Strengthening the Regulatory Capacity for Noncommunicable Disease (NCD) Risk Factors

Report as of December 11, 2014

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

TABLE OF CONTENTS

Expert Meeting to Discuss the Initiative to Strengthen the Regulatory Capacity in the Region of the Americas for Noncommunicable Disease (NCD) Risk Factors

17-18 November, 2014

On November 17-18, the Risk Factors Unit (RF) of the Department of Noncommunicable Diseases and Mental Health (NMH) carried out an expert meeting to discuss the need to strengthen the regulatory capacity of the Region, in order to reach the global targets for NCDs by regulating their main risk factors, including tobacco, alcohol, physical inactivity and unhealthy diet.

The agenda (see Annex 1) was divided into six main sections:

1. Presentations by selected national regulatory agencies (Brazil, Canada, Colombia, Mexico and USA)
2. Presentations by PAHO/WHO representatives with identified country needs for regulation
3. Expert presentations for concept clarification
4. Presentation and discussion of the Draft TRD prepared by the RF Unit
5. Working groups to discuss the way forward

The meeting was attended by thirteen representatives from Member States' Ministries of Health, nine PAHO/WHO representatives and international advisors, four external experts from academia and international organizations and twenty regional advisors, including Department Directors from the Regional Office (see Annex 2). This report highlights the main findings of the meeting; the detailed contributions are to be addressed and included in the revised TRD. The meeting was documented through graphic recording. The final product of this recording is included at the end of each section to help synthesize the key messages of the meeting. This innovative documentation process allowed for a visual dynamic recollection of the most important issues addressed.

The meeting was opened by PAHO's Assistant Director, Dr. Francisco Becerra. He expressed that regulatory action is the only state function that cannot be abdicated: it has to be based in evidence and needs a considerable amount of human and institutional capacities; and it requires transparency and governance to be effective. Dr. Becerra addressed the need for PAHO, in its role as secretariat, to support the Region in this important area. He also highlighted the importance of the meeting and the need to work towards an action plan to go forward.

Panel 1: Country Experiences

- ANVISA (Brazil) started its presentation by emphasizing that regulation can be understood as an intervention done by the state to prevent possible damage of health risks in the population. Regulatory good practices include publication of the regulatory initiative, impact analyses and transparency in decision making. Transparency depends on multiple factors: a management contract between the Agency and the Ministry of Health, a published regulatory agenda, public consultations and public hearings. Public hearings collect inputs, expertise and information for decision making. They provide economic agents, consumers and users the opportunity to clarify or reinforce opinions and suggestions. They help identify, in the broadest possible manner, all relevant aspects of the subject matter of the public hearing. They also give publicity, transparency and legitimacy to ANVISA's regulations. Authority is granted for enforcement in order to establish binding norms and rules under existing laws and impose penalties on those who violate the law. ANVISA has financial autonomy and is in charge of implementing policy.
- Health Canada is investing $20 million each year in innovative multisectoral partnerships among governments, businesses and not-for-profit organizations which promote healthy living and active lifestyles to help prevent NCDs. They believe that information is helping Canadians make healthier food choices. They also stressed that the involvement of interested and affected parties at an early stage is key to generating agreements. Other important strategies included strong government leadership, monitoring and follow-up. According to Health Canada, conflicts of interest must be known and managed. They also stressed the importance of a strong evidence base. Canada makes monetary contributions through the federal government to NGOs for their participation in the regulatory process in order to address participatory equity. They believe the involvement of civil society is very important.
- INVIMA (Colombia) expressed that the surveillance and control processes should be based in three principles: attribution, competence and capability. They have three priorities: to strengthen regulatory capacity at national and local levels, make national alliances to improve inspection, surveillance and control processes and increase intersectoral coordination. INVIMA supports the creation of a consortium to help to move the regional regulatory agenda forward and recommended creating a database with regulation experiences.



- COFEPRIS (Mexico) presented their experience in obesity. They considered three perspectives: the public health perspective (including information on burden, health promotion and educational communication and prevention); the access perspective (focusing on quality and effective access) and the regulatory policy perspective (including labeling and advertising).
- FDA (USA) presented an explanation on how they regulate health claims. Health claims are statements that communicate information about nutrients and reducing risk for disease (e.g., cholesterol and heart disease) and have to be approved by the FDA. They believe that labeling helps people make healthy choices. For tobacco, the Center for Tobacco Products (CTP) stands between tobacco products and consumers. CTP has the authority to regulate tobacco products intended for human consumption to reduce harm across the population. CTP's three main actions are to prevent youth tobacco initiation, encourage adults who use tobacco to quit and reduce the product's harms and addictiveness.
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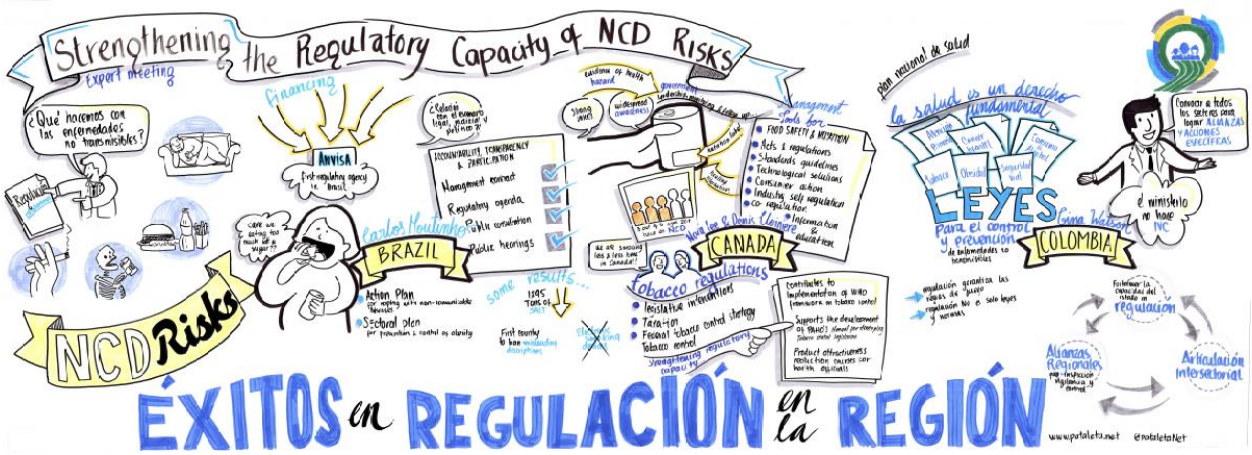


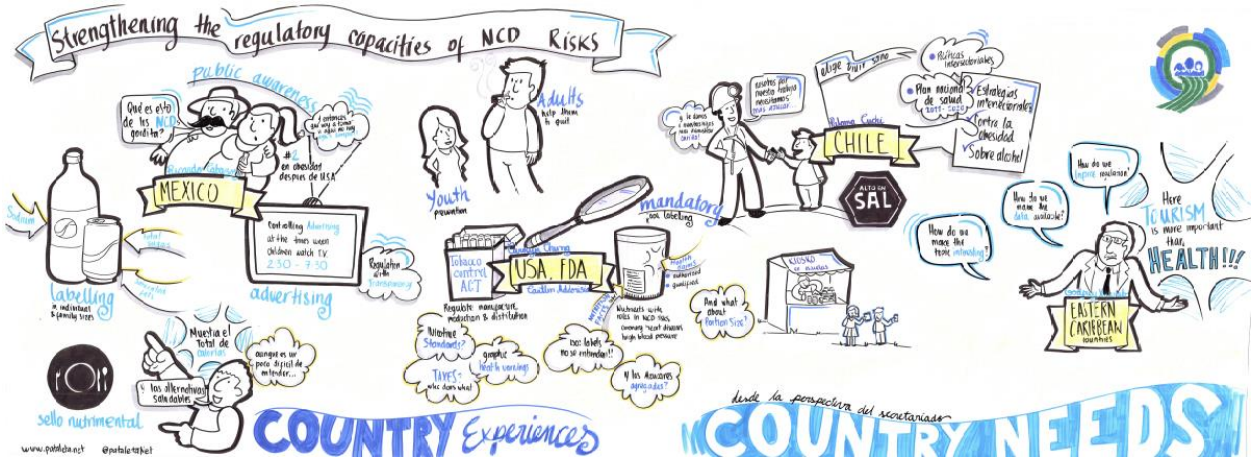
Panel 2. Country Needs

- Paloma Cuchi (PWR Chile), expressed the country's capacity needs for regulation in each phase of the policy cycle. Dr. Cuchi emphasized the importance of adapting global policy recommendations and evidence into the local context, prioritizing across different policy options and knowing which interventions work and which don't. She also stressed that translating technical measures into regulatory requirements must take into account existing regulatory regimes, regulatory traditions, jurisprudence and enforcement mechanisms. Finally, she recognized the need to map out litigation risks.
- Godfrey Xuereb (PWR ECC) had some questions: How do we get the health ministries interested in regulation? How can we use the available data to make them interested? How does regulation affect other sectors? How should the industry be involved, given that it is very powerful and has influence at very high levels? When the issue is a health issue but the law has to go through the attorney general's office, how can they be involved? Dr. Xuereb also

mentioned that even when regulations exist, both enforcement as well as the capacity of human resources remains a problem.

- Fernando Leanes (PWR Peru) emphasized the need to have clear recommendations from the PAHO secretariat. He highlighted the controversies around healthy food legislation and the required role of PAHO. According to Dr. Leanes, PAHO needs to continue providing evidence and technical assistance. It needs to compile the lessons learned from tobacco control, food safety, human rights and health legislation. Finally, he mentioned that secretariat needs to endorse the Union Nations development goals and incorporate the dimension of damage from the risk factors into WHO language.

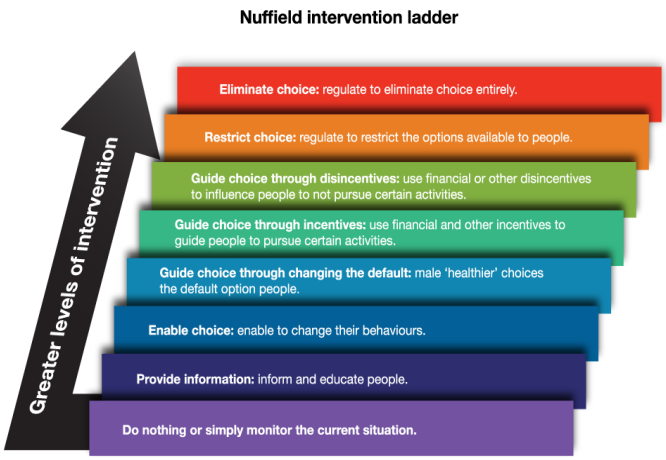
The panel expressed the need for clear recommendations and technical support from PAHO to better prepare for litigation. Sometimes, litigation fails because the law was not well designed or sustained. When technical language is not clear, confusion gives opportunity to the industry to retaliate. The panelists highlighted the importance of national surveys to support regulation and the relevance of civil society.



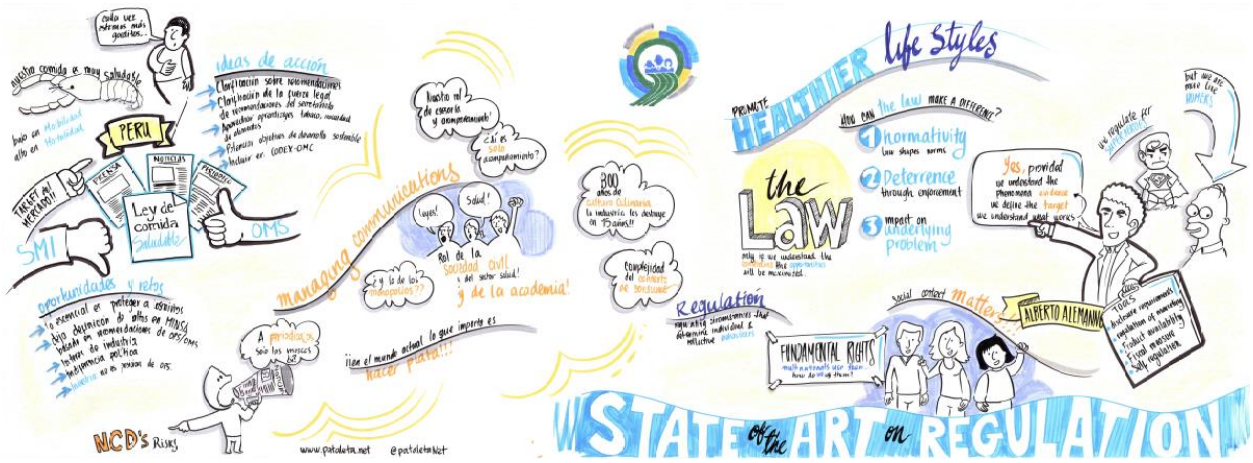
Panel 3 Experts presentations

Dr. Alemanno expressed that law and public policy are among the most powerful tools to improve population health. Dr. Alemanno's presentation included the solutions that require action through the implementation of international agreements and strategies, education, legislation, regulation and fiscal measures. He raised three ideas of why law matters: normativity, as laws shape norms; deterrence through enforcement and the impact on underlying problems.

Dr. Alemanno stressed the need to understand the phenomena (evidence), define the target (what are the forces against) and acknowledge limits of laws and their capacity for rapid transformation. He recognized that laws need to be legally sound and scientifically substantiated as relevant industries will challenge them**.** Levels of intervention were also presented:



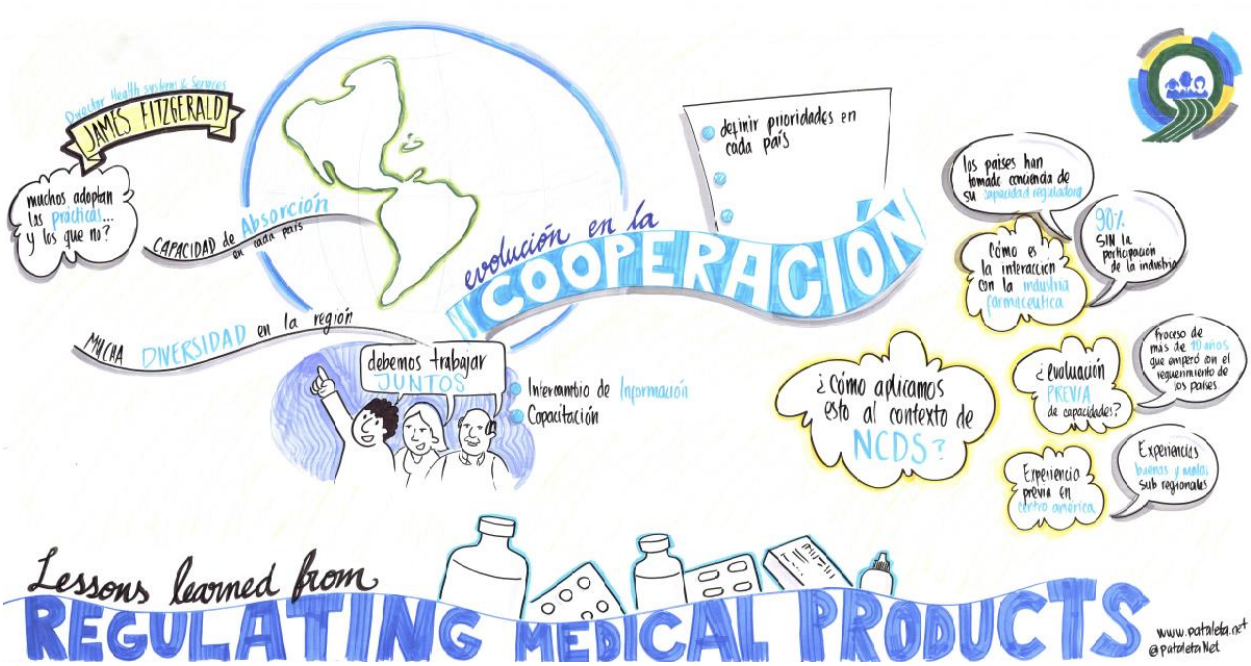
Finally, he addressed the regulatory constraints for NCDs: Legitimacy (to what extent are we entitled to regulate behavior), legality (constitutional law, international law (trade, investment) and fundamental rights), culture and design.



Dr. Fitzgerald. Lessons Learned from Regulating Medical Products.

Dr. Fitzgerald presented his experience with advancing medical product regulation in the Region and globally. Dr. Fitzgerald and his team created nine diagnostic functions with indicators for each and found that the development of institutional capacity was key when regulating medical products. In his view, it is important to consider the capacity development priorities of each country, which can be done with the help of other agencies. For this task, the creation of an exchange network is crucial. He and his team created sub-regional mechanisms to focus on the particularities of different countries. According to Dr. Fitzgerald's presentation, it is important to recognize that each country has its own competence and

requirements. In this case, the industry was interested in the development of standards and worked together with Dr. Fitzgerald's team. The process took them 10 years.



Dr. McGrady. Trade agreements and investment contracts are the main instruments for the industries to challenge regulation in court.

Dr. McGrady presented on trade agreements and how they compel states to lower barriers to trade (liberalization). Dr. McGrady's presentation focused on a number of points:

- Barriers include tariff and 'non-tariff barriers,' such as regulations;
- Rules governing non-tariff barriers seek to prevent regulatory protectionism (discrimination) and unnecessary regulation;
- Agreements also restrict the use of agricultural and other subsidies and provide minimum standards of protection for intellectual property rights;
- Investment contracts between the state and an investor provide legal protection for the investor, including in the contexts of taxation and regulation;
- Investment treaties between states protect the property rights of foreign investors and are increasingly used to challenge regulations through international arbitration rather than domestic courts.

Dr. McGrady also offered a few lessons learned. He stressed the importance of horizontal training (basic skills) as well as using vertical approaches (through regulation of specific risk factors). He also maintained that sustainability is a challenge both at the international and domestic levels. Finally, he

recommended that inter-departmental training can help bridge gaps between government agencies, though it is unlikely to solve cooperation problems.

Comments from the panel included the importance of eliminating perverse incentives and planning ahead for possible retaliation against the proposal. Two jobs were recommended for the secretariat (PAHO): coordinating the different stakeholders and showing them the commitments and agreements.

Panel 4. Technical Reference Document (TRD)

The draft version 1.0 of the TRD (annex3) was presented by Lynn Silver, who consulted for PAHO on the document. A round table with Heidi Jiménez, Joaquin Molina and Michele Cecchini commented on the document. Heidi Jiménez highlighted the importance of creating a robust legal framework based in useful legal evidence.

First, it was stated that the organization (PAHO) has done little to develop a legal and regulatory technical cooperation. There has been an increase in legal cooperation requests from Ministries of Health, and therefore the elements of the currently proposed law and the health regional strategy were explained in consultation with Member States.

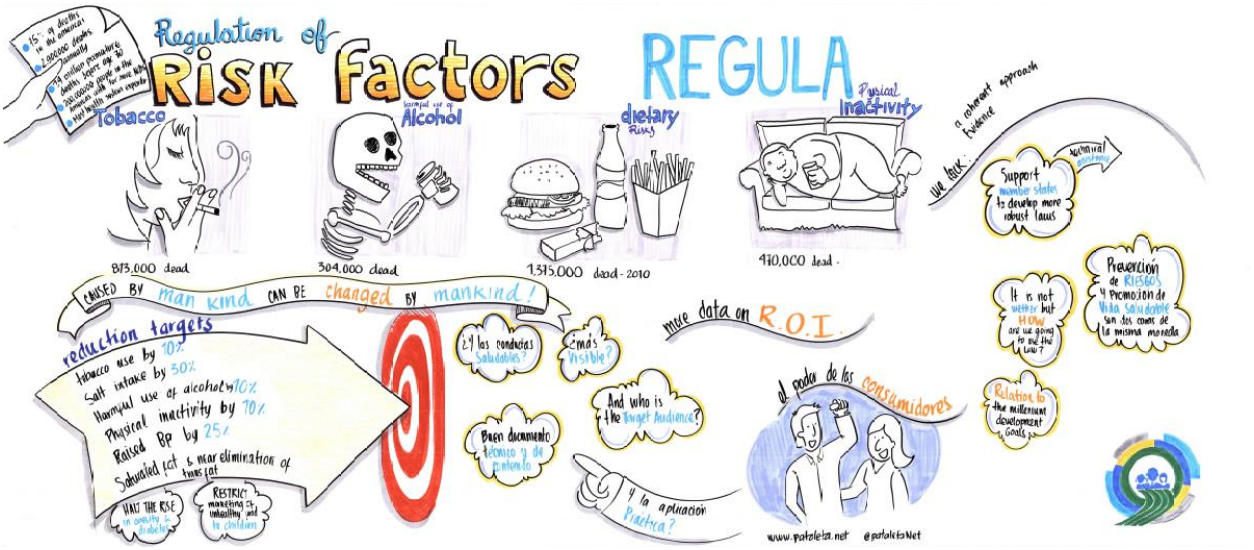
Joaquín Molina pointed out the need to give an emphasis to prevention measures to combat risk factors. He believes that the promotion of healthy lifestyles is and important goal and that public consultation to legitimize regulation is important and should be mandatory.

Michele Cecchini recommended that risk factors should be discussed together but not regulated together. He appreciated the way the TRD presents prevention and regulation as the best option to lower the burden represented by NCDs. Mr. Cecchini recognized that evidence is fundamental to support regulation. He commented that while the document centered mainly in mortality rates, the

economic burden of the morbidity rates and loss of productivity are more important. He also mentioned that there are different means of regulation and stressed the important of explaining each one as well as its implications, from the subtle to full enforcement.

During the open discussion some recommendations were offered:

- Explain more clearly how to implement the regulatory proposals;
- Emphasize the need for surveillance;
- Explain what happens after an agreement is signed;
- Include more experiences like the Colombia or tobacco control cases;
- Define the audience for the document;
- Add a more complete diagnosis;
- Describe different goals that can be achieved if major changes are not possible;
- Create a short version to help the representations in their work with the ministries. This short version should be like a toolbox with different options and a clear perspective of what can happen if you follow each path;
- Define clearly the roles for the different institutions;
- Include how to develop capacity;
- Identify sustainability problems as well as the importance of distinguishing between coordination and cooperation issues.



Panel 5. Working groups.

The objective of this section was to discuss the way forward. The group was divided in 4 working groups.

Group 1. Institutional capacity development.

The group proposed:

a. Create lines of action;
b. Build a framework of regulatory processes;
c. Strengthen competencies in the health sector;
d. Provide evidence and data collection that speaks to institutional strengthening (M&E);
    i. Potential return on investment of intervention
e. Delineate the legal structures and reach within the Region;
f. To create a sort of menu of considerations and practices that are necessary for decision-makers to take into account;
g. Advocate for regulation within the health sector;
h. Provide a comparative analysis of the regulatory capacities;
i. Gather best practices as elements upon which decision makers can structure actions.

Group 2. Development of technical capacity for risk factor control.

The group reflected that it is not advised to create a body of laws or model legislation. Instead, strong technical and scientific guidelines and capacity to determine the risks should be provided to establish where regulation is needed. International and regional agreements are positive elements, because governments need collective protection. This protection is especially pertinent when considering that most individual government actions receive external pressures from economic interests, which eventually affect governance.

Group 3. Evaluation of regulatory process.

The group identified the following priorities:

1. Working on risk communication;
2. Working together with and providing a guide to journalists and development agencies;
3. Assuring surveillance in each country for each risk factor (needs to be funded). PAHO could give technical assistance;
4. Map the region with what has been done and how and what is missing;
5. Clarify PAHO's position regarding the recommendations;
6. Organize a high level meeting with other parties, including the World Bank, Inter-American Development Bank, and people in countries to get them working together;
7. Look for cross cutting lessons - like on communication trade;
8. Look for unintended effects of regulations, both in the regulatory assessment/risk management sections and afterwards;
9. Secure the funding for monitoring and evaluation activities.

Group 4. Research for pertinent knowledge.

The group identified the following challenges and recommendations:

Challenges:

- How to translate the evidence into actions;
- Ensuring that legislation supports the changes that need to be done;
- Providing risk analysis to support any intervention.

Recommendations:

- Share an agenda with research institutions to stablish research lines and to coordinate efforts;
- Get to know the research criteria in each country and how it is established;
- Look for robust evidence to support the measures needed;
- Share and communicate what we already know.
- Ensure that the Member States know what they have to know when taking decisions;
- Check conflicts of interest on funded research and what the priorities for each institution in each country are.

The experts meeting was closed by Dr. Anselm Hennis, the NMH Department Director, who highlighted the need to do a gap analysis that identifies what we have as a Region, where we are and what needs to be done that could justify collaboration between countries.