



GUIDE

HAI'S 2018

EUROPEAN UNION

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Publisher

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Health Action International (HAI) is a non-profit organisation that conducts research and advocacy to advance policies that enable access to medicines and rational medicine use for all people around the world. We pursue advocacy from the patient level up to the highest levels of government through our ‘official relations’ status with the World Health Organization and respected relationship with the European Medicines Agency. To safeguard our objectivity and integrity, we are resolutely independent of the pharmaceutical industry and protect ourselves from all other conflicts of interest.

EUROPEAN PROJECTS

Medicines are crucial for improving our health and well-being. But in the European Union (EU), the price of new patented medicines is growing higher every year, jeopardising the ability of patients to access them when needed and threatening the sustainability of our healthcare systems. At the same time, research shows that most new medicines that are brought to market offer little, or no, added therapeutic value over those that are already available. In addition, the increasing push to accelerate market approval involves evaluating medicines on the basis of limited clinical data. This leads to greater uncertainty about a therapy’s true effects.

HAI’s EU Projects team focuses on three core areas of medicines policy to improve public health outcomes in the EU.

This guide explains our work in these areas.

“The right to the highest attainable standard of health is a fundamental right of every human being.”

—World Health Organization

Increasing Access to Needed Medicines

In addition to calling for greater transparency of medicine price setting in the EU, HAI urges Member States to support effective mechanisms that make medicines affordable. We support policies that promote generic and biosimilar competition that put an end to pharmaceutical monopolies. We also advocate for complete transparency of pharmaceutical research and development (R&D) and for the use of new, needs-driven models of R&D.

Because access to safe and affordable medicines is also affected by international trade agreements, HAI advocates for EU trade policies that are aligned with public health needs.

We:

- Facilitate EU discussions on the impact of intellectual property (IP) rights on access to medicines, including during trade negotiations.
- Promote the use of legal and policy tools that allow governments to manage the rising cost of medicines in EU Member States (e.g., compulsory licensing and other IP management tools).
- Contribute to discussions about the best ways to strengthen collaboration between Member States on medicine price negotiation, procurement and health technology assessments (HTA), an approach that informs policy and decision-making in healthcare.
- Promote alternative innovation models, including those based on ‘delinkage’, which untie the price of a product from the purported cost of R&D.



Improving the Rational Use of Medicines

HAI calls for the safety and efficacy of medicines to be thoroughly assessed, and believes new medicines should offer an added benefit to patients compared to others already on the market. They should also be appropriately prescribed, with all data relating to safety and efficacy being transparent and publicly accessible. Because pharmaceutical marketing negatively impacts the way medicines are prescribed and dispensed, we also monitor EU regulations that govern medicines information, such as the rules on pharmaceutical advertising. In addition, we raise awareness among healthcare students and professionals about the impact of pharmaceutical promotion.

We:

- Develop recommendations on ways to strengthen medicines marketing authorisation procedures and safety monitoring in the EU.
- Promote the safe and rational use of medicines. Take part in discussions about best ways to regulate and ensure responsible off-label use of medicines.
- Promote greater transparency of clinical trial data and its use for independent review and information on medicines.
- Push for increased attention on the effects of pharmaceutical marketing as part of medical training and provide online resources to help healthcare students and professionals to understand and respond critically to pharmaceutical marketing techniques.
- Participate actively in the European Medicines Agency's Patients' and Consumers' Working Party.

Making Medicines Policy More Democratic

Health Action International calls for the highest levels of transparency, accountability and impartiality in all aspects of medicines policy. Our network represents the public health perspective on medicines issues by participating in formal consultations at the national, EU and global levels, and through membership of relevant EU/United Nations platforms.

In Europe, we play an active role in providing a consumer voice to policy initiatives that advance the public interest.

We:

- Campaign for greater action on transparency and affordability under the *Our Medicines, Our Right* campaign in The Netherlands, raising public voices for greater action to promote transparency and tackle high medicine prices.
- Respond to EU public consultations and raise consumer voices at the European Medicines Agency and in the HTA Network Stakeholder Pool.
- Continue to build on civil society engagement in the European debate on access to medicines and encourage the involvement of HAI members in our work.



Examples of the Impact of EU Project Work in 2017

Exposing Efficacy Shortfalls on Cancer Medicines

Our funded research showed that over half of new cancer medicines that recently entered the European market demonstrated no evidence of increased survival or quality of life—and sparked calls for a higher evidence bar.

Directly Influencing European Medicines Policy

Through our advocacy work, HAI policy recommendations were incorporated in a report on options for improving access to medicines in the EU, adopted by the European Parliament.

Getting to the Bottom of Pharmaceutical Marketing

We provided tools and guidance for medical faculty members, students and healthcare providers across Europe to identify and respond to pharmaceutical marketing techniques and their perilous impact on prescribing practices.

HAI EUROPE ASSOCIATION

The HAI Europe Association is a formal membership body of organisations and individuals that are interested in promoting access to, and the rational use of, needed medicines in the EU. It welcomes new members who wish to work collaboratively on important EU medicines policy issues.

To maintain the independence of the Association, members must not have financial ties to the pharmaceutical industry and make a declaration of interests stating they are free of potential conflicts of interest.

For more information, email info@haiweb.org.

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