



EU POLICY
>>> IN ACTION >>>
In whose interests?

Overview

There is often a divergence between policy and action in political decision-making. In order to assess the effectiveness of policies, it is essential to understand how and why decisions are made in reality. Medicines' policy in the European Union represents a prime example of such divergence and HAI Europe's campaigns have sought to research and analyse areas of incoherence in order to present policy recommendations that ensure EU policies match its actions.

This year's HAI Europe Open Seminar will examine the European Union's policies and actions in relation to medicines and provide an opportunity for stakeholders to publicly debate their views.



Keynote Address

Keynote Speaker: Jim Murray, Former Director, European Consumers' Organisation (BEUC)

For our food and medicines we rely to a large extent on large, complex and multi-national organisations operating in a market environment. While competing with each other for market share, these large entities have great economic resources, and therefore the power to influence and shape the political agenda - for example, in relation to science, regulatory policy or public affairs more generally. The challenge is not to demonise but to counteract this influence, so as to align public policy more closely to the public or common good.





Panel 1

Unwrapping the Pharma Package: What's in it for Consumers?

Moderator: Teresa Leonardo Alves, Health Action International (Europe)

Speaker One: Jörg Schaaber, International Society of Drug Bulletins

Speaker Two: Barbara Mintzes, University of British Columbia

The European Union currently prohibits advertising of prescription-only medicines to the public (Directive 2001/83/EC, article 88), as in all industrialized countries except for the United States and New Zealand. However, the 'information to patients directive', a proposal for legislative change currently under discussion in Europe, would allow several forms of advertising of prescription medicines that are currently prohibited.

This presentation reviews the proposed changes in terms of the existing European and international experience with disguised and direct advertising targeting the general public. The experience to date raises serious public health and consumer rights concerns, as well as significant cost implications. If the aim is to inform health care choices -- rather than to drive them -- the public needs better access to publicly financed, independent, unbiased information on the pros and cons of all available treatment options, including the option not to treat. This information can be provided without any change to the EU advertising directive.

Speaker Three: Florence Vandeveld, La Revue Prescrire

A series of public health disasters (from thalidomide in the 1960s to rofecoxib (Vioxx[®]) at the beginning of this century) have served to remind us of the crucial nature of pharmacovigilance. However, the European Commission's proposed legislative changes would represent a serious regression in the protection of European citizens.

Among the key issues of concern:

- the spread of weak marketing authorisation practices, using post-authorisation safety studies and 'risk management' programmes that would allow insufficiently evaluated medicines to reach the market;
- the dissemination of data on adverse drug reactions, where the responsibilities for data collection and interpretation are left to pharmaceutical companies, even though they have an interest in delaying pharmacovigilance decisions;
- the increased financial and intellectual dependency of health authorities on pharmaceutical companies (due to the lack of public funding for pharmacovigilance activities, and the hierarchical dependency of pharmacovigilance authorities on marketing authorisation committees), which leads to secrecy and increasingly biased decision-making processes.

Member States have a responsibility to protect their population. They must not accept the exposure of their populations to adverse drug reactions from medicines that were marketed prematurely. Neither should they support the delegation of tasks that clearly fall under the scope of public health to pharmaceutical companies.

The EU Commission proposals on pharmacovigilance can still be refocused in defence of the public interest, provided they are profoundly amended to put an end to the conflation of the public and private roles.



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Panel 2

Trading Away Access to Medicines

Moderator: Andrew Jack, Financial Times

Speaker One: Rohit Malpani, Oxfam International

The presentation will discuss how the European Commission's intellectual property policy adversely affects access to medicines in developing countries and is incoherent with EU development policy and the Union's own domestic efforts to improve access to medicines. To illustrate civil society concerns, the presentation will signal the similarities with earlier US trade policy, which has been criticized in recent years for its negative impacts on public health. Finally, the presentation will discuss how global innovation policy and spending by the European Union has not yet recognized nor sufficiently addressed the public health needs of developing countries.

Speaker Two: Sophie Bloemen, HAI Europe

The presentation will discuss the EU negotiations with the Andean countries that have taken place of the course of 2008 and 2009. The negotiations started out as towards an Association Agreement with all the Andean Community (CAN) countries: Peru, Colombia, Ecuador and Bolivia. In the latest stage, the process has evolved into purely trade negotiations with only Peru and Colombia. The EU CAN Alliance, a coalition of European and Latin American NGOs, has been working to limit the damage of the negotiations on public health in the Andean countries. The EU CAN Alliance has commissioned impact studies on the negotiations regarding the Intellectual Property provisions and Access to Medicines. The prospective studies are based on the IP proposal made by the EU half way through the negotiations, and look at what these would mean for expenditure and consumption on medicines in Peru and Colombia. The studies show that the ambitions of the EU would have a very negative effect on Access to Medicines in Peru and Colombia. After strong pressure, the problematic provisions on data exclusivity and patent extensions were taken out of the trade agreement, but remain part of the agenda of DG Trade regarding IP in developing countries. This agenda is in contradiction with the EU's own development objectives.

Speaker Three: Henrique Choer Moraes, Permanent Mission of Brazil to the European Community

The presentation will discuss the EU Enforcement agenda, highlighting aspects of the EU proposals for intellectual property chapters in trade agreements, but also the EU enforcement strategy for third countries, from the perspective of the possible impact on Access to Medicines. One example would be how the European Commission deals with proposals to establish a link between patent registration and the granting of market authorisations. While, on one hand, EC legislation forbids such linkage (a point that was underscored by the recent DG-Competition enquiry), DG-Trade criticizes third countries for not having made this link.