

Exceptions and limitations on patent rights, practice in selected latinoamerican countries.



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TRIPS FLEXIBILITIES TO BE REVIEW

ART 44.2 TRIPS LIMITATIONS TO INJUNCTIONS	ART 31 NON AUTHORIZED USES	ART 30 EXCEPTIONS	ART 6 EXHAUSTION
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ANDEAN COMMUNITY	ECUADOR, PERU,	COLOMBIA	CHILE URUGUAY
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Intellectual Property Legislation and Regulations

- **Ecuador**

The Organic Code of the Social Economy of Knowledge, Creativity, and Innovation

- the Knowledge Management Regulation, issued by Agreement No. SENESCYT-2020-077 from the National Secretariat of Higher Education, Science, Technology, and Innovation, provides guidelines for managing intellectual assets in Ecuador.

- **Colombia**

The Single Circular of the Superintendence of Industry and Commerce (SIC)

- Decree 4302 of 2008 establishes the procedure for declaring the existence of public interest reasons, as stipulated in Article 65 of Decision 486 of the Andean Community Commission, related to compulsory licenses and public interest.

- **Chile**

Chile's industrial property regime is governed by Law No. 19,039,

- Decree No. 82, which approves the regulation implementing Law No. 19,039 on industrial property.

- **Uruguay**

- Decree No. 11/000 of January 13, 2000, which regulates Law No. 17,164.
- Law No. 17,164, concerning patents for invention, utility models, and industrial designs

- **Andean Community**

Decision No. 486 of the Cartagena Agreement establishes the Common Regime on Industrial Property

IMPLEMENTATION ARTICLE 44.2 TRIPS

**ANDEAN
COMMUNITY
DECISION 486/**

ECUADOR

**COLOMBI
A**







PERU

CHILE

URUGUAY



IMPLEMENTATION ARTICLE 31 GOVERNMENT USE DIFERENTIATED FROM COMPULSORY LICENSING.

ANDEAN COMMUNITY DECISION 486/	ECUADOR	COLOMBI A	PERU	CHILE	URUGUAY
					

ART 31 Compulsory Licensing

JUSTIFICATION	ANDEAN COMMUNITY DECISION					
	PERU	ECUADOR	COLOMBIA	PERU	Chile	Uruguay
licencia obligatoria por no explotación de la patente,	48 ✓ 589	✓	✓	✓	✗	✓
Interés de público, de emergencia, o de seguridad nacional.	✓	✓	✓	✓	✓	✓
Prácticas que afectan la libre competencia	✓	✓	✓	✓	✓	✓
permitir la explotación de otro patente.	✓	✓	✓	✓	✓	✓
negativa licenciar voluntariamente en términos razonables.	✗	✓	✗	✗	✗	✓

Best practices

Chile: The entity requesting CL might be granted provisional use of the license.

The granting of the license allows use of relevant data for health authorization.

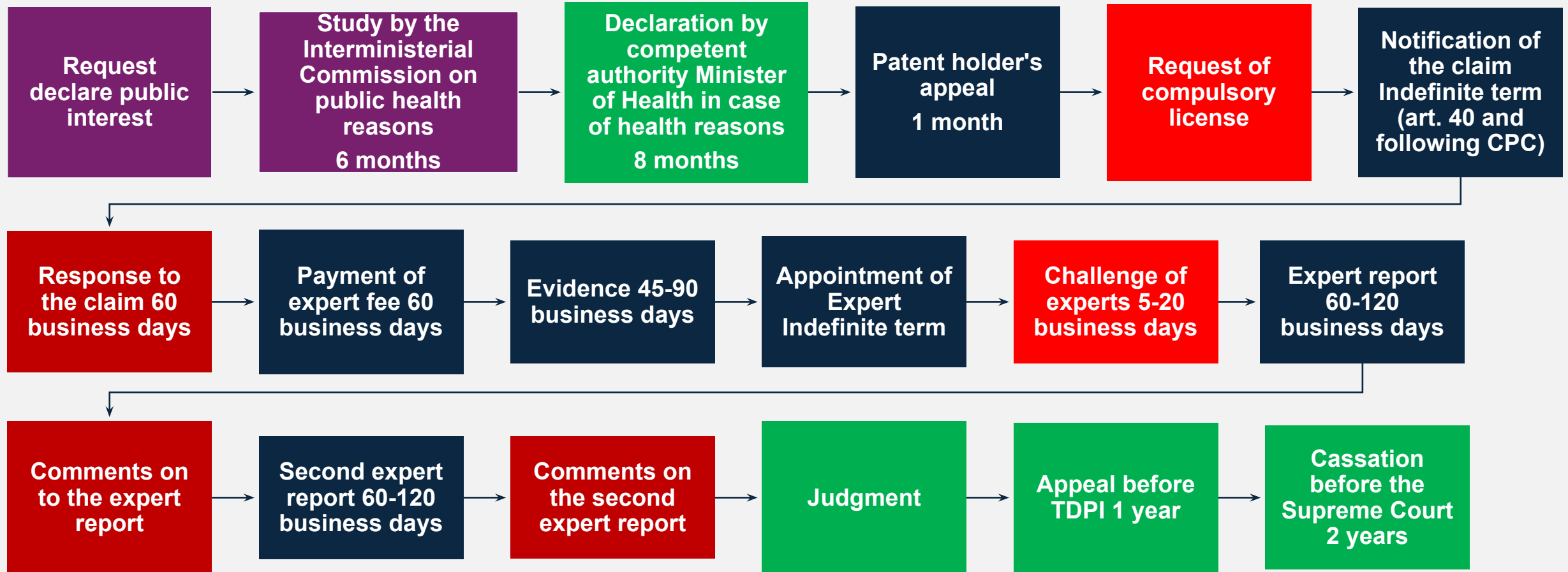
Ecuador: Recognizes Government use expressly and with a simplified process.

Uruguay provides for a simplified process for compulsory licensing, in case of emergency.

Compulsory licensing proceeding for public interest reasons restrictions

- **All but Ecuador , do not include separated proceeding for government use. If the government need a public non commercial use, needs to follow the process of compulsory license.**
 - Non of them, but Ecuador could benefit from EE.UU. Type of government use fast mechanism.
 - All require that there is a declaration by the President and relevant Ministers or Minister that public interest justify the compulsory license, before the CL process itself.**
 - Need to identify each patent.
 - No reference to pending patents**
 - Process for obtaining license might take several years. Subject to different legal challenges.

Chilean proceeding to obtain compulsory license (UP TO 3 to 4 years to be completed).



Compulsory Licensing for Dolutegravir Colombia

Junio 2023

1

Resolución N°881 de 2023 de Ministerio de Salud y Protección Social. Inicia procedimiento declaración interés público

2

Agosto 2023

Se rechaza solicitud revocacion

3

Agosto 2023

El Comité Técnico Interinstitucional sesiono.

October 2023

6

Septiembre 2023

El Comité Técnico Interinstitucional publicó sus recomendaciones

5

Septiembre 2023

El Ministerio de Salud y Protección Social resolvió solicitudes de recusación y suspensión del proceso administrativo.

4

El Ministerio de Salud y emitió la Resolución N°1579 de 2023, declarando oficialmente la existencia de razones de interés público modalidad de uso gubernamental.

7

Diciembre 2023

La Resolución N°1579 queda en firme tras la resolución apertura de la presentación de los recursos interpuestos, confirmando la existencia solicitudes para el otorgamiento de razones de interés público.

8

Enero 2024

la licencia obligatoria por razones de interés público.

9

Febrero 2024

El Ministerio de Salud y Protección Social presenta solicitud de la licencia obligatoria para la patente correspondiente al Dolutegravir.

Dolutegravir Colombia

Abril 2024

10

Febrero 2024

La Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo (en adelante "AFIDRO") demanda de nulidad declaración b ante el Consejo de Estado –

1

Febrero 2024

La Superintendencia de Industria y Comercio inicia proceso licencia

1

**La Superintendencia
LICENSE IS GRANTED.**

2

13

Abril 2024

1. Titulares demanda a la República de Colombia por el supuesto incumplimiento del artículo 65 de la Decisión 486.

1

Mayo 2024

Los titulares de la patente interponen un recurso cuestionando la modalidad de uso gubernamental y la compensación económica establecida.

1

Junio 2024

La Superintendencia rechaza el recurso de reposición

5

1

Julio 2024

ViiV, SHIONOGI y GSK, solicitan anular ante Tribunal administrativo por ilegales declaración interés público

1

Julio 2024

ViiV, SHIONOGI y GSK solicitan ante Tribunal administrativo medida cautelar de suspensión provisional de declaración interés público.

1

7

INTERPRETACION REQUISITOS PARA DECLARACION INTERES PUBLICO TRIBUNAL ANDINO proceso 144-IP-2019 ETORICOXIB

• REQUIREMENTS FOR DECLARATION PUBLIC INTEREST IN CASE OF PANDEMIC. :

- Identify the pathogen (e.g., specific virus).
- Describe the characteristics of the disease.
- Determine the percentage of the affected or at-risk population.
- Identify the most vulnerable populations.
- Evaluate the contagion rate and the mortality or severity of symptoms.
- Analyze the availability and efficacy of other treatments.
- Assess the capacity of public and private healthcare facilities.
- Demonstrate the indispensability of the compulsory license.
- Prove that, without the license, the intended objective would not be feasible.

ARTICLE 30 Comparison of Exceptions by Country

EXCEPTION	ANDEAN COMMUNITY DECISION	ECUADOR	COLOMBIA	PERU	CHILE	URUGUAY
	486/ 689					
PRIVATE ACTS FOR NON-COMMERCIAL PURPOSES						
TEACHING OR SCIENTIFIC OR ACADEMIC RESEARCH						
EXPERIMENTACIÓN						
BOLAR EXCEPTION						
PREPARATION OF MEDICINES	NO PRESS	NO PRESS	NO PRESS	NO PRESS		
EXHAUSTION OF RIGHTS						

Comparison of Exceptions by Country

EXCEPTION	ANDEAN COMMUNITY DECISION 486/ 689	ECUADOR	COLOMBI A	PERU	CHILE	URUGUAY
5 ter PARIS. NAVES						
ACTOS PREVIOS						

BEST PRACTICE:

-
- Ecuador :
 - Art. 95 Limitaciones y excepciones.- Los derechos y beneficios que resulten de las limitaciones y excepciones establecidas en el presente Libro son irrenunciables. Cualquier estipulación en contrario será nula.
 - Exceptions are non-waivable"

RESTRICTIVE:

- **Peru:—**
- **Article 39-A:**

Exceptions to patent rights are limited as per Article 53 of Andean Community Decision 486. If these exceptions unjustifiably interfere with the normal exploitation of the patent or cause undue harm to the legitimate interests of the patent holder, considering the legitimate interests of third parties, the patent holder may exercise rights under Article 52 of the same Decision.

 - *Applicable to teaching, scientific, and academic research.*
- **Chile:**
- Chile distinguishes itself by *lacking specific exceptions* for academic or research use of patented inventions. Even in these settings, permission from the patent holder is required.
 - The experimentation exception offers partial relief but does not fully address the gap.
- **Bolar Exception:**
- **Uruguay:**
 - The Bolar exception is more restrictive, only allowing experimental acts during the final year of the patent's life. This contrasts with broader exceptions in **Ecuador**, **Colombia**, and **Chile**, where regulatory preparation rights are permitted throughout the patent's life.

RESTRICTIVES.

- **PREPARATION OF PRESCRIBED MEDICINES**

Peru, **Ecuador nor Colombia**: Neither country recognizes this expressly this exception, but is generally understood to follow within private use.

- **Uruguay**: The regulation in Uruguay is **more restrictive**. In addition to requiring that acts be private and non-commercial, they **must not cause economic harm** to the patent holder.

CONCLUSION AND RECOMENDATION

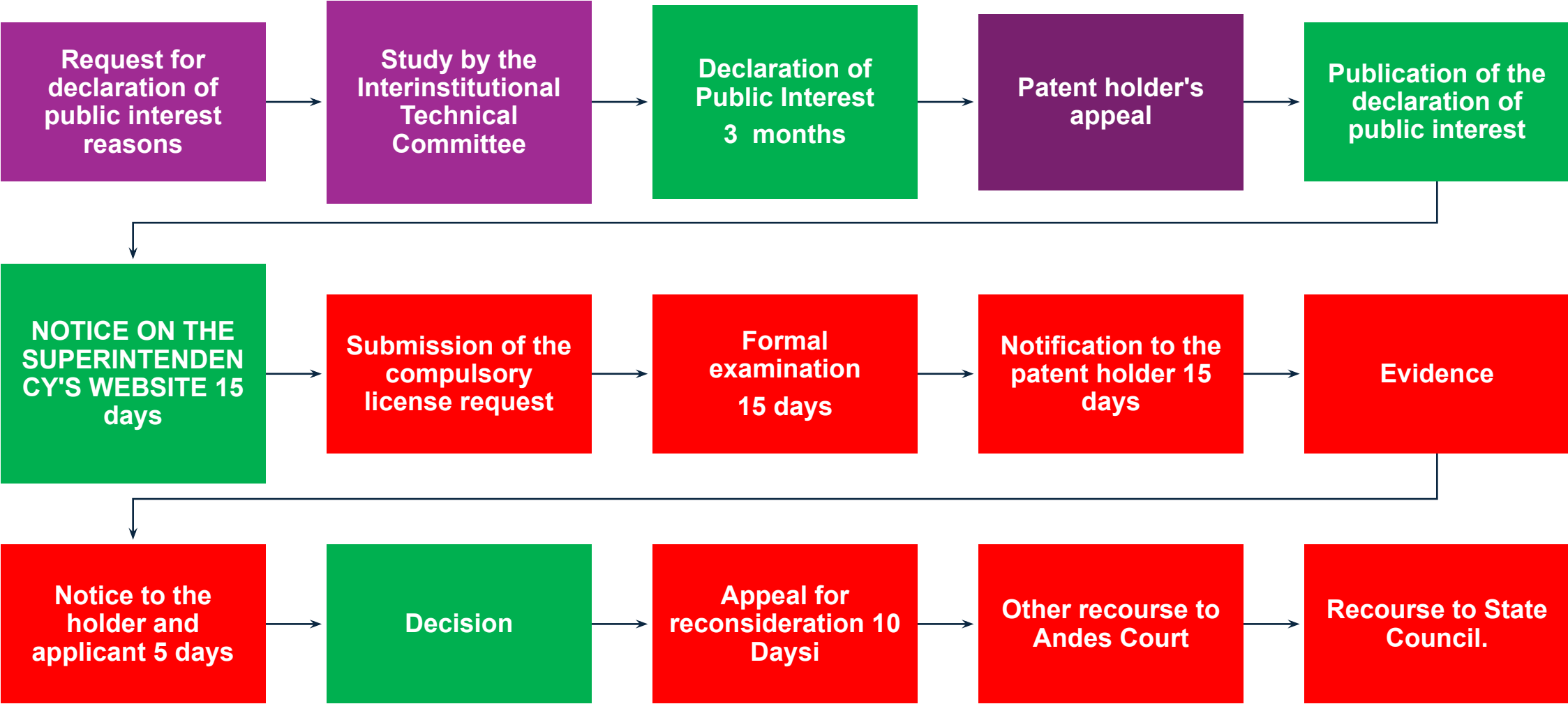
- **Compulsory licensing provisions in the law are not enough—simplification of the process is needed.**
- **Capacity Building for Effective Implementation**
Strengthen capacity-building efforts to implement all relevant TRIPS provisions on exceptions and limitations, especially:
 - **Article 44.2** – Limitations on remedies
 - **Article 31** – Government use
- **Technical Assistance for IP Courts**
Provide technical assistance to IP courts on best practices for using flexibilities, highlighting their importance for public good and innovation.
- **Patent Law Updates**
Countries should update patent laws to:
 - Simplify the compulsory licensing process
 - Establish separate government use regulations

THANK YOU

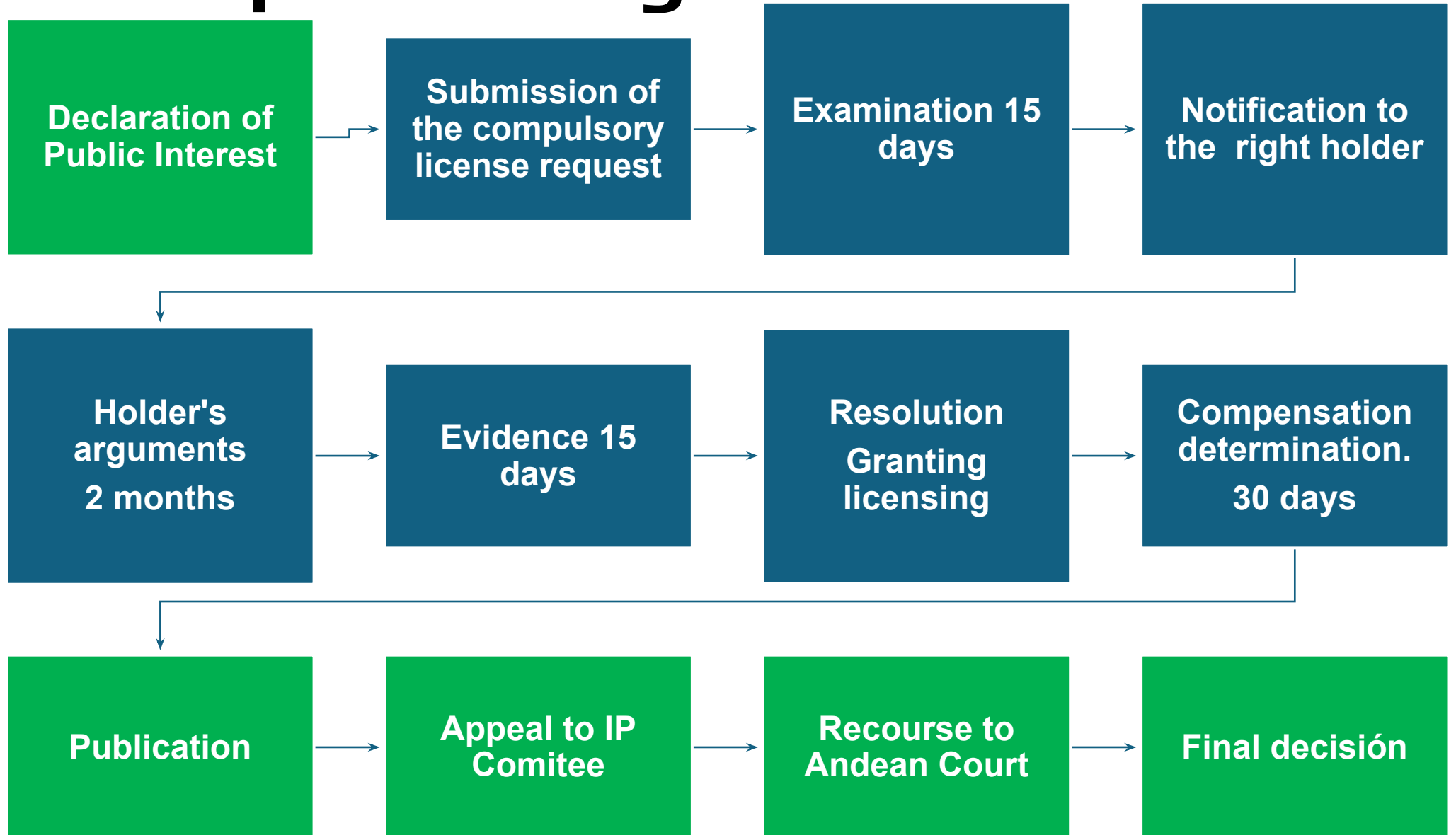


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Colombian proceeding 2 years.



Ecuadorian proceeding



Uruguay Interés público.



Ecuador: Revocación licencia de Raltegravir

El Tribunal concluyó que la revocación de la licencia obligatoria otorgada para el medicamento Raltegravir estaba justificada debido a varias fallas. En primer lugar, no se demostró adecuadamente que el uso del medicamento sería exclusivamente para fines de salud pública o prioritario dentro de los programas del Ministerio de Salud de Ecuador. Además, la Dirección Nacional de Propiedad Industrial no fundamentó correctamente el interés público, como lo requiere el artículo 65 de la Decisión 486 de la Comunidad Andina, que exige que se justifique caso por caso y no de manera generalizada.