Economic Benefits of the Regulation Risk-Based

*The Case of Medical Device*

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What is Risk?

• The risk is defined as the probability that an adverse event occurs, multiplying the harm that would cause in case of materializing. The risk is simply the expected loss and it’s commonly identified more frequently in situations which affect life, health, environment, finance and everyday life.

• However, the valuation of the expected loss implies to measure the probability of all possible events, situation that complicates as uncertainty increases. Faced this situation, regulation implies a decision with incomplete information.

Risk = Probability of occurrence by Harm

\[ R(X) = E(X \cdot P(X)) \]
• There are risks which are more sensitive than others, for which by facing risks that have a very high valuation, the regulator is encouraged to emit rules that attend to what it is known as Precautionary Principle: «it is better to prevent than to regret»*

«In order to protect the environment, the states must apply amply the precaution criteria according to their capacities. When there`s danger of great harm or irreversible, the lack of absolut cientific certainty must not be used as an excuse to postpone the adoption of effective measures in function of the costs to prevent the environmental degradation»

«When an activity generates threat of harm against human health or to the environment, precautionary measures must be taken, even if it`s not completely stablished in the cientific field the relations of causality and the efects related to the problem»

Regulators' dilemma

- The **governments are intended to protect citizenship** from social risks, environment, health, labor, economic, financial, etc., so they seem to be **encouraged to act accordingly with the precautionary principle**.

- However, as **available information and experience grow**, uncertainty is reduced, and therefore, it is possible that the regulator keeps on evolving into an approach in which the **rules emitted correspond to the level of risk** it is faced.

- In all cases, the regulator must assume that **zero risk is unreachable**, because invariably reducing a risk another risk is increasing in other areas.

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**Minimizing Error Type I and Error Type II**

**Error Type I**

Failes in regulate (sub regular or non regular) when is required to and, therefore, loss and damage are generated (eg.: entrance of harmful products).

**Error Type II**

Regulate where there's no need or regulate more than proportional to the risk, promoting other risks and reducing benefits to population (eg.: lack of access to needed health products).
Principles for emitting regulation risk-based

Given the difficulty that represents to be able to generate regulation that attends in optimal way the risks faced by society and, at the same time, generates an efficient and effective use of resources, the OECD has generated a set of general principles.\(^1\)

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\(^1\)Risk and Regulatory Policy: Improving the Governance of Risk, OECD Reviews of Regulatory Reform, OCDE, 2010
Once this analysis is made, the OECD identifies four types of regulatory alternatives to attend every problem:

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Avoid Risk**| - Prohibit Activities  
|               |   - Ejemplos: Smoking, Industrial Waste                                      |
| **Transfer Risk** | - Make another economic agent to accept risk  
|               |   - Ejemplos: Contracts, Insurances                                          |
| **Retain Risk**  | - Accept risk losses  
|               |   - Ejemplos: Low risk activities, Dangerous Hazards Management Programs    |
| **Reduce Risk**  | - Reduce risk probability  
|               |   - Ejemplos: Licencees, Standards                                           |
As good regulatory practice, there can be made some ex–post assessments which allow to check if the risks are lower or higher than the originally posed and, in this way, improve regulations.

**Cycle Regulation**

1. **Planning**
   - Objetives, resources, capacities and tools to be used are identified preliminary.

2. **Consultation**
   - The views of stakeholders are collected and get political support from the highest level that the strategy is viable.

3. **Design**
   - The objetives, responsables, compliance times, resources, capacities and tools are established definitively.

4. **Implementation**
   - The simplification and deregulation is implemented; working groups and negotiation are carried out to review the regulation.

5. **Evaluation and Monitoring**
   - The strategy is checked in order to see if it is achieving the proposed objetives. The evaluation is quantitative and qualitative.

Application on Medical Device formalities

Based on this principles, it was found possible to check the regulatory frame of the applicable formalities to medical device for their merchantibility.

- In 2007 it was estimated that the worldwide market value of devices was around 160 mmd.*
- United States dominate about half of the total market.*
- Japan, Germany, England and France have the biggest markets just after US.*
- Mexico is in the first 15 places as market size refers.*
- It is estimated that the world market rate growth is 4.6%.*

<table>
<thead>
<tr>
<th>Mexico Indicator (2008)*</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maket value</td>
<td>2.31 mmd.</td>
</tr>
<tr>
<td>% of GDP</td>
<td>0.26%**</td>
</tr>
<tr>
<td>Total exports</td>
<td>4.92 mmd.</td>
</tr>
<tr>
<td>Total imports</td>
<td>2.17 mmd.</td>
</tr>
<tr>
<td>Economic Units</td>
<td>595</td>
</tr>
</tbody>
</table>

*FUENTE: ProMéxico, **Estimación propia
Application on Medical Device formalities

In this way, it was found that the Health Record for Medical Device is classified in three types which vary with risk level, which were revised based on the principles outlined by the OECD, determining possible to make the modifications.

COFEPRIS verified, based on their risk level, from a total of 12,000 medical device with the obligation to obtain health registration, the registration and extension processes can be simplified for the 9.8% of this products.

- **1172** Products actually considered medical devices
- **95** Medical devices with very low risk

**Products not to be considered medical devices**

**Eliminate requirements for Sanitary Register**

**Issuance of a Product List**

**Creating a Class IA very low risk**
Standard Cost Model is a tool from OECD\(^2\) which COFEMER has adopted in order to assess the improvements in formalities. In countries where it has been implemented, it was calculated that the use of the model generated a reduction from 25% of the administrative burden, equivalent from 2% to 3% of GDP.

\[ CT_{i,t,a} = \sum_{t=1}^{T} \sum_{a=1}^{A} (CT_{i,t,a})_{t=0,1} \]

**Administrative Burden**

- 8 standard activities (generation of information, transfers, shipments, meetings, servicios externos, llenado de formatos, archivos de respaldo, etc.)
- Time dedicated to every activity
- Salary costs of personnel involved in each standard activity

\[ CAT_t = \sum_{i=1}^{I} \sum_{a=1}^{A} (CT_{i,t,a})_{t=0,1} \]

**Opportunity Cost**

- It's a measure of capital cost as opportunity cost (compared to the risk-free rate)
- For the case of this formalities it was considered the weighted average cost of capital (WACC) from the pharmaceutical industry of medical device.
- The OC considers the response times of the authority.

\[ CO = \left( \frac{(K_i + C_i + W)}{M} \right) \times T_i \]

Donde:
- \( K_i \): Formación bruta de capital del subsector económico
- \( C_i \): Costos fijos del subsector económico
- \( W \): Ingreso promedio de los socios
- \( T_i \): Plazo de respuesta del trámite

\( M = \) Unidades económicas por sub sector económico

\( r = WACC \) Industria farmacéutica de dispositivos médicos

\(^2\)The Standard Cost Model – A Framework for Defining and Quantifying Administrative Burdens for Businesses, OCDE, 2004
Results

Administrative Cost for a representative firm

<table>
<thead>
<tr>
<th>Costo Económico Total Asociado al Registro</th>
<th>Costo Económico Total Asociado a la Prórroga</th>
<th>costo Económico Correspondiente a la Propuesta</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2,186</td>
<td>$8,702</td>
<td>$0</td>
</tr>
</tbody>
</table>

Source: COFEMER with data from COFEPRIS

La mayor parte la constituye el costo de oportunidad

Distribution of administrative cost

Costo Económico Total Asociado al Registro: $2,186
Costo Económico Total Asociado a la Prórroga: $8,702
Costo Económico Correspondiente a la Propuesta: $0

Total: $827 mdp

Registro: $825.47
Prórroga: $1.23

Entregue a una empresa representativa, el costo administrativo es mayor para el trámite de prorroga, aunque la propuesta tiene mayor efecto en el trámite de registro porque es donde apoya a más empresas.

Source: COFEMER with data from COFEPRIS
Benefits of the regulatory approach to risk-based DM.

The extent of deregulation presented by COFEPRIS generates a resource release of 0.03% of GDP and 11.55% of the medical device market in Mexico.

<table>
<thead>
<tr>
<th>Total de Beneficios Económicos</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Total de Beneficios Económicos (mdp)</td>
<td>3,601.7</td>
</tr>
<tr>
<td>Tamaño del mercado de DM en México (mdp)</td>
<td>31,185</td>
</tr>
<tr>
<td>Tamaño del mercado como porcentaje del PIB</td>
<td>0.26%</td>
</tr>
<tr>
<td>Liberación de recursos como porcentaje del valor del mercado</td>
<td>11.55%</td>
</tr>
<tr>
<td>Liberación de recursos como porcentaje del PIB</td>
<td>0.03%</td>
</tr>
</tbody>
</table>
Appropriate risk measurement and management allows to develop regulations that promote economic activity, while protecting the health of the population.

- This proposals create great benefits representing opportunities for implementation in other areas and products.
- Start by areas where is evident that risk is lower than the originally estimated.
- More free resources for productivity and economic development
- Standard Cost Model as a tool for evaluating and socialization of regulatory reform
Thank you

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