IMPROVING **ACCESS TO MEDICINES** IN THE EUROPEAN UNION

A Guide to HAI's European Projects 2019

HAI HEALTH ACTION INTERNATIONAL

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Health Action International
Overtoom 60 (2) | 1054 HK Amsterdam
The Netherlands
+31 (0) 20 412 4523

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Medicines are crucial not only for improving our health and well-being, but also to fulfil our human right to health. But in the European Union (EU), the price of many 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.

This situation is aggravated by a narrow interpretation of intellectual property (IP) rights that creates harmful monopolies. At the same time, it has been reported that new medicines and indications often offer little—or no—added therapeutic value over those that are already available.[1] Added to this, the trend of accelerating market approval involves evaluating medicines on the basis of limited clinical data, leading to greater uncertainty about a therapy's true effects.

In this booklet we take you through the work Health Action International (HAI) does to improve access to affordable, safe, effective, and quality-assured medicines in the EU.

Why not test your knowledge on access to medicines with our quiz on page 7?

OUR FOCUS

HAI's work in the EU in 2019 can be broken down into three main areas:

Equitable access to affordable medicines	Sustainable access to medicines and vaccines remains an issue in a number of EU Member States. The challenges of affordability and availability of medicines are linked to a research and development (R&D) model that incentivises innovation through monopoly rights (e.g., patent protection and other forms of market exclusivity), enabling high medicines prices.
Medicines safety, added therapeutic value and rational use of medicines	The EU has a well-established medicines marketing authorisation system, but concerns remain about an often too permissive approach to efficacy requirements for medicines, and lack of consideration of added value.
Democratisation of medicines policy	Good governance in the pharmaceutical sector is crucial to ensure that decisions are aligned with the public interest. Transparency and inclusiveness with patient and consumer groups is needed to generate trust, accountability and legitimacy. At the same time, robust policies on conflicts of interest are necessary to prevent private interests being put ahead of the common good.

OUR ACTIVITIES

In Europe, the fulfilment of the universal right to health is not always assured. That is why we work with a broad range of partners, agencies, officials (at both EU and national level) and other stakeholders on an extensive plan of work that aims to improve the health and wellbeing of all EU citizens.

Through this work, we take part in various meetings and forums around Europe, bringing an independent civil society voice to discussions and debates currently shaping the EU public health agenda. In a European election year, this is perhaps more important than ever. But this is just the tip of the iceberg. Below we give a taste of some of the 2019 highlights.

Continue the work to improve transparency of medicine prices and procurement decisions across Europe	The 'Our Medicines, Our Right' campaign in the Netherlands focused on the need for increased transparency of medicine prices, R&D costs and promotion of alternative innovation models that do not rely on IP incentives (e.g., delinkage). In 2019, our work in this area takes on a more political focus, engaging with policy makers and Members of Parliament at national level, including through a series of breakfast meetings.
Push for a more systematic use of TRIPS flexibilities and other IP management tools as part of a public health agenda	We work to ensure that the EU honours its public support for the use of flexibilities provided in the Trade Related Aspects of Intellectual Property (TRIPS) Agreement, both when negotiating trade agreements, and in other international forums. We advocate for an enhanced competitive environment for generic and biosimilar products, including greater transparency and accountability, both at the national and European levels. We expect EU institutions to protect the right of national authorities to make use of TRIPS flexibilities when facing pressure from third parties and pharmaceutical companies.
Monitor EU trade deal negotiations to assess their impact on access to medicines	We continue to follow and respond to free trade negotiations led by the European Commission, focusing our attention on where they affect access to medicines conditions, both in the EU and its counterparts. It is particularly important to look at where so-called TRIPS-plus clauses, and certain other measures, might limit the use of flexibilities.

Issue policy recommendations that steer the European Commission's proposal on Health Technology Assessments (HTA)	In doing so, we call for alignment with the highest standards of quality, transparency and independence to make sure the Commission's proposals on HTA work for all EU citizens. We also remain member of the HTA Network Stakeholder Pool and promote better engagement of patients and consumers at EUnetHTA.
Launch a public platform to report on clinical trial results and risk bias for new cancer drugs	The platform will report on the findings of a study partly sponsored by HAI. In collaboration with researchers at King's College London and London School of Economics, the database will form a centralised and reliable source of information for healthcare professionals, patients and researchers on the underlying evidence on new cancer medicines approved by the European Medicines Agency.
Hold a public event in Brussels on opportunities and remaining challenges for clinical trial data transparency	An event to discuss the implementation of EU provisions on clinical trial data transparency with a view to identify best practice and areas for improvement.
Continue to raise awareness about the risks to prescribing practices posed by exposure to pharmaceutical promotion	To address this problem, we develop educational materials and provide free webinars to help fill the educational gap for students at various universities in Europe, giving the tools to critically assess pharmaceutical promotion and ensure rational prescribing.
Publish a policy paper on HAI's vision for EU pharmaceutical policy	The European elections form an important milestone around which we identify initiatives to be prioritised by the EU in the coming years.

QUIZ TIME!

1. True or False: Between 1969 and 1992, Canada issued 413 compulsory licences for medicines.
2. According to a 2017 study, what percentage of new cancer medicines approved by the European Medicines Agency between 2009 and 2013 failed to offer clear evidence of benefit on survival or quality of life?
3. What percentage of global health spending on research and development is publicly funded?
4. How many people does the European Centre for Disease Prevention and Control estimate die each year in the EU as a result of antibiotic-resistant bacteria?
5. True or False: A European Commission inquiry revealed that pharma spent 23% of turnover on marketing.

Answers at the bottom of the page 10

How Did You Do?

1–2 Hmmm, perhaps it's time to brush up on your knowledge. Why not keep up to date with the latest access to medicince news by following us on Twitter (@HAImedicines), Facebook (www.facebook.com/HAImedicines) or Instagram (healthactioninternational)

3–4 That's more like it. But there's always more to find out on the website—www.haiweb.org

5 Are you sure you're not Jaume Vidal?

OUR SUCCESSES

Our work this year is also framed by our successes of 2018, which included:

IP and Access to Medicines in Europe

A full-house at the European Parliament in May, with over 50 representatives from EU institutions, permanent representations, civil society and the pharmaceutical industry, to discuss the impact of the current EU IP protection framework on access to medicines. We particularly focused on IP incentive mechanisms, such as Supplementary Protection Certificates (SPC), and their effect on medicines affordability and accessibility. Building on recommendations from that event, we lobbied MEPs from across the political spectrum on the European Commission proposal for an export-only SPC manufacturing waiver. This was subsequently approved by the European Parliament—and with it a number of our suggested amendments—and was endorsed by the European Council. Further, we published a brochure for European policy makers on the use of TRIPS flexibilities to improve access to medicines.

Health Technology Assessments

We issued statements and recommendations to MEPs on HTA throughout 2018, with a view to improving a European Commission proposal establishing a mandatory framework of cooperation. Importantly, a report adopted by the European Parliament was aligned with our position in key aspects.

Open Science, Open Health

We made a substantial contribution to the debate around the drafting of Horizon Europe, the EU's public research programme. We organised a well-attended event in the European Parliament on Open Science, Open Health, with the participation of MEPs, academics and advocates. Particularly important to the discussion was access policy, public return on public investment and a research agenda based on health needs.

Our Medicines, Our Right

HAI also released a research report on *New and Affordable Medicines in the Netherlands: Tracing the Dutch Government's Policy Commitments and Actions*. The research scored the Dutch Government on its fulfillment of promises to improve transparency of the cost of R&D and pricing decisions, and affordability of new medicines. The report's release was strategically timed to coincide to inform a debate in the Dutch Parliament on Initiatiefnota: "Big Farma: niet gezond!" (Big Pharma: Not Healthy)

Education on Pharmaceutical Marketing

Leading expert in the field of pharmaceutical promotion, Dr Barbara Mintzes, joined us in October to lead a webinar on 'Unbiased Information on Medicines, Why is it Needed?' Participants registered from 27 countries in Europe and around the world, with feedback showing how much of an impact our work in this area can have on the views of medical and pharmacy students, and how it can be used in their future work.

GET IN TOUCH

To find out more about HAI's work in the European Union, please contact one of our expert team:

Jaume Vidal
Policy Advisor
jaume@haiweb.org

Alex Lawrence
Communications Manager
alex@haiweb.org

(For media enquiries)

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.

Quiz Answers: 1) False, it was 613; 2) 57 percent[2]; 3) 30–40 percent[3]; 4) 33,000[4]; 5) True[5]

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