



# Research Synthesis: Compulsory Licensing

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The research synthesis is available at: <https://www.knowledgeportalia.org/compulsory-licensing>

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- WIPO's Draft Reference Document on the Exception Regarding Compulsory Licensing
- WIPO's Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels

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- Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents
- South Centre's Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries
- Medicines Law & Policy's "model" document for an authorization of government use of a pharmaceutical patent
- World Bank's Compulsory Licensing for Public Health
- UNDP and WHO's Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies

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- Actual issuances and threats to use compulsory licenses have led to reductions in medicine prices

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- Actual issuances and threats to use compulsory licenses have led to reductions in medicine prices.
- Views expressed on the literature regarding the caveats raised in Urias and Ramani (2020):
  - 1<sup>st</sup> caveat: international market procurement settings only result to lower medicine prices when there are no patent restrictions involved

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  - 2<sup>nd</sup> caveat: compulsory licensing may be pursued not only to lower medicine prices but also to build domestic manufacturing capabilities



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- Views expressed on the literature regarding the caveats raised in Urias and Ramani (2020):
  - 1<sup>st</sup> caveat: international market procurement settings only result to lower medicine prices when there are no patent restrictions involved
  - 2<sup>nd</sup> caveat: compulsory licensing may be pursued not only to lower medicine prices but also to build domestic manufacturing capabilities
  - 3<sup>rd</sup> caveat: Article 31bis allows countries lacking domestic manufacturing capacities to credibility use threats of compulsory licensing when negotiating for lower medicine prices

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The issuance of compulsory licenses or government-use licenses was not observed, by a few papers, to result to decreases in:

- FDI inflows towards issuing countries
- Innovation/patenting activities of affected companies

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Challenges to the use of compulsory licenses:

- National compulsory licensing framework and implementation

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## Challenges to the use of compulsory licenses:

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## Challenges to the use of compulsory licenses:

- National compulsory licensing framework and implementation
- The implementation of Article 31*bis*
- Political pressure exerted on countries who used or attempted to use compulsory licenses

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- Limitations imposed by data exclusivity and trade secret protection

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- Free-Trade Agreement provisions

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- Lack of data on the impact of compulsory license on innovation activities of affected originator companies
- Limited data on broader economic impacts of compulsory licensing, such as in terms of effect on: (i) the issuing country's foreign direct investment flows, and (ii) the accessibility to patients of resulting medicine prices in the context of private medicine procurement settings (especially in countries where medicine expenditures are largely out-of-pocket expenses)

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- Limited data on broader economic impacts of compulsory licensing, such as in terms of effect on: (i) the issuing country's foreign direct investment flows, and (ii) the accessibility to patients of resulting medicine prices in the context of private medicine procurement settings (especially in countries where medicine expenditures are largely out-of-pocket expenses)
- Limited information on compulsory licensing timeframes, i.e. length of time involved in negotiating a voluntary license before an application for compulsory license is pursued, the length of time involved from submission of such application to the grant or refusal of a compulsory license

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- Lack of information on costs involved in undertaking compulsory licensing applications, whether significant, reasonable, or negligible



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- Lack of information on costs involved in undertaking compulsory licensing applications, whether significant, reasonable, or negligible
- Lack of information on terms and conditions included in voluntary licensing and other agreements that arose out of compulsory licensing threats

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- Lack of information on costs involved in undertaking compulsory licensing applications, whether significant, reasonable, or negligible
- Lack of information on terms and conditions included in voluntary licensing and other agreements that arose out of compulsory licensing threats
- Lack of information on the likelihood of litigation (risk involved) with respect to compulsory licensing applications, particularly if made by generic manufacturers, including duration, grounds invoked and costs of litigation, whether significant, reasonable, or negligible



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Thank you!