RISKS AND NEGATIVE IMPLICATIONS OF COMPULSORY LICENSING FOR PHARMACEUTICALS IN RUSSIA: MYTHS VERSUS FACTS

1 Myth: The use of compulsory licensing in Russia would enable greater and more rapid access to innovative medicines in areas of unmet need.

Fact: Manufacturing a generic version of a drug under a compulsory license may not necessarily result in a more affordable price or a dependable supply of the drug in Russia. It could also limit incentives for conducting domestic clinical trials and manufacturing of new, specialty drugs – some of the fastest ways of accessing these drugs.1

• Yet clinical trial activity in Russia is already falling: there were 13.6% fewer trials between 2012 and 2013.2

• Local manufacturing of innovative drugs, though increasing somewhat, is relatively stifled as it stands – the volume of all locally produced drugs, innovative and generic, sold in pharmacies dropped by 7% between Q2-2013 and Q2-2014.3

• The use of compulsory licensing in Russia risks further hampering R&D and local manufacturing there.

2 Myth: Russia will be able to secure lower drug prices as a result of compulsory licensing.

Fact: A generic drug manufactured under a compulsory license will not necessarily be much more affordable than the original drug.4

• Average prices of most off-patent drugs (71%) are higher in Russia than the average prices of the same drugs in many other countries, including among the BRICs, the EU and the CIS region.5

• Prices of generic drugs are even at times higher than the original drug.6 In this context, compulsory licensing may not lead to the prices anticipated for needed medicines in Russia.

• Small gains in price may be outweighed by larger, long-term impacts on the economy and the availability of innovative medicines.

3 Myth: Compulsory licensing would be an effective method of achieving favorable negotiations on patented medicines that currently have limited availability in Russia.

Fact: The act of issuing a compulsory license will create a hostile negotiating environment for the Russian biopharmaceutical market.7

• It is likely to reduce the willingness of all parties to collaborate in future negotiations and investment decisions.

• In Russia, it could introduce challenges to achieving coverage for patented medicines on the EDL and specific reimbursement schemes for specialty drugs.8

4 Myth: Intellectual property protection is the reason why innovative drugs are not accessible in Russia.

Fact: IP protections are not barriers to access. On the contrary, without IP protections most innovative products, and in turn the generic products that are produced after those protections lapse, would not exist. Rather, many factors lead to higher cost and inadequate supply of specialty medicines in Russia.9

• Peripheral regions in Russia lack human and technological resources to effectively supply and administer drugs treating cancer and rare diseases.10

• Taxes on medicines, low levels of health spending and gaps in reimbursement are additional contributing factors. 60% of prescription drugs in Russia are paid for out-of-pocket.11

• Compulsory licensing does not address these elements.
RISKS AND NEGATIVE IMPLICATIONS OF COMPELLARY LICENSING FOR PHARMACEUTICALS IN RUSSIA: MYTHS VERSUS FACTS

5 Myth: Compulsory licensing would involve no risks for Russian patients or the health system.
Fact: The production of advanced medicines by Russian manufacturers under a compulsory license may lead to serious risks for Russian patients.
- Too many Russian manufacturers lack capacity to ensure that drugs produced under a compulsory license meet international safety and quality standards.12
- Only around 30% of Russian manufacturers currently comply with standards of Good Manufacturing Practice (GMP) and are not fully required to do so until 2016.13
- Producing substandard medicines under a compulsory license could lead to adverse drug reactions and faster than normal drug resistance.14

6 Myth: Compulsory licensing would benefit Russia’s pharmaceutical industry.
Fact: The benefits of compulsory licensing to Russian companies are limited at best.15 Moreover, compulsory licensing reduces incentives for the foreign investment and technology transfer needed by Russia to build an innovative industry and meet its Pharma 2020 goals.16
- Imported products continue to represent the majority of the Russian market.17
- Imported medicines represent around 26% of the market (in terms of value), while locally produced medicines represent around 74%.18
- The use of compulsory licensing in Russia risks further stalling the realization of its industrial and economic goals.

7 Myth: Compulsory licensing is one of the only policy instruments capable of enabling access to needed high-cost medicines.
Fact: Several alternative and voluntary channels may be used for securing access to needed medicines for Russian patients.
- Short-term solutions may include enhancing coverage schemes for specialty drugs, such as the proposed scheme for orphan drugs currently considered by the Russian parliament,19 and spreading cost across different parties and coverage schemes.20
- Capacity building in R&D and manufacture of innovative drugs in Russia is a fundamental route for providing long-term access to these drugs.21
- It will also drive improvements to infrastructure and health care delivery across Russia, likewise crucial for ensuring effective access.
- Existing efforts toward this end include new biomedical research clusters and substantial R&D tax incentives.22
Countries with a robust level of pharmaceutical IP protection, such as the U.S. and Singapore, tend to host a higher number of clinical trials, while countries with a relatively weak level of protection, such as India and Thailand, have a very low number of clinical trials. (Pugatch, M. & Chu, R. (2011), “The strength of pharmaceutical IPRs vis-à-vis foreign direct investment in clinical research: Preliminary findings”, Journal of Commercial Biotechnology, Vol.17, Iss 4, pp.308-318). In relation to manufacturing and in the case of India, a 2013 survey of top locations worldwide to invest in advanced biopharmaceutical manufacturing facilities indicates that India’s attractiveness for advanced manufacturing has plummeted. India issued the compulsory license on Nexavar in 2012. Between 2012 and 2013, the percentage of respondents who said the likelihood of investing in India dropped by 50%. (Langer, E. “Biopharmaceutical Outsourcing Countries”, Pharmaceutical Outsourcing, 1:28(2014), www.pharmoutsourcing.com/Featured-Articles/153801-Biopharmaceutical-Outsourcing-Continues-to-Expand!)


Economics and Life (Translated), “Nine of the ten most important drugs in the country have to be Russian”, 5/23/2014, www.eo-g.com/article/24779/”

For example, according to local sources the expected price of the generic version of sorafenib, produced in India under a compulsory license in 2012, would still not be affordable to most people there. (Health, India, “Despite compulsory licensing, generic cancer drug too costly for the poor,” 4/23/2013, http://health.india.com/diseases-conditions/despite-compulsory-licensing-generic-cancer-drug-too-costly-for-the-poor/)


Compulsory licensing directly undercut the exclusivity rights of the patent holder without his consent, generating suspicion and reduced accommodation in price and supply negotiations throughout the market. (Gilbert, R. & Shapiro, C. (1994), “An Economic Analysis of Legal Refusals to License Intellectual Property”, Proceedings of the National Academy of Sciences, Vol.93, pp.12749-12755) Article 31 of the TRIPS Agreement permits compulsory licensing only on a limited basis (such as public health emergencies) and as a last resort.


Temporary exclusivity in the market is only one factor contributing to the price of patented medicines. Compulsory licensing does not address other factors leading to high cost or lack of supply of specialty medicines in Russia, including include the cost of delivery and of providing associated health care, supply chain and infrastructure inefficiencies, low levels of health spending, direct and indirect taxes on medicines and gaps in coverage/reimbursement of certain pharmaceuticals.

In practice regions with smaller and lower income populations and relatively poor economic performance tend to lack funding, technology and skilled human resources needed to provide adequate delivery of cancer treatments and orphan drugs, and patients must await the treatments in other regions’ centers with the associated costs. (Gross, P. et al. (2014), “Challenges to the effective control cancer control in China, India, and Russia”, The Lancet Oncology, Vol.15, Iss 5, pp.489-538)

PMLive, “Putin – pharma’s friend or foe in Russia?,” 10/29/2013, www.pmlive.com/-pharma_intelligence-factors_pharmas_friend_or_foe_in_russia_312893

Countries that have issued compulsory licenses for complex and sophisticated drugs have oftentimes lacked the domestic capacity to produce the drug to a safe standard or in a timely manner. For example, studies on the production of generic versions of anti-retroviral and cardiovascular drugs in Brazil and Thailand, respectively, surrounding compulsory licenses suggest that local manufacturers lacked the internal capacity to reverse engineer and manufacture the drug properly. In several cases, these medicines were not included on the WHO’s Prequalification Program, one standard indicating quality of medicines. (Norrin, J. & Adelman, C. (2013), Compulsory Licenses under TRIPS: An Analysis of Good Intentions vs. Untapped Consequences to Patients’ Health, Hudson Institute, May 2013, p.6; Nunn, A., Massard da Fonseca, E., Bastos, F. & Gruskin, S. (2009), “AIDS Treatment in Brazil: Impacts and Challenges”, Health Affairs, Vol 28, No 3, pp.1103-1113)


For instance, in the case of a copy of the anti-retroviral GPO produced in Thailand, an extremely high rate of drug resistance was found in patients treated with it (roughly 40%-60%) and they were required earlier than anticipated to switch to a stronger treatment (Bate, R. (2007), “Thaiing Pharma Down”, Wall Street Journal Asia, 2/7/2007). Lybecker, K. & Fowler, E. (2009), “Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules”, Journal of Law and Medical Ethics, Vol.17, No 2, pp.222-39

Local manufacture of compulsory licensed medicines may provide domestic companies with a competitive advantage in the supply of generic versions of the drug in the Russian market, however not necessarily. Moreover, domestic companies must bear liability and costs if they produce substandard medicines under the license.

Compulsory licensing and an overall weak intellectual property environment have negative implications for countries’ ability to attract investment and technology transfer. For example, coinciding with India’s compulsory license in 2012, the Indian government itself has identified a drop in the level of FDI in the drugs and pharmaceuticals sector of 30-40% compared to before the compulsory license was issued. (Department of Industrial Policy & Promotion (DIPP), “Fact Sheet on Foreign Direct Investment, 2000-2014,” p.2, http://dipp.nic.in/english/Publications/FDI_Statistics/2014/India_FDI_Feburary2014.pdf; Shapiro, R. & Mathur, A. (2014), How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP “The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers, Sonecon, Jan. 2014, www.sonecon.com/docs/studies/FDI_IP_and_the_Pharma_Sector_in_India-Shapiro-Mathur-Final-January2014.pdf)

Economics and Life (Translated), “Nine of the ten...”

Ibid.


