FAST*facts*

August 2018

COMPULSORY LICENSING

Latin Americans are living longer than ever before. But like people in other regions, Latin Americans also suffer from numerous chronic conditions, such as diabetes and heart disease.[1] This is why it is vital that policymakers encourage investments in medical innovation and ensure access to life-saving medication that has been proven safe and effective.

Compulsory licensing doesn't do either of these. Nevertheless, governments in Colombia,[2] Chile[3] and Peru[4] are considering adopting this scheme. Here's what patients, health care providers and policymakers need to understand about compulsory licensing.

Q: What is compulsory licensing?

For a limited period, patents provide an exclusive right to the manufacturer of a new medicine to sell that medicine. Compulsory licensing occurs when regulators ignore that right and allow other companies to sell copies of the medication before the exclusivity period has ended.[5]

Q: Is compulsory licensing good for patients?

While some patients may benefit from increased access to cheaper copies of medications, they do so at the expense of the larger population for years to come. Compulsory licensing has long-term consequences that can hinder broader access to future medical innovations.

GAfPA
Global Alliance for Patient Access

Q: Is compulsory licensing safe?

A compulsory license transfers only patent rights; it does not transfer know-how, capacity or product quality. The copies that come to market quickly because of compulsory licensing haven't necessarily been held to the highest standards of efficacy and safety.

Instead of issuing compulsory licenses, regulators should adopt policies that promote expedited approval of medications that the U.S. Food and Drug Administration or the European Medicines Agency has already scrutinized and approved as safe for patients.

Q: Does compulsory licensing help patients access medication?

Compulsory licensing is meant to increase the availability of one medication in the short term by allowing copies of that medication to come to market quickly outside of normal regulatory channels. Ideally, these alternatives are less expensive than the original drug.

But it doesn't always work that way. In Brazil, for example, patients waited two years between when a compulsory license was issued and when copies of the medication were actually launched.[6] In another instance, antiretroviral medications produced under compulsory licenses cost 25 percent more than the originals.[7]

Compulsory licensing hurts patients' access to treatments in the long term because it disincentivizes medical innovation. Patents ensure manufacturers can earn profit from the investment they made in developing a new medicine. Without that patent protection, manufacturers are less able to plan for future investment and to bring new medicines to Latin America.

IMPACT OF COMPULSORY LICENSING

FAVORABLE

- ✚ May increase short-term access to cheaper copies of a single medicine

UNFAVORABLE

- ⊗ Copies may not have been held to the highest standards of efficacy and safety
- ⊗ Undermines the development of new treatments and medical innovation
- ⊗ Hurts patient access in the long term
- ⊗ Reduces manufacturers' ability to plan for future investment and to bring new medicines to the region
- ⊗ Discourages companies from establishing clinical trial sites
- ⊗ Impacts a region's long-term economic vitality

GAfPA
Global Alliance for Patient Access

Q: Does compulsory licensing affect new drug development?

Governments that issue compulsory licenses discourage companies from establishing clinical trial sites in their countries. Clinical trials allow access to cutting-edge research and may also provide basic health screenings. Conversely, governments who adopt policies that encourage research stand to improve their population health and fiscal position as clinical research can reduce the economic cost of illness while also boosting jobs and the economy.[8]

Q: Does compulsory licensing happen often?

Issuing compulsory licenses is an extraordinary measure reserved for public health emergencies. In Colombia, for example, the Ministry of Health must make a declaration of public interest before the government grants a compulsory license.[9]

Opting for compulsory licensing under any other circumstances could impact a region's long-term economic vitality and undermine the development of new treatments. Therefore, decisions about compulsory licensing should include all stakeholders in a transparent, fact-based process.

Q: What are the alternatives to compulsory licensing?

A better option for long-term patient access is voluntary licensing. Voluntary arrangements allow patent holders to partner with other companies to make, use, sell or import a patented medicine. Partners in voluntary arrangements collaborate to ensure necessary know-how, capacity and product quality. In sub-Saharan Africa, for example, the majority of antiretroviral medicines to treat HIV are produced under voluntary licenses to local generic drug companies.[10]

CONCLUSIONS

Compulsory licensing has the potential to save lives and preserve public health during national emergencies. But governments that use the practice routinely as a way to save money or create fast access to new medications are bound to experience negative consequences. The overuse of compulsory licensing has the potential to harm patient access and economic development in the long term.

REFERENCES

1. Cuevas, A, Alvarez, V, & Olivos, C. (2009). The emerging obesity problem in Latin America. *Expert Rev Cardiovasc Ther.*, 7(3), 281-8. doi: 10.1586/14779072.7.3.281.
2. Silverman, E. (2018, June 26). U.S. trade rep is urged to revamp trade deal with Colombia over compulsory licensing. *Stat*. Retrieved August 1, 2018, from https://www.statnews.com/pharmalot/2018/06/26/trade-rep-colombia-compulsory-licensing/
3. Silverman, E. (2018, January 26). Chile's congress votes to pursue compulsory licenses for medicines. *Stat*. Retrieved August 1, 2018, from https://www.statnews.com/pharmalot/2017/01/26/chile-license-medicines/
4. Silverman, E. (2017, May 26). Peruvian lawmakers seek a compulsory license for a Bristol HIV drug. *Stat*. Retrieved August 1, 2018, from https://www.statnews.com/pharmalot/2017/05/26/peru-compulsory-license-bristol-drug/
5. U.S. Food and Drug Administration (2018, May 2). Frequently asked questions on patents and exclusivity. Retrieved July 31, 2018, from https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm
6. Bond, E W & Saggi, K. (2014). Compulsory licensing, price controls, and access to patented foreign products. *Journal of Development Economics,* 109, 217-28. doi: 10.1016/j.jdeveco.2014.04.001.
7. Beal, R F, Kuhn, R & Attaran, A. (2015). Compulsory licensing often did not produce lower prices for antiretrovirals compared to international procurement. *Health Affairs,* 34(3). doi: 10.1377/hlthaff.2014.0658.
8. Lang T, Siribaddana S. (2012). Clinical trials have gone global: Is this a good thing? *PLoS Med,* 9(6): e1001228. doi: 10.1371/journal.pmed.1001228.
9. World Intellectual Property Organization (2008, November 13). Colombia Decree No. 4302 of 2008 (November 13) - For which is fixed the procedure for declaring the existence of public interest in accordance with Article 65 of Decision 486 of the Andean Community Commission. Retrieved July 31, 2018, from http://www.wipo.int/wipolex/en/text.jsp?file_id=190459
10. Chien, C V. (2007). HIV/AIDS drugs for Sub-Saharan Africa: How do brand and generic supply compare? *PLoS One,* 2(3): e278. https://doi.org/10.1371/journal.pone.0000278

GAfPA
Global Alliance for Patient Access

The Global Alliance for Patient Access
is a network of physicians and patient advocates with the shared mission of promoting health policy that ensures patient access to appropriate clinical care and approved therapies. GAfPA accomplishes this mission through educating physicians and patients on health policy issues and developing education materials and advocacy initiatives to promote informed policymaking.

gafpa.org facebook.com/globalafpa @globalafpa