

About I-MAK

The Initiative for Medicines, Access & Knowledge (I-MAK) was established in 2006 with the mission to increase global access to affordable, lifesaving medicines. People worldwide – including in high-income countries – are not receiving the lifesaving treatment they need due to skyrocketing prices. I-MAK's years of research, patent landscaping, and successful legal challenges show that all too often, drug companies hold unmerited patents on old science. This enables a few companies to corner the market on entire diseases, artificially inflating the price of treatment, and blocking access to affordable generic drugs for decades. We believe that current patent systems disproportionately represent and uphold private interests over public good, and must be challenged and ultimately repaired or redesigned.

I-MAK envisions a world in which lifesaving medicines are readily available to the people who need them without excessive individual or social cost. Our team brings unique private-sector expertise and an evidence-based approach to this mission. With more than two decades of experience in patent law, health policy, market dynamics, and the pharmaceutical sciences, I-MAK is increasingly called upon to advance thought leadership and policy solutions with our partners around the world.

Access to medicines is a nonpartisan issue and we work across the political spectrum to bring integrity back to the patent system. By educating the public, reforming laws and policies, and engaging in strategic legal interventions, we have been able to remove barriers to treatment for some of the world's deadliest diseases such as hepatitis C and HIV. I-MAK helps governments, patent offices, and consumers to create systems that support a competitive market where the needs of patients and payers come first.

Track Record: Saving Money and Saving Lives by Winning Lower Drug Prices

In 2006, I-MAK began working on one disease in one country. Our role and scope of work has expanded significantly over the past decade: we have prioritized treatments for high-profile diseases such as the hepatitis C virus (HCV), and now work on 20 therapies for eight diseases in 49 countries. **I-MAK's efforts have helped enable over \$1 billion in actual savings to government health programs and patients worldwide**, and our work is poised to achieve billions more savings in the future. Because of the impact of our interventions, high-income markets now seek our expertise.

Here are several examples of the catalytic change our legal and policy strategies bring to governments trying to lower costs and increase access to lifesaving medicines for their citizens:

- I-MAK's first few years were focused on ensuring generic competition for four lifesaving HIV drugs in India. I-MAK successfully challenged multiple unmerited patent applications for Kaletra®, Ziagen®, Viread®, and Viramune®. These wins are estimated to have unlocked over **US\$500 million** in cost savings for lower-income country governments – money that can be reinvested to treat more than **one million patients**.
- Over the past decade, I-MAK has filed or technically supported legal action against **33 unmerited patents behind six major HCV and HIV drugs** across significant markets.
- As a result of successful patent challenges filed by I-MAK on HIV drugs, prices for these lifesaving medicines are **51-89%** lower than the branded version prices.

- I-MAK has worked alongside five patient advocacy organizations since 2014 to reduce drug prices in Argentina, Brazil, Thailand, and Ukraine¹. Legal interventions on seven HIV drugs in these four countries has so far enabled price reductions that have resulted in actual savings of US **\$549 million per year**.

Transforming the Patent System and Protecting Patients

All of our work supports I-MAK's vision for a patent system that serves the public and protects a competitive market that better ensures fair pricing of lifesaving drugs. In high-income countries, drug prices are rapidly increasing to unsustainable levels and must be addressed.

For example, Louisiana estimates that it would cost \$783 million to treat the 35,000 HCV patients in the state who are on Medicaid or uninsured; and Kentucky spent \$70 million to treat just 833 patients last year. While states are struggling to pay to treat their patients, the U.S. Patent and Trademark Office has granted Gilead Sciences more than 30 Sovaldi®-related patents that extend their hold on the hepatitis C market until at least 2034. This means that this lifesaving medication will be too expensive for most payors for another two decades, while Gilead has made more than \$35 billion in U.S. sales in just the last three and a half years.

This is a critical time: over 80% of patients diagnosed with hepatitis C are not getting access to treatment each year; and across all diseases, the price of branded drugs has tripled since 2008. One in four Americans reports that they or a family member could not afford to fill a prescription due to high branded costs, which in turn adversely affects health outcomes. Given this stark reality, I-MAK is calling for a coordinated approach by policymakers, health advocates, payers, and consumers to demand:

- A system that is more accessible to patients and the public;
- Laws and policies that accelerate generic competition to drive down prices in the marketplace; and
- A higher bar for how patents are granted and how innovation is defined, to prevent branded companies from blocking competition and the entry of affordable medicines.

Independent, Patient-Driven Approach

I-MAK is currently funded by several foundations and philanthropists, including the Laura and John Arnold Foundation, Doctors Without Borders (Médecins Sans Frontières), Open Society Foundation, and Unitaid. Independent of commercial motivations, I-MAK does not take any support from generic or branded pharmaceutical companies and exclusively represents the interests of the public.

¹ In partnership with International Treatment Preparedness Coalition (ITPC), Fundación Grupo Efecto Positivo (Argentina), Associação Brasileira Interdisciplinar de AIDS (Brazil), AIDS Access Foundation (Thailand), and The All-Ukrainian Network of PLHIV.