A High Price to Pay
Access to Medicines Ireland Policy Document

Overview

- Fair and equitable access to effective medicines is critical to public health in Ireland and around the world.
- Exorbitant prices charged by the pharmaceutical industry for drugs used to treat serious illnesses like cancer, hepatitis, and HIV mean that medicines are often rationed or completely inaccessible.
- Strict patent protections grant pharmaceutical companies a monopoly over the drugs they produce, raising prices. Multiple studies have shown that these prices are not justified by research and development or production costs.
- The Irish Government is under huge pressure to reimburse these high-price drugs, however it lacks effective policy tools that would give it more leverage when negotiating.
- This policy document informs on measures that can be taken to ensure prices are fair and affordable and research is directed proportionally to health need.

Introduction

Access to Medicines Ireland (AMI) was formed in 2015 to join the global effort to achieve access to medicines. The barriers to access are many, and AMI focuses on problems caused by the commercialisation of drug research and development.

These problems can be broadly defined as a lack of research into areas of greatest health need and a lack of access to existing medicines.

The current research and development model is largely driven by commercial interests. A major consequence of the profit-driven system is that there is no incentive to develop drugs for conditions that predominantly affect poor populations. This lack of financial incentive is also largely responsible for the failure to develop new antibiotics to address the growing problem of antimicrobial resistance. Furthermore, the patent incentive prioritises competition between researchers over collaboration, creating inefficiencies and adding significantly to costs.

This profit-motivated system results in exorbitant prices for drugs, particularly for cancer treatments, severely restricting access. High prices are levied because the exclusive patents of pharmaceutical companies allow them to charge as they please. The escalating prices for new medicines put an ever-greater strain on the overall health budget. The solution is not to ration the medication but to secure a fair price.

This policy document gathers together key and timely information on these and other issues of fair access to new medicines.

“Big Pharma is holding governments across the world hostage, and is using fear and secrecy to drive up the cost of medicines.”

Dr Ellen ‘t Hoen is a lawyer and public health advocate with over 50 years of experience working on pharmaceutical and intellectual property policies. She is an independent consultant in medicines law and policy, and is a researcher at the University Medical Center Groningen. From 1999 she was the director of policy for MSF’s Campaign for Access to Essential Medicines. In 2009, she established the Medicines Patent Pool with UNITAID.
**Transparency**

While the pharmaceutical industry claims that it can cost up to €2.6bn to bring a new drug to market, the Drugs for Neglected Diseases Initiative (DNDi) puts this figure closer to $150mn. There is a serious lack of clarity on the cost of research and development (R&D), marketing, production and distribution of new medicines. This discrepancy and lack of openness puts officials trying to negotiate a fair price for the public health system at a disadvantage.

Transparency is therefore necessary to hold the private sector and other stakeholders to account for the impact of their actions on access to medicines. **Ireland should add its voice to the global movement advocating for greater transparency.**

**Patents**

The current incentive of market exclusivity in the pharmaceutical industry grants the patent holder the freedom to charge whatever price the market can bear, which for life-saving drugs can be very high indeed.

This model is **exploitative, expensive and exclusionary.**

**Alternative incentives for needs-driven and transparent R&D should be implemented. Examples include grants, prizes and advance market commitments from public funds.**

This would result in more affordable medicines, priced closer to production cost without the need to pay a commercial patent holder an exorbitant price.

Specific licensing tools include:

- **Non-exclusive licenses** allow multiple competitors onto the market and drive down prices,
- **Intellectual property rights donations** award royalty-free licenses to not-for profit R&D organisations like DNDi
- **Public sector patent pools** like Medicine Patent Pool remove the profit motive of the pharma industry.

One of the most effective licensing tools is **compulsory licensing**, a legal process used to override a patent when deemed necessary to ensure access to a medicine in the interest of public health. Compulsory licensing was enshrined within international law by the WTO’s TRIPS agreement in 1995, and has been used successfully to acquire medicines for cancer in India and hepatitis C in Malaysia.

**International Cooperation**

We commend the Irish government on joining the BeNeLuxA initiative. Together with Belgium, The Netherlands, Luxembourg and Austria this inter-governmental collaboration aims to increase transparency in pricing and encourages:

- Information sharing and policy exchange
- Joint price negotiations
- Horizon scanning
- Health technology assessments

This initiative will greatly strengthen Ireland’s strategic position when negotiating with the pharmaceutical industry. **We hope that this step will mark the start of greater collaboration at EU and global level, and that Ireland will take a leading role in advocating for fair prices.**

**Hepatitis C**

In 2017, the Irish Medical Organization passed a motion calling upon the government to issue a compulsory licence for **Sofosbuvir** - an important medicine used to cure hepatitis C. Currently, in Ireland a full 12-week course costs the HSE €47,361, or €564 per pill, when the full treatment costs **just €104 to produce**, including a 50% profit.
Cancer

**CART Cell Therapy** is an emerging immunotherapy for use in the treatment of haematological cancers. Developed with public funds at the University of Pennsylvania, its inventor estimates the production cost of the one-time treatment at **$20,000**. Swiss drug company Novartis instead set the price at **$475,000** for a single infusion, making the treatment one of the most expensive medicines in history and drawing criticism from patient advocate groups.

Publicly-Funded Innovation

In universities and research centres in Ireland and across the world, the public sector subsidises, supports and commissions research that lays the foundation for vital scientific knowledge. For example, the Mayo Clinic estimates that **85% of cancer research is publicly funded**.

Yet once a promising compound is discovered, it is liable to be licensed for further development by pharmaceutical companies. In the US, federally-funded studies contributed to the science behind **every one** of the 210 new drugs approved from 2010-16.

In Ireland the R&D tax credit allows for a 25% credit against corporation tax, in effect subsidising the private costs of research with public money.

Public funding should be directed preferentially towards projects that are needs-driven, demonstrate transparency, and are likely to result in an affordable end product.

Antibiotics

Antimicrobial resistant bacteria are responsible for **700,000 deaths** a year worldwide. But by 2050, antimicrobial resistant bacteria could kill an estimated **10 million people annually**, a death toll higher than all cancers combined. In recent years, pharmaceutical companies Novartis, AstraZeneca and Eli Lilly have shut down their antibiotic research programmes, mainly because it is not seen as a profitable area.

Needs-Driven Research

Research priority-setting should be based on health need as opposed to market interests.

There is an innovation gap in areas such as:

- diseases that predominantly affect neglected populations
- rare diseases
- the development of new antibiotics.

In accordance with the UNHLP on Access to Medicines 2016 recommendations, **priority-setting should be made on a regional and global level, with a global pool for R&D investment.**

Come to our Annual Conference

One of our most visible and successful activities has been our two annual conferences. Our most recent conference drew more than 150 attendees from the health, pharmaceutical and NGO sectors, and featured the speakers highlighted in this document. If you are interested in hearing more about access to medicines, we would encourage you to get in touch and **come to our next conference, to be held in RCSI, Dublin on April 16th, 2019.**

“I hear people talking about prices. I hear people talking about profit. For me it is a matter of life and death.”

**Babalwa Malgas** is a South African lawyer and activist. She was diagnosed with breast cancer in 2011 but was unable to afford the recommended treatment. She is a committed advocate for breast cancer treatment, and formed the advocacy group Cancer Alliance. Babalwa is the proud mother of two boys aged 7 and 12.
Fighting for fair prices for new medicines.

Recommendations

- For-profit medicines production leaves gaps in vital areas such as vaccines and antibiotics. Policies must be implemented in Ireland to incentivise needs-based R&D, in conjunction with other governments, the European Union, and international institutions.
- Ireland should encourage the EU to explore alternative means for financing pharmaceutical innovation in order to relieve the financial burden that is currently placed on health services and patients.
- The EU should insist on greater transparency when negotiating with the pharmaceutical industry to ensure that the final prices for new medicines reflect actual investment in R&D and production.
- Public funding offers an effective means of influencing the process and outcomes of research. The EU should attach conditions to public funding to ensure that medicines research is needs-driven, transparent, and results in an affordable end product.
- Compulsory licensing and other patent flexibilities should be considered in the case of drugs that are shown to be effective, but whose price is prohibitive for widespread use.
- Ireland should maintain its involvement with BeNeLuxA and increase EU and international collaboration.

References:

- Cleary et al., Contribution of NIH funding to new drug approvals 2010–2016; https://doi.org/10.1035/pnos.17i536815
- Iyengar et al., Prices, Costs, and Affordability of New Medicines for Hepatitis C in 30 Countries: An Economic Analysis; https://doi.org/10.1371/journal.pmed.1002032

This policy document is endorsed by the following organisations:

About Access to Medicines Ireland
We are a membership group of Comhlámh composed of medical professionals, activists, and concerned members of the public. We are committed to ensuring that medicines are made accessible at a fair price and that medical research and innovation is directed at areas of greatest global health need.

Access to Medicines Ireland
Comhlámh
12 Parliament Street
Dublin D02 HV05

Email: accesstomedicinesireland@gmail.com
Twitter: @AccessToMedisIRL

www.accesstomedicines.ie