Panel C: MEDICAL PRODUCTS OF HUMAN ORIGIN AND OTHER BIOLOGICALS

Participation of different actors in the regulation of some health technologies: *Blood and blood products - The regulatory plurality.*

CPANDRH - Mexico City October 19-21, 2016

Ariel E. Arias MD, PhD,
Centre for Biologics Evaluation - Biologics and Genetic Therapies Directorate
The views expressed in this presentation do not necessary reflect those of Health Canada or the Government of Canada.
Blood is not a single therapeutic product
Effects of blood therapies depend on multiple factors
Blood - Relevant Regulatory Frameworks

**Drug** – *Food & Drugs Act*

- Blood Derived Products
  - *Food & Drug Regulations*

- Blood Components
  - *Blood Regulations*
  - *Medical Device Regulations*
  - *Cell, Tissues and Organs Regulations*

**Others**

- Federal vs Provincial Authorities
- Practice of Medicine
- Research - *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS).*
- National Standards
<table>
<thead>
<tr>
<th>Federal</th>
<th>Provincial / Territorial</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <em>Food and Drugs Act</em> and relevant <em>Regulations</em></td>
<td>• Health Professionals</td>
</tr>
<tr>
<td>• National Surveillance (Regulatory and Public Health)</td>
<td>• Hospitals &amp; Health Authorities</td>
</tr>
<tr>
<td>• Compliance &amp; Enforcement</td>
<td>• Public Health</td>
</tr>
</tbody>
</table>

**SAFETY**

<table>
<thead>
<tr>
<th>Manufacturers</th>
<th>Other Players</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Private Companies</td>
<td>• Donors &amp; Recipients</td>
</tr>
<tr>
<td>• Blood Establishments (Cell &amp; Stem Cell Banks)</td>
<td>• NGOs</td>
</tr>
<tr>
<td>• Public &amp; Private Organizations</td>
<td>• Standard Associations</td>
</tr>
<tr>
<td>• Processors</td>
<td>• International Authorities and Organizations</td>
</tr>
<tr>
<td></td>
<td>• Academic Institutions</td>
</tr>
</tbody>
</table>
• There are several key stakeholders involved in blood therapies
• A single regulatory framework is most probably highly impractical
• Useful regulatory frameworks need to take into account the role of the different players and the scope of the authority
THE END ... ?

Muchas Gracias!

Merci beaucoup!

ariel.arias@hc-sc.gc.ca