

COLOMBIA

OPPORTUNITIES AND REGULATORY CONSIDERATIONS

OPORTUNIDADES Y ASPECTOS REGULATORIOS

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Corporate law

- Contracts
- Corporate / Tax Law
- Fusions and acquisitions
- Due Diligence



Intellectual Property

- Brands
- Patents
- Copyright
- Consumer protection



Regulatory Affairs

- Permits, Licenses
- Vigilance
- Port issues
- Advertising
- Training
- Audits

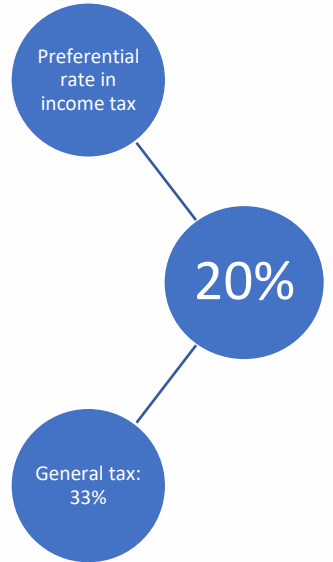
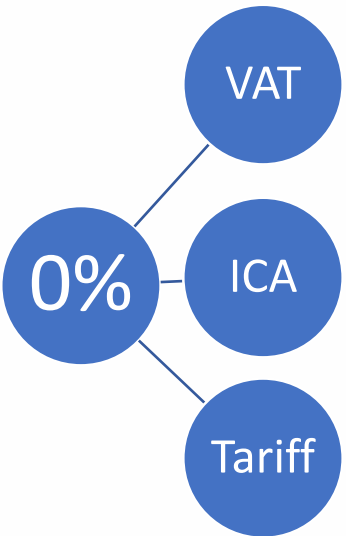


Colombia Offers:

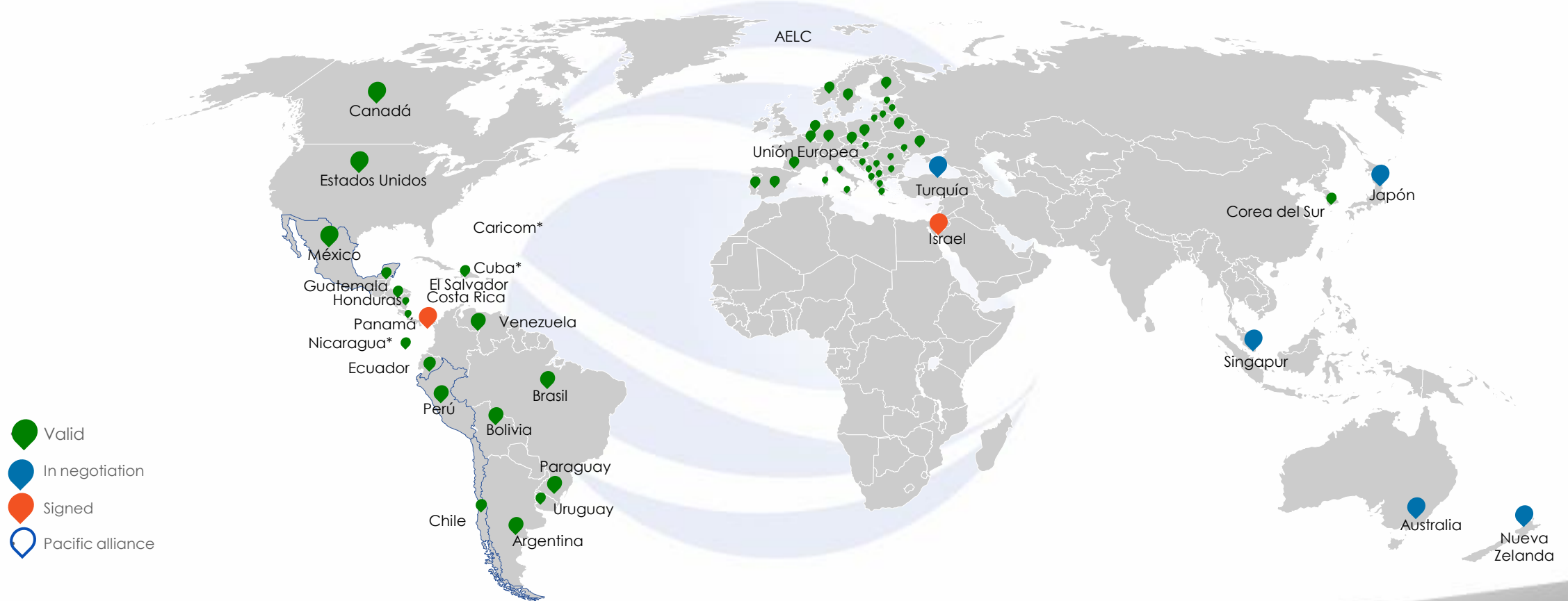


- Stable economy
- More than 16 commercial agreements
- Growing market
- Investment opportunity in several sectors
- Ease of access to the local market
- More than 100 free zones
- First place in investor protection (protection index)

Investment Incentives



Access to 60 countries with more than 1,500 million consumers, through its network of FTA



Pacific Alliance: Colombia – Chile, Perú y México.
Source: Ministerio de Comercio Industria y Turismo, 2017
Processed by ProColombia

Strategic location



Access to more than 45 countries

1 109 Direct international frequencies per week

More than 5600 Domestic weekly frequencies

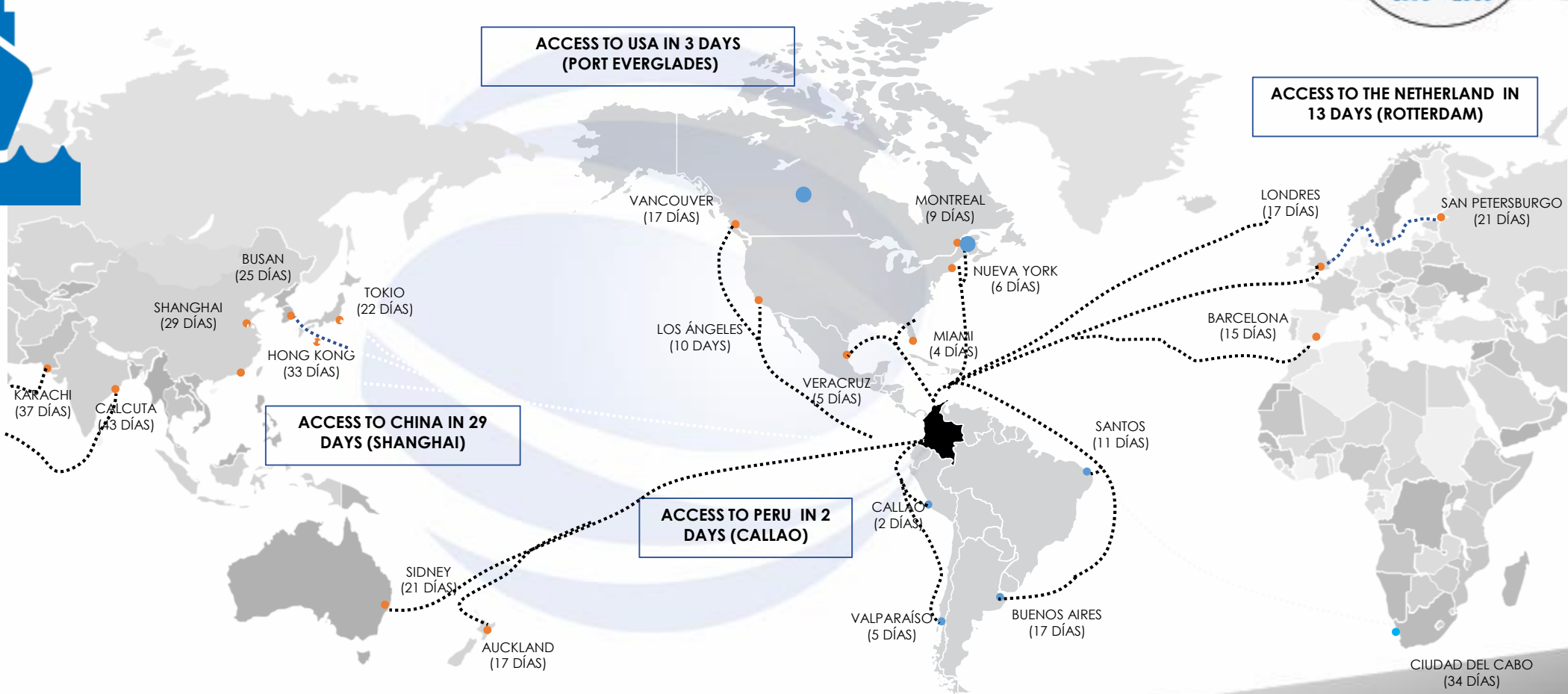
Less than six hours by plane from main cities in Americas

Strategic location in the middle of America.

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• Routes from international airports: Barranquilla, Bogotá, Cali and Medellín. For a typical week of the month of December 2017.
Source: Routes and Tariffs - Tools for Colombian exports, processed by ProColombia.

Strategic location



Coasts in both oceans

+4,500 export shipping routes

Access to 680 ports in the world

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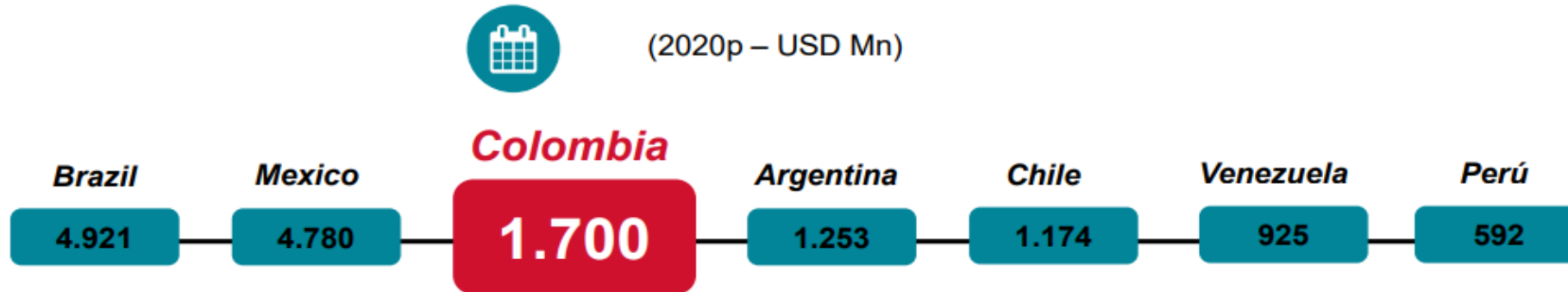
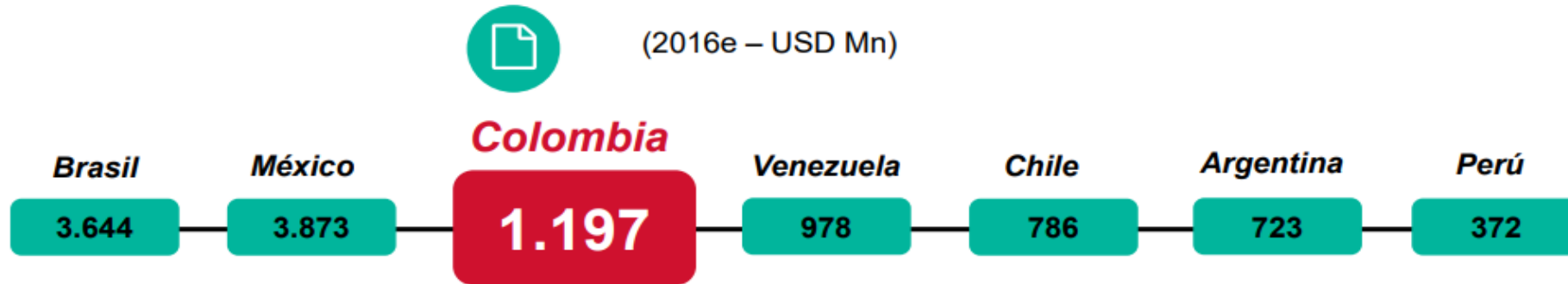
Source: Routes and Tariffs - Tools for Colombian exports, processed by ProColombia.

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Teléfonos: (57 1) 7562594 Celular: (57) 314 296 8186
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Opportunity sectors

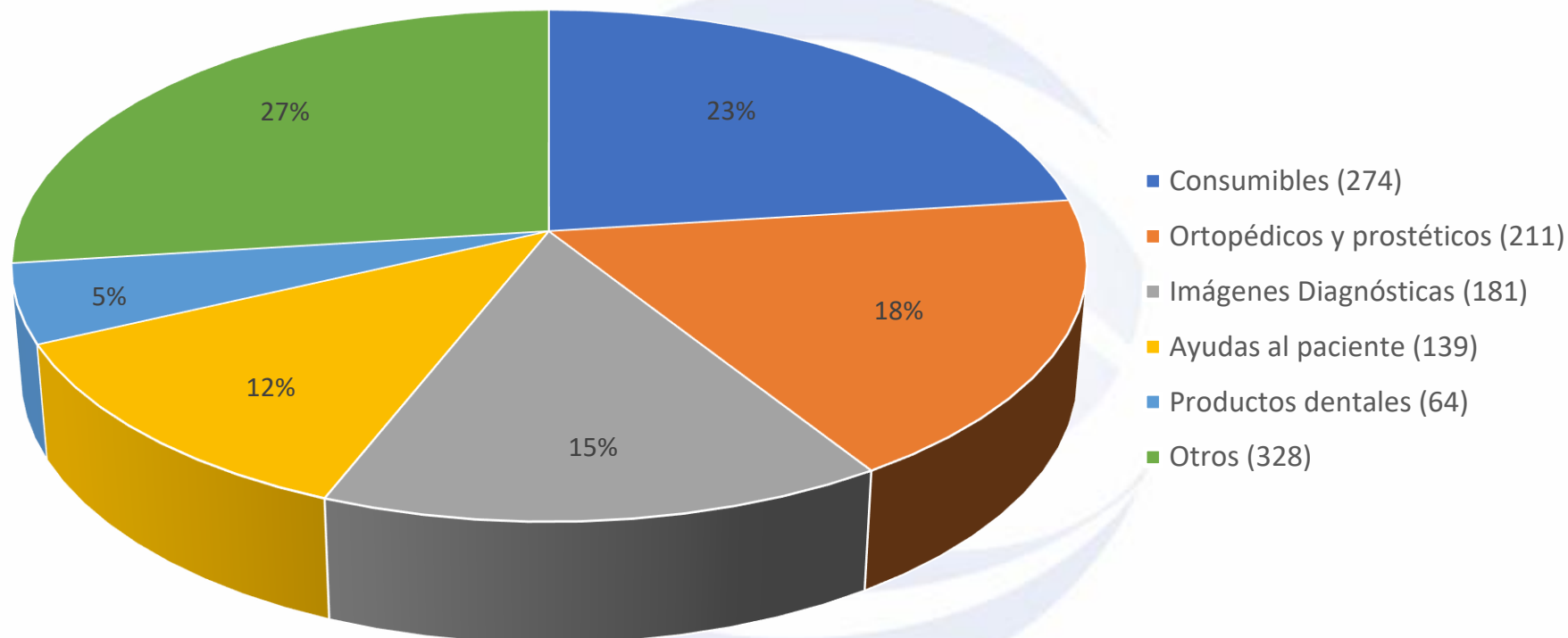


Colombia in MD market / LATAM



MD in Colombia

USD mill.



+80% imported



REGULATORY
CONSIDERATIONS

Colombia



- ✓ National Authority:  **invima**
Instituto Nacional de Vigilancia de Medicamentos y Alimentos.
- ✓ MD regulations are based in European MDD
- ✓ Classification according to health risk
- ✓ Post marketing Surveillance system
- ✓ Alliances with other countries (CAN, Pacific Alliance)

Alliances



Andean Community (CAN)

- Colombia, Ecuador, Perú, Bolivia
- Harmonization for Cosmetics (PCP) & Home care products



Pacific Alliance

- Colombia, Chile, México, Perú
- Pharmaceutical cooperation
- Bioequivalence / GMP
- Rules for MD Commercialization



Colombia. Regulatory conditions



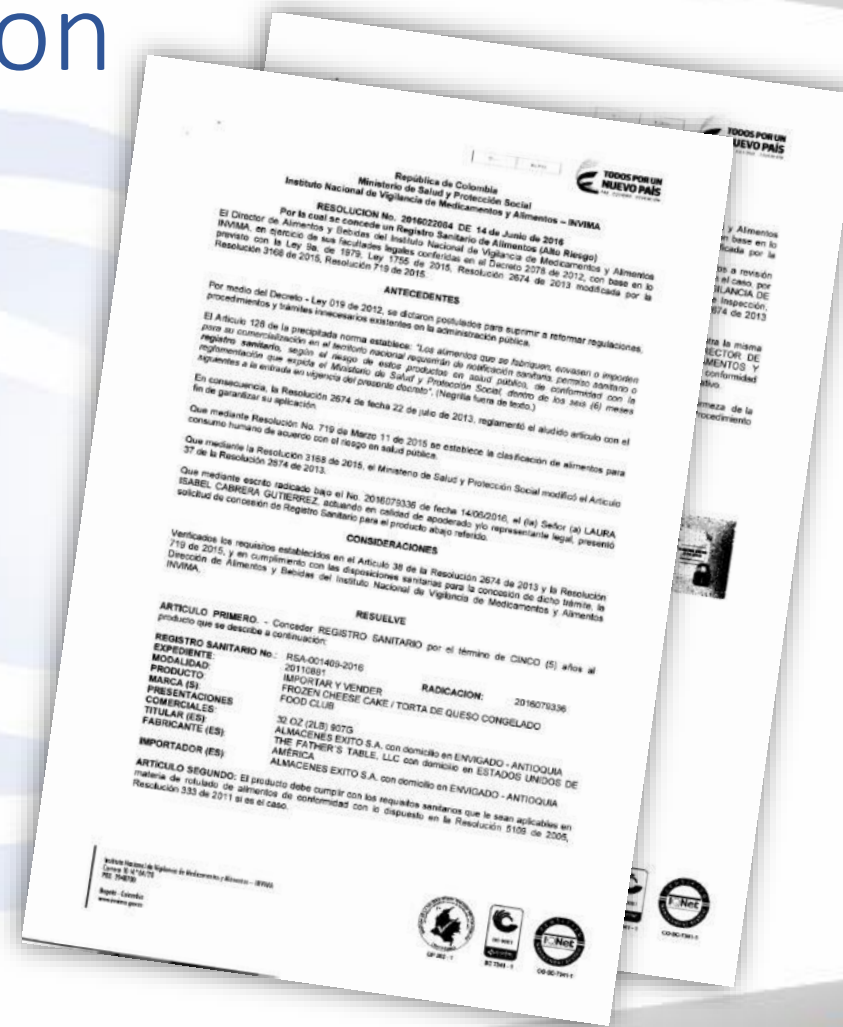
- ✓ Permit Owner: foreign company
- ✓ Families of products (same composition, type, risk, manufacturer and intended use)
- ✓ Multiple importers/ Conditioning facilities
- ✓ Multiple Brands, formats, references, models
- ✓ No samples required
- ✓ “Automatic” renewal and modifications *

 Hosting

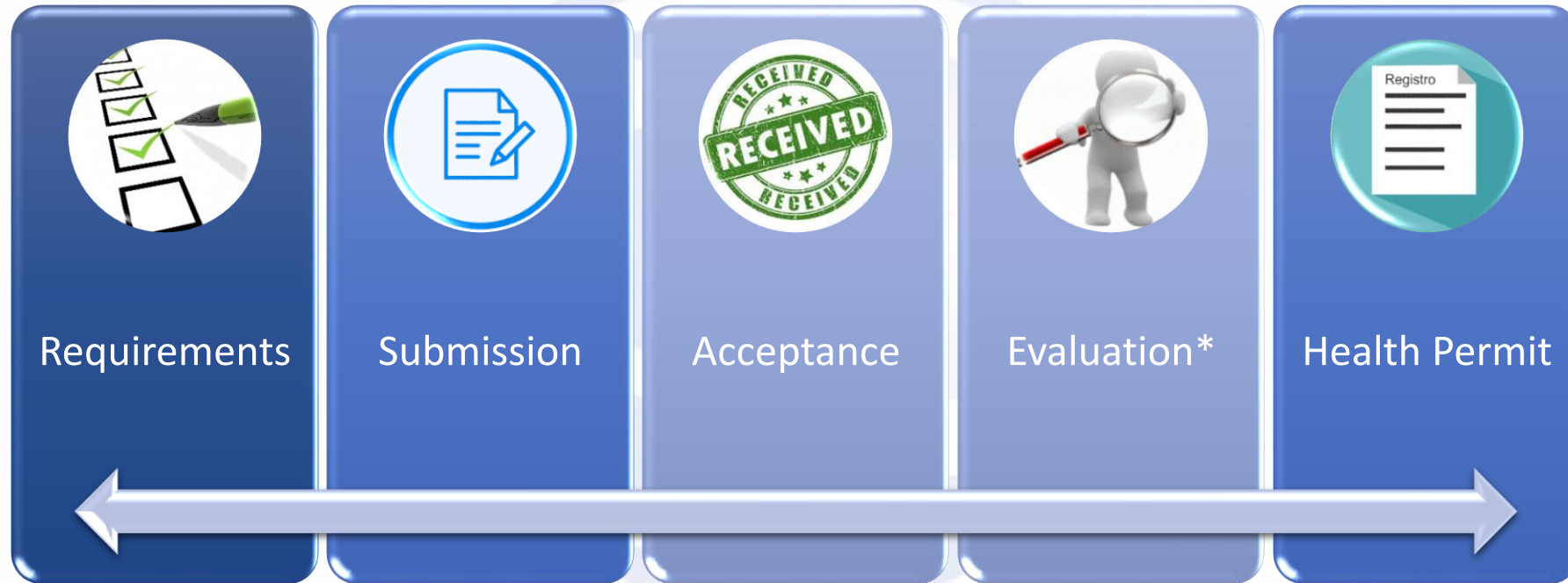


Health permit /authorization

Authorization given by the government, to manufacture, import, export, sell and related activities defined products.



Registration system



** Request of additional information can be made by the authority*

Period of validity - MD

10
Years

Associated processes



Modifications

Renewals

Cancellations

Suspensions

Appeals

Other regulatory activities

HABILITATIONS

AUTHORIZATIONS

CERTIFICATIONS

POST MARKETING
SURVEILLANCE

FACILITIES
CERTIFICATIONS &
AUDITS

ADVERTISING
AUTHORIZATIONS



Frequent mistakes

- ✓ Incorrect groups of products
- ✓ Name different from CFS/CFG
- ✓ Manufacturer doesn't match (legal /Contract)
- ✓ Typing mistakes
- ✓ Misclassification
- ✓ Wrong definition of families
- ✓ Name not adjusted to the regulation



TIPS

- ✓ References / codes / part numbers must be included in CFS/CFG – DoC
 - ✓ Demonstrate relationship between all parts involved in the permit
 - ✓ Detailed composition (qualitative)
 - ✓ Complete and correct data in application
 - ✓ Supply all required documents / information
 - ✓ Required documents should be legalized
 - ✓ Official translations when required
 - ✓ Timely and accurate consultancy

Recommendations



- ✓ Protect your trademarks /Brands
- ✓ Negotiate and sign agreements with your distributors
- ✓ Apply for your health permits and modifications with priority
- ✓ If possible, own your permits
- ✓ Report on time news related with the devices
- ✓ Include complete and truthful information
- ✓ Carefully review your advertising



Lets work together!



THANK YOU FOR YOUR ATTENTION!