

# We're solving the drug patent problem.

I-MAK envisions a world in which lifesaving medicines are readily available without excessive social or individual cost.

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 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.

80%

Reduction in HIV drug prices after patent challenges şΙΒ

In cost savings to governments around the globe

M+

People able to be treated with these savings

Our team brings unique private-sector expertise and an evidence-based approach to this mission. With more than two decades of experience in 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.

We've been working to restore integrity to patent systems **for over a decade**. So far, we've driven law reform, supported legal challenges in 47 countries, and **improved the lives of people in over 70% of countries worldwide**.

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## 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.

"We believe that current patent systems disproportionately represent and uphold private interests over public good and must be challenged and ultimately repaired or redesigned."

TAHIR AMIN, CO-FOUNDER

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<sup>®</sup>,



Ziagen<sup>®</sup>, Viread<sup>®</sup>, and Viramune<sup>®</sup>. 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 legal 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 Ukraine.<sup>1</sup> 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 Alongside Patients**

Since its inception, I-MAK's approach has centered around the needs of patients and communities. In highincome countries, drug prices are rapidly increasing to unsustainable levels and must be addressed. One in four Americans reports that they or a family member could not afford to fill a prescription due to high branded costs, and many Americans report having to make unimaginable choices about whether and when to get treatment due to economic realities that are crippling households nationwide.

*"I-MAK envisions a patent system that serves the public and protects a competitive market that better ensures lifesaving drugs reach families struggling to afford treatment."* 

PRITI KRISHTEL, CO-FOUNDER

<sup>&</sup>lt;sup>1</sup> 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.



This is a critical time: across all diseases, the price of branded drugs has tripled since 2008, and is poised to double again in the coming decade. For hepatitis C alone, 85% of patients who have been diagnosed are not getting access to treatment each year. 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<sup>®</sup>-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.

Gilead's U.S. sales for HCV in 3 years

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.