adult to provide a minor with tobacco products
  - Sanctions could include fines and/or community support addressing youth access prevention
- Prohibits toys, confectionary, etc. in form of cigarettes or other tobacco products
- Bans branded non-tobacco items for children (e.g., toys, child-size clothing)
- Requires education on smoking and health in all elementary and secondary schools
- Requires health care system to provide for cessation programs for minors

- Consider proposing retail licensing (*see discussion of licensing below*)

- Consider earmarking of tobacco excise taxes, specific per unit fees, licensing fees, and user fees (in which manufacturers would pay the administrative costs of regulatory requirements) that would be applied equally to all industry members and all products.[6]

- Scope of regulations – Will regulations apply to all products to create a level playing field?

  - Propose legislative language addressing the scope of the law in well defined terms and ensuring application of rules equally to all tobacco products (domestic and imported products, products sold over the internet/direct mail sales from other countries, manufactured cigarettes and OTP[7]) and all manufacturers and importers.

- Stakeholder engagement – How can stakeholder engagement help achieve regulatory objectives? Are local tobacco control groups willing to work with the market? If not, how can the market begin a dialogue with those groups?

  - Developing a working relationship with tobacco control advocates and public health officials in the market should be a high priority.

    - Understand fully the views and positions of local tobacco control groups, what they hope to accomplish, and consider where our actions and assistance can complement their strategies and goals.

    - Share PMI's positions on tobacco regulation. Explain what PMI can offer in the way of technical expertise and knowledge and can contribute to the development of tobacco control policy and regulation.

  - Consider engagement with a variety of other key stakeholders (*e.g.*, competition, trade, suppliers, growers) and, where appropriate, seek their support.

- Market and PMI capacity – What resources are necessary to manage new regulatory framework? Does the market and/or PMI have the necessary capacity and infrastructure?

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[6] See PMI's TobReg Submission at pages 82-83.

[7] Regulations should apply to OTP whether or not OTP have a significant presence in your market and whether or not scientific standards for OTP have been established. For both public health and competitive reasons, proactive forward-looking requirements are needed to ensure OTP will have to compete on the same regulatory playing field as manufactured cigarettes.

14) Regulation of internet sales

Our objective is to obtain regulation governing the sale of cigarettes via the internet. Regulations should prevent the sale of product over the internet to minors and in violation of applicable laws, including customs duties and excise taxes.

Specific Actions to Consider

- Legislation should require that internet sales only be allowed by licensed, bonded players with strictly controlled websites that assure payment of applicable taxes and application of appropriate age controls
- Recommend that regulations require:
    - appropriate youth access prevention processes in place to prevent sale to minors.
    - payment of all applicable taxes and duties,
    - all cigarettes sold over the internet to comply fully with all domestic regulatory requirements, including health warnings and product regulation requirements.

15) Prevention of illicit trade

PMI shares the objectives of the FCTC to eliminate "all forms of illicit trade in tobacco products, including smuggling, illicit manufacturing and counterfeiting."[75] Our objective is to obtain regulation that protects the legitimate tobacco industry and provides governments with necessary authority and mechanisms to stop illicit trade.

PMI has implemented strong business processes that we employ to deliver our products to their intended destination for sale and to the intended consumer, and we work closely with governments around the world to support their efforts to prevent illicit trade, entering into voluntary agreements and providing technical support and training. Establishing regulation that puts into place strict and formal mechanisms for all industry participants should be a central part of a market's regulatory strategy.[76]

As WHO and others have noted, illicit trade prevention is not only important to protect government revenues, it is important to accomplish public health goals and must be viewed, as Article 15 of the FCTC states, an essential component of tobacco control.[77]

Specific Actions to Consider

- Support legislation/regulation that implements commercially reasonable mechanisms for controlling illicit trade, including:
    - tracking, tracing, labelling and record-keeping requirements
    - requirements that manufacturers should implement know-your-customer policies and state of the art monitoring systems of their sales and distribution practices
    - requirements that manufacturers stop supplying vendors who are shown – and appropriately confirmed -- to be knowingly engaged in illicit trade.[78]

[75] FCTC Article 15.

[76] A full description of various measures and PMI's positions will be available in a BI/CA position paper Initiatives to Fight Illicit Trade as Part of Comprehensive Regulation (available April 2007)

[77] According to the WHO, illicit trade results in "*cigarette prices that are lower than expected, with the results in higher consumption leading to greater smoking-related health consequences.*" Taxation of Tobacco Products in the WHO European Region: Practices and Challenges (2004) ("WHO EU Region Report") at page 14. Further, "*the illegal market can undermine efforts to limit youth access*" and "*the lack of implementation of appropriate regulations and warnings on smuggled products encourages an increase in consumption.*" Id. at pages 14-15. Counterfeit products pose additional concerns in that they are manufactured and marketed without government controls and regulations. While all tobacco products cause diseases, some government authorities have said that counterfeit products may pose additional concerns.

[78] These requirements can be based upon the relevant provisions of the EC Agreement. PMI does not support extensions of the monetary and penalty provisions of the Agreement to other markets.

- Working closely with PMI CA and Operations, seek implementation of a cost-effective product authentication system that can be implemented without affecting production or distribution efficiency.[79]

- Propose legislation that would:

    - Require governments and trademark-holders to collaborate promptly following the seizure of contraband products to determine whether the product is counterfeit or genuine,

    - Require the seizure and destruction of counterfeit tobacco products and the machinery used to manufacture them[80]

        - Include provisions for a simplified procedure on destructions, to be used with the right-holder's agreement, which enables national authorities to have illegal cigarettes and machinery destroyed in a timely fashion

        - Prohibit the auctioning or reselling of illegal cigarettes or manufacturing machinery by governments

    - Require manufacturers to suspend or cease doing business with any supplier (non-tobacco material suppliers, cut-filler providers and printers) found to have knowingly or negligently supplied materials used to produce counterfeits

    - Require suppliers to cooperate with government and manufacturers to combat counterfeiters and to implement know-your-customer, anti-money laundering and tracking and tracing procedures

- Legislation should treat counterfeiting as a serious criminal offence, equivalent to fraud, with serious consequences.

    - Strong penalties should be imposed for the manufacture and trade in counterfeit cigarettes, with effective remedies being available to impose punishment and to act as a deterrent.

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[79] The market for product authentication solutions is developing rapidly as more governments seek to prevent illicit trade, and numerous diverse companies promote their systems to governments our product authentication system. Markets should be aware of the product authentication system developed by PMI ("CVS") and understand that systems developed by other companies are both not as effective as CVS and much more costly. We have seen these competitive systems adopted by governments, for example in Malaysia, with significant cost impacts for us. Although we are not in the business of marketing authentication and tracking systems, we have a strong interest in ensuring that, when mandated, such systems are efficient and cost-effective. To that end, PMI has licensed the CVS technology to the SGS Group (http://www.sgs.com) to commercialize the system as an independent third party provider to governments around the world. However, markets should coordinate with PMI central functions (BI, Operations, and CA) on this issue.

[80] Article 15 of the FCTC agrees with that belief, as it states, "each Party shall take appropriate steps to ensure that all confiscated manufacturing equipment, counterfeit and contraband cigarettes and other tobacco products are destroyed, using environmentally-friendly methods where feasible, or disposed of in accordance with national law."

- Where necessary, propose incorporation and implementation of basic legislation/international standards protecting trademark rights-holders such as the Trade-Related aspects of Intellectual Property Rights agreement ("TRIPS").[81]

- Encourage regulation to protect borders from both the import and export of illegal products and provide law enforcement and customs officials with the authority to enforce effective measures

    - Provide customs officials with the jurisdiction and control over all cross-border movements (imports and exports) of tobacco products and with the resources to exercise that jurisdiction effectively.

    - Recommend that the local Customs Code clearly provide customs authorities with the ability to take action against counterfeit and contraband goods that are in the process of being exported, re-exported or leaving the national customs territory, i.e. moving into a free zone.

        - Customs should be required to enforce the regulation, both when prompted by manufacturers and on their own accord

    - Address goods in free zones and goods in transit/transhipment[82]

        - Provide customs officials jurisdiction over goods transiting, trans-shipping or being manufactured, stored or sold in free zones and ports and make certain that national laws (other than tax) are equally applied in those free zones.

- Seek restrictions on internet sales (*see discussion above on regulating internet sales*)

- Seek licensing systems (*see discussion below on licensing*)

[81] Markets should understand the relevant anti-counterfeiting and smuggling regulations that currently exist and how they compare to accepted international standards.

[82] "Free zones" or "free trade zones," which are used by many governments to promote trade by providing a free trading environment with a minimum level of oversight regulation, have become vehicles for a significant expansion of the illegal trade in cigarettes.

16) Licensing

PMI's objective is to obtain "all-inclusive licensing systems" in our markets which can serve as the cornerstone of comprehensive tobacco regulation.

Licensing is most commonly discussed in PMI and by third-parties as a means to prevent illicit trade prevention and it is clearly an effective tool for that purpose, as recognized by the FCTC.[83] However, licensing can also be effective in achieving other regulatory requirements for the tobacco industry.[84] For example, a licensing scheme could be used to ensure compliance with:

- Ingredients testing and reporting requirements
- Tobacco content testing and reporting requirements
- Smoke constituent testing and reporting requirements
- Toxicity testing and reporting requirements
- Regulations and standards for next generation tobacco products
- Good manufacturing practices
- Youth access prevention requirements.[85]

Although licensing of distributors, wholesalers, and retailers raises substantial issues in many markets (including the ability to adopt and enforce licensing in markets with hundreds of thousands of points of sale),[86] many public health groups have recommended retailer licensing to address not only illicit trade, but youth access enforcement.[87] PMI supports such proposals, but recognizes the difficulties of implementation and enforcement for this part of the supply chain.

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[83] FCTC Article 15 ("Each Party shall endeavour to adopt and implement further measures including licensing, where appropriate, to control or regulate the production and distribution of tobacco products in order to prevent illicit trade.")

[84] The Framework Convention Alliance has stated, "Licensure sanction also can provide a powerful mechanism to compel compliance with legal requirements."

[85] The Framework Convention Alliance has stated, "Licensure sanction also can provide a powerful mechanism to compel compliance with legal requirements."

[86] The FCA recognizes the difficulties of licensing retailers:

> "Licensing retailers can be costly to administer, and difficult to establish if the country's infrastructure is not well developed. Where there is a large informal sector, retail licensing probably will not be feasible. Nonetheless, all of the benefits discussed above will be more likely to be achieved if retailers are included in the licensing scheme. Even if it cannot be done at the present time, licensing retailers should be an objective in the process of working toward achieving a best practices approach to tobacco control." *fctc.org/modelguide/lsection05.html*

[87] See Licensing of Tobacco Retailers and Wholesalers - Desirability and Best Practice Arrangements Australia: Dept of Health and Ageing ("The report confirms that there is a strong case based on economics and public health benefits for introducing licensing of tobacco retailers, and indicates that best practice involves licensing both wholesalers and retailers."); Canadian Public Health Association, "(The strongest deterrent for a retailer selling to a minor is revocation or suspension of a license. Currently, fines are not enough of a deterrent"); California Lung Assoc. Cigarette License Requirements: California Cigarette and Tobacco Products Licensing Act of 2003 ("The primary purpose of the new licensing program is to reduce cigarette smuggling.... In addition, [the law] sets up

Finally, markets should understand that there is no single uniform approach to the adoption of a licensing scheme. In each market local factors will dictate the appropriate strategy. For example, licensing could be implemented in stages, beginning with manufacturers and importers and moving down the supply chain to retail stores. Local ability to enforce licensing is also a significant issue: without enforcement licensing systems are not effective.

Specific Actions to Consider

- Consider whether a licensing system would be feasible in the market, whether all or some of the supply-chain could be licensed, and whether or how to complement the system with a specific, fully-funded enforcement mechanism.

- Raise awareness of the concept of licensing with governments and other stakeholders, providing examples.

- Proposed a licensing system, depending on market factors, that could address the entire supply chain or, as a starting point, manufacturers, importers and exporters. A proposal may address only illicit trade or take a broader approach which would include requirements based on the regulatory framework.

- Propose licensing for manufacturers, importers, wholesalers, and exporters that would require entities to satisfy basic requirements to participate in the tobacco business and comply with specific regulatory requirements, including:

    - Measures to address illicit trade (*see discussion above*)

    - Product regulatory requirements, including testing and disclosure requirements (ingredients, smoke constituents, etc), laboratory standards, and GMPs (see discussion above)

- Propose licensing systems for retailers that would address both illicit trade and compliance with youth access laws

    - Legislation should specifically require the revocation of a retailer's license if outlets are caught knowingly and repeatedly selling to under-age consumers or illicit product.

    - If a retailer's license is revoked all tobacco industry participants should be prohibited from trading or supplying this retailer and there should be ramifications for noncompliance.

- Ensure that licensing systems are complemented with specific, fully-funded enforcement mechanisms.

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a system for suspending or revoking a tobacco retailer's license if they are convicted a certain number of times for selling tobacco to minors.")

17) Education, cessation and related measures

Most regulatory frameworks should include measures that address education of the public about the serious diseases caused by tobacco use, provide support and infrastructure in the health care system for cessation, and establish coordination/surveillance/tracking of tobacco control issues by regulators and public health officials.

PMI supports such measures. However, where those measures are funded through financial requirements imposed on the tobacco industry (including excise taxes, "health fees," or licensing fees), obligations should be applied equally to all industry participants and all tobacco products.

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18) Fiscal measures

Although we do not support excessive tax increases, we strongly support the FCTC's view that fiscal policy is an important element of comprehensive tobacco regulation.[88] Consistent with the views of WHO, the World Bank and other public health groups, fiscal policy must take into account a wide range of factors, including the tax structure in place, and unintended consequences of excessive tax increases.[89] Tax policy should not encourage a shift in demand to lower taxed, and therefore, lower priced tobacco products.[90]

Specific Actions to Consider

- An excise tax structure that is consistent with the fact that all tobacco products are harmful and should thus be equally taxed;
- Regular tax increases indexed to inflation and growth in real income for tax systems with a specific tax component;
- A minimum excise tax for all tobacco products where tax systems are *ad valorem* or mixed;
- A minimum benchmark reference price for all tobacco products;
- Equalization of excise tax rates across all tobacco products, including roll-your-own and smokeless tobacco;

[88] Article 6 of the FCTC states "price and tax measures are an effective and important means of reducing tobacco consumption by various segments of the population, in particular young persons." The Framework Convention Alliance has stated, "It is no accident that price and tax measures are the first item listed in the FCTC. Tax and price measures are widely recognised as one of the most effective means of reducing tobacco consumption, particularly among the young. Article 6 commits Parties to treat tobacco taxation as a health measure, rather than solely a fiscal measure, and encourages Parties to adopt tax and price policies that will discourage tobacco consumption."

[89] WHO has said that in considering tax levels governments must consider "all factors relevant to its particular situation. The purchasing power of local consumers, rates and tax structure in neighbouring countries, the ability of tax and customs authorities to enforce compliance, the need for revenue and the need to tackle the growing burden of tobacco-related illnesses are important considerations." *WHO, Building Blocks for Tobacco Control* at *190 (2004)*. Similarly, the International Monetary Fund has stated, "Ultimately, tobacco excise tax rates must reflect the purchasing power of the local consumers, rates in neighboring countries, and, above all, the ability and willingness of the tax authority to enforce compliance." *World Bank, Curbing the Epidemic: Governments and the Economics of Tobacco Control (1999) ("World Bank 1999 Report"), Appendix A: Tobacco Taxation: A View From The International Monetary Fund.*

[90] WHO's European Region stated that "Research has shown that some cigarette consumers react to price increases by shifting consumption to cheaper tobacco products. To achieve a reduction in overall tobacco consumption, taxes would have to be raised at the same time and in a comparable amount for all tobacco products." WHO EU Region Report at 6.

- Strong controls and enforcement to prevent an influx of illicit tobacco products, and enforceable restrictions on cross border sales and duty free sales;[91]

- Earmarking of tobacco tax revenues for tobacco-specific programs, including control of illicit trade and health programs.

[91] Tax is an incentive and therefore an important factor in regard to illicit trade in tobacco products. As excise taxes and other costs increase, smokers may seek lower-priced cigarettes from a variety of alternative venues and channels, including cheaper products sold on the black market. The World Bank has stated: "Differences in price between countries or states will clearly increase the incentives to smuggle cigarettes. However, the determinants of smuggling appear to be more than price alone." *World Bank, Curbing the Epidemic: Governments and the Economics of Tobacco Control*, chapter 5 (1999). That is why when fiscal measures are adopted that will increase the price of cigarettes, such as increasing taxes, it is critical that governments implement appropriate policies to effectively counter illicit trade in tobacco products. These policies could include a tobacco industry licensing system, strengthening customs agencies, strictly enforce existing anti-counterfeiting, smuggling and IPR laws, creating deterrent penalties and implementing systems for the tracking and tracing of tobacco products.

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APPENDIX A

The Conference of Parties Working Groups

The following working groups have been established by the Conference of Parties. Each market whose government is on a working group should consider how to reach out to the representative on the working group to provide assistance.

Bear in mind that continued (and inaccurate) allegations have been raised that PMI has tried to improperly influence the outcome of the FCTC. We maintain our right to participate in discussions with governments, regulators, and public health officials and advocates. However, any communications with governments on a Working Group should be transparent and consistent with our overall objectives and our desire to be a legitimate and preferred partner of public health. Finally, you should always check with PMI CA before contacting government representatives about a Working Group.

Working Group on Cross-Border Advertising

- Facilitating Countries: European Community, India, Sweden.
- Countries Assigned to Develop Guidelines: China, Hungary, Malaysia, Mexico, Thailand
- Reviewing Countries: European Community

Working Group on Packaging and Labelling

- Facilitating Countries: Brazil, Canada
- Countries Assigned to Develop Guidelines: Australia, China, Djibouti, EC, Hungary, Mexico, Panama, Singapore, Thailand, Uruguay
- Reviewing Countries: New Zealand

Working Group on Product Regulation

- Facilitating Countries: Canada, EC, Norway
- Countries Assigned to Develop Guidelines: Brazil, China, Denmark, Finland, Hungary, Jordan, Mexico, Netherlands
- Reviewing Countries: Australia, France, Jamaica

  - Before proposing comprehensive regulation, markets must determine whether they and/or PMI have the resources to handle additional regulatory requirements.[8]

- Communications – How can communications and media support the market's regulatory objectives?

  - Develop an integrated communications plan to build momentum and support for regulation.

In each Region, "lead" markets will be identified by the Operating Team in conjunction with CA and the MDs. These markets, working closely with the OT and senior CA executives, will push the envelope on regulatory strategy, seeking to implement a range of broad and novel approaches. The following are markets under consideration.[9]

- European Union: France, Germany, Hungary, Ireland, Italy, Netherlands, Nordics, Switzerland, UK.

- Latin America & Canada: Canada, Brazil, Mexico, Panama, Uruguay, Colombia.

- EEMA: Israel, Turkey, South Africa.

- Asia: Australia, Hong Kong, Japan, Malaysia, New Zealand, Singapore.

This list is not meant to exclude any market from seeking innovative and comprehensive regulation.

When considering strategy, markets should keep in mind that PMI's objectives are long-term. Weigh the short-term challenges to your business against the long-term opportunities; consider what you can do today to achieve our objectives for future growth.

4. Regulatory Proposals and Actions to Consider

The following discussion, which is intended to guide the markets in their development of regulatory strategy, is based on existing legislation/regulation and/or recommendations in published literature, including scientific and public health publications. Suggestions are not mandates, and must be viewed in the context of local factors, as well as PMI's global objectives. For many of these recommendations,

[8] For example, before advocating regulations requiring by-brand testing and reporting of smoke constituents other than T/N/CO, the market should determine whether R&D and/or Operations have the capacity to support such requirements for the market.

[9] Many of these markets have governments that are participating in the Working Groups established by the FCTC's Conference of the Parties. A list of those groups and their members are in Appendix A.

Working Group on Public Smoking

- Facilitating Countries: Finland, Ireland, New Zealand
- Countries Assigned to Develop Guidelines: Brazil, Djibouti, Fiji, France, Germany, Hungary, Jamaica, Mali, Mexico, Panama, Peru, Sweden, Uruguay, Vanuatu
- Reviewing Countries: Marshall Islands, Norway, Palau

Working Group on Illicit Trade

The Working Group on Illicit Trade is chaired by Austin Rowan, from the EC's OLAF. A list of experts to assist the Conference of the Parties has been published on the WHO's internet site. The experts come from several countries[92] and are grouped into four categories as follows:

- Public Health: Belgium, Bhutan, Comoros, Jamaica, Kuwait, Fiji
- Law Enforcement/Justice: Bangladesh, Central African Republic, China, Pakistan, Spain
- Finance/Taxation: Armenia, Brazil, Korea, Pakistan, South Africa, Thailand
- Customs (Excise)/Trade: Canada, EC, India, Pakistan, Philippines, Sao-Tome Principe

[92] For names of the individuals see www.who.int/tobacco/framework/cop/illict_trade/en/index.html.

Appendix B

Australia's Approach to Point of Sale Display Restrictions

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Appendix C

Product Based Exemptions on Public Smoking Bans

In addition to restricting smoking based on the nature of the location, the government should consider restrictions based on the nature of the product. Environmental tobacco smoke is a combination of the smoke (gases and particles) coming from the lit end of a cigarette plus the smoke exhaled by a person smoking. The chemical compounds that comprise ETS are generally known, and over the past two decades, many studies have been conducted to investigate levels of, and exposure to, ETS and other indoor air constituents in numerous environments. It is possible, therefore, to do a quantitative and qualitative assessment of ETS generated by tobacco products.[93]

Further, technological advances have made it possible to develop tobacco products that substantially reduce generation of ETS. The WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob) stated in 2003 that "Many of the new products may claim reductions in generation of environmental tobacco smoke and there is clear reduction when shifting from burned tobacco products to products that heat rather than burn tobacco or to smokeless tobacco."[94] Although SACTob did not address (and has not supported) the assessment of products for the purpose of permitting their use in public spaces, the Committee recommended the evaluation of emissions from new products under conditions of actual use including second hand smoke emissions.[95]

We believe, therefore, that the legislation should authorize a designated national body such as the Federal Health Office, to permit the indoor use of products that, following a review of objective scientific data, are determined to substantially reduce or eliminate ETS.[96] It is crucial that this exception is applied only after a rigorous scientific evaluation is conducted by the manufacturer and by the national body.

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[93] For example, the International Standards Organization provides for a standard test method to measure certain environmental smoke constituents. See ISO International Standard ISO 18145. 2003; ISO International Standard ISO 15593. 2001.

[94] WHO SACTob. 2003. Statement of Principles Guiding the Evaluation of New or Modified Tobacco Products. WHO (available on-line at www.who.int/global_interaction/tobreg.) In November 2003 the status of SACTob was changed and it became the WHO Study Group on Tobacco Product Regulation (TobReg).

[95] To date, public health authorities, such as WHO , the International Agency for Cancer Research, the US Surgeon General, and the US Centers for Disease Control, have taken a zero-tolerance approach to ETS (see, e.g., the US Surgeon General has concluded that there is no "risk free" level of ETS), with a few exceptions, where maximum limits of ETS constituents have been promulgated (e.g., Norway: Becher, R.; Hongslo, J.K.; Dybing, E. 2000. Guidelines for indoor air in Norway – A practical approach. *Pollution Atmosphérique* **166**: 245-246). However, the Surgeon General's Report acknowledges that no regulatory agency has yet sought to determine a "de minimus risk level" of ETS in the manner that limits have been established for other hazardous air pollutants. [SG Report at 638.] Further, the views of the public health community are based on conventional products and the concern that certain alternatives, such as ventilation, do not provide adequate solutions to address the health effects of ETS generated by conventional products. While we do not believe that ventilation provides a solution to health concerns, we note that the recent European Standard on indoor air quality provides ventilation requirements for indoor environments where smoking occurs (CEN European Standard EN 13779. 2004. *Ventilation for non-residential buildings – Performance requirements for ventilation and room-conditioning systems.* European Committee for Standardization, Brussels, September 2004 (approved by CEN on 2004-01-16))

[96] Any such approval should not, however, include the use of the product in venues that are frequented predominantly by minors, such as schools, or in health care facilities, such as hospitals.

Manufacturers should be required to substantiate reduced ETS exposure by demonstrating that concentrations of potentially harmful ETS constituents are substantially lower when smoking their product than when smoking a conventional cigarette. The data provided should establish a quantitative and qualitative assessment of differences of concentrations of ETS under controlled laboratory conditions and under simulated "real-world" scenarios.[97] The details of the review and the data required in order to qualify for this exemption should be determined by the national authority. Following the review, the national body could certify the use of the product in specific indoor public places, such as workplaces, restaurants and nightclubs. Of particular relevance for judging whether or not the anticipated and/or expected ETS reduction is sufficiently large, an analysis of data should be made that measured indoor air contaminants before and after a smoking ban.[98] Available data indicate that following a smoking ban, a reduction of potentially harmful indoor air contaminants occurs in the order of 80-90%.

[97] The data should address use of the product and levels of ETS in several controlled environments, modelled after "real-world" scenarios such as simulated office and hospitality environment in which smoking rates, occupancy density and ventilation rates in the environmentally controlled room are similar to those reported in "real-world" environments.

[98] A number of published studies support this approach. See, e.g., Ellingsen DG, Fladseth G, Daae HL, Gjolstad M, Kjaerheim K, Skogstad M, Olsen R, Thorud S, Molander P. 2006. Airborne exposure and biological monitoring of bar and restaurant workers before and after the introduction of a smoking ban. *J Environ Monit* **8**, 362-8; Travers MJ, Cummings KM, Hyland A, Repace J, Babb S, Pechacek T, and Caraballo R. 2004. Indoor Air Quality in Hospitality Venues Before and After Implementation of a Clean Indoor Air Law — Western New York, 2003. *MMWR* **53**, 1038-104, November 12, 2004.. We would be pleased to provide citations to those studies if requested.

HQ and Regional CA can provide markets with examples and precedence from enacted or proposed regulations, public health recommendations and other sources.

The categories of regulation that follow are not exclusive, and markets have the flexibility to address other areas of regulation or, as noted above, to make the decision that certain areas of regulation are not appropriate or feasible at this point in time. In most markets, it is not possible to achieve progress in all of these categories, and markets should prioritize their plans and apply their resources accordingly.

1) Health warnings on packs
2) Descriptor bans
3) Tar, nicotine and CO numbers on packs and in ads
4) Pack size restrictions
5) Marketing restrictions
6) Point of sale display bans
7) Generic packaging
8) Product regulation: conventional products
9) Product regulation: next generation products
10) Regulation of alternative (non-tobacco) products
11) Reduced cigarette ignition propensity standards
12) Public smoking restrictions
13) Youth smoking prevention
14) Regulation of internet sales
15) Prevention of illicit trade
16) Licensing
17) Education, cessation, and related measures
18) Fiscal measures[10]

[10] Fiscal strategy is not addressed at length in this memorandum under the assumption that most markets are aware of and have experience in fiscal strategy. However, as described below, public health groups, including WHO, have stated that fiscal measures (tax and price) are one of the most effective means to achieve public health objectives. In preparing strategic plans, markets therefore should integrate fiscal measures, considering how their fiscal action plans can address their brand portfolio, competitive position *and* the objective of harm reduction.

1) **Health warnings on packs**

Our objective is to obtain legislation requiring HWs in all of our markets, while maintaining space on the pack for our trademarks and brand imagery. The FCTC establishes a minimum size requirement for HWs of 30% of the front and back of packs, but recommends 50% front and back.

Specific Actions to Consider

- Seek text warnings that are aligned with the FCTC's 30/30 requirement.
- Ensure that governments determine specific warning requirements and do not leave discretion to manufacturers to choose from several warnings.
    - Seek specificity in the law as to placement, font size and colour of text and background.
    - Support rotating warnings.
- In markets where proposals for warnings are 50% of front and back of the pack, consider proposing alternatives such as:
    - Australia: 30% front, 90% back
    - Brazil: 0% front, 100% back
- Where new HWs are required – or the legislation permits the regulator to change HWs in the future – obtain a provision in the legislation allowing adequate time to implement changes.
- Where no HW requirements exist, adopt voluntary HWs in line with the FCTC's 30/30 requirement, as PMI is doing in certain African countries and for duty free.

2) **Descriptor bans**

Our strategy is to propose, as an alternative to descriptor bans, regulation requiring manufacturers to provide consumers with information clarifying that descriptors such as "lights" do not mean that a product has been proven to be safer than full flavour brands. However, the inevitability of descriptor bans may lead markets to decide not to oppose proposals for descriptor bans.

Specific Actions to Consider

- Propose a requirement to provide information to consumers that "lights" and other descriptors do not mean that the brand is proven safer.
    - This could be accomplished through onserts, inserts, internet communications, one of several rotating health warnings, or a requirement that any brand using a descriptor bear an additional on-pack warning.
- Propose amending legislation that bans descriptors to include a ban on printing of tar, nicotine and CO numbers on packs and in advertisements (except where regulations require printing of a range based on ISO and Health Canada method – *see discussion at p. XX below*).
- Obtain a provision in the law allowing regulators to approve the use of a descriptor if, based on objective scientific data, the product is determined to have the potential to reduce risk.
- Oppose a descriptor ban that would prohibit the use of colours differentiating brand extensions.[11]

[11] Colours, which are an intrinsic component of consumer goods packaging and are often elements of registered, protected trademarks, are an important way for adult consumers to choose and find their preferred brand – and an important way that manufacturers compete. A ban on colours to distinguish brand extensions is also the first step to generic packaging and should be opposed on the same principles. *See discussion below on generic packaging.*

3) Tar, nicotine and CO numbers on packs and in ads

Our objective is to seek regulation on the use of T/N/CO numbers on pack or in ads where those numbers are based on the current ISO test method. This is particularly important in markets where descriptors are banned. If governments require both ISO and Health Canada testing, we would support communication to consumers of a range of yields.[12]

Specific Actions to Consider

- Continue to communicate PMI's view to government on the limitations of the ISO test method and the use of T/N/CO yields on pack and in ads.
- Seek a prohibition of the use of T/N/CO numbers on packs, in ads and in brand names when those numbers are based solely on the current ISO test method, especially in markets where descriptors are banned.
- Support legislation that would supplement ISO numbers with Health Canada numbers and would require communication of a range of yields to consumers.[13]
- Whether legislation or regulations require testing based on ISO alone, ISO and Health Canada, Health Canada alone, or any other test method(s), a provision should be included that would allow amendment of the requirement to adopt other test methods in the event that alternative, internationally accepted scientific test methods are developed.
- Where ISO numbers are required on pack or in ads, legislation (or regulation) should:
    - specify placement, font size, and colour of text and background
    - incorporate the ISO provision on tolerances.[14]

[12] See PMI's TobReg Submission at pages 8-15.

[13] WHO has explicitly stated that no quantitative information on tar, nicotine or CO yields should be provided to consumers, even where the numbers are based on both the ISO method *and* the Health Canada methods. We do not agree with this position.

[14] See footnote XX below on performance standards for tar, nicotine and CO yields.