

What Role Can Civil Society Play in the European Regulatory Process?

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The formal engagement of patients and consumers in the pharmaceutical regulatory process helps ensure that important decisions about medicines take into account the thoughts and views of the people they most affect. The European Medicines Agency (EMA) has a long tradition of this kind of stakeholder involvement.

Health Action International (HAI) supports patient and consumer engagement, with adequate safeguards on conflicts of interest. We play an active role in providing a consumer voice to policy initiatives that advance the public interest. This is not only appropriate, but essential to counterbalance lobbying by the pharmaceutical industry.

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Over the years, we have closely followed a number of EMA initiatives, strongly supporting the move towards proactive publication of clinical trial data, and contributing recommendations on how to shape the policy. We have seen civil society calls for greater transparency bearing fruit, with the first clinical reports published in October 2016, and the continued expansion of the repository ever since. We have called on the EMA to keep up the momentum of this proactive approach to publication, joining forces with partner organisations in [response to a public consultation](#). A fundamental principle of the EMA approach must be that public interest always prevails over commercial confidentiality.

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A crucial part of the medicines regulatory process is drug safety, or pharmacovigilance. Through our relationship with the EMA, we have pushed for robust and proactive pharmacovigilance frameworks to ensure effective regulatory action to safeguard patient safety. Meanwhile, we follow the EMA's initiative on [Adaptive Pathways](#) and the [Priority Medicines](#) (PRIME) scheme with great interest. Through various interventions, we have raised concerns about accelerated approval schemes and advocated for their restricted use, including through a clearer definition of 'unmet medical need', and guarantees that companies comply with commitments after being awarded marketing approval for a medicine. We have also issued [recommendations](#) on how to improve the EMA's scientific

advice procedures, especially with regard to transparency and conflicts of interest.

This is just the tip of the iceberg of the contribution that civil society, patient, and consumer groups can make to ensuring a regulatory process is in place that is focused on the needs and interests of those it affects most. We are proud to play a broad role throughout the regulatory cycle, and will continue to engage positively to influence the important work carried out by the EMA.

Other HAI contributions to the European regulatory process in 2017 alone:

- HAI remained an active member of the EMA's Patients' and Consumers' Working Party ([PCWP](#)).
- In December 2017, we participated in the workshop 'Data Anonymisation—A Key Enabler for Clinical Data Sharing', organised by the EMA.
- In November, two representatives attended EMA's annual training session for patients and consumers, building capacity within HAI to contribute actively to discussions.
- The first EMA public hearing on medicines was organised in September 2017, with our support in disseminating information through social media and members.
- We attended an EMA joint workshop with the Healthcare Professionals Working Party (HCPWP) on Personalised Medicine, and an Information Session on Antimicrobial Resistance.
- We shared an EMA survey on reporting adverse drug reactions, including for medicines under 'additional monitoring' and, together with members, contributed to an awareness raising campaign, launched by European medicines regulators, about adverse drug reaction reporting.
- HAI became a member of the Health Technology Assessment (HTA) [Network Stakeholder Pool in 2017](#). Working with other patient and consumer groups, we contribute to stakeholder engagement and make recommendations to optimise patient and consumer involvement in HTA processes.
- We presented our Addressing the Challenge and Constraints of Insulin Sources and Supply ([ACCISS](#)) Study to the PCWP. This intervention was an opportunity to increase awareness of our work to address challenges and constraints of access to insulin, and explore areas of collaboration with other patient groups.
- As a member of the drafting group for the [PCWP-HCPWP](#) work plans 2018-2019, we have helped to identify priority areas of work in the upcoming years.