Health Action International (HAI) is a non-profit, independent, global network of over 200 consumer groups, public interest non-governmental organisations (NGOs), healthcare providers, academics and individuals in more than 70 countries. In official relations with the World Health Organization (WHO), HAI pursues the highest level of global medicines policy advocacy at the World Health Assembly and regional WHO meetings. The following report reflects the activities of Stichting HAI, based in Amsterdam, The Netherlands.
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About HAI

**Vision**
HAI and its partners recognise that poverty and social injustice represent the greatest barriers to sustainable health and development. Together, we work for just and equitable societies where people can participate in making the decisions that affect their health and well-being. Only by achieving sustainable levels of good health can citizens take a full and active role in development.

**Mission**
HAI supports rational and economic medicines policy and advocates for social justice in health care by improving access to essential medicines and promoting the rational use of medicines.

**Goal**
HAI is working toward a world where all people, especially those living in poverty, are able to exercise their human right to health. Our goal is to achieve universal and equitable access to affordable essential medicines of assured quality and to ensure that those medicines are used rationally to promote the highest standards of health throughout the world.
Programme Areas

1. Access to Essential Medicines
   Increasing access to essential medicines by ensuring they are available at affordable prices when
treatment is needed, especially for those living in poverty.

2. Rational Use of Medicines
   Promoting the rational use of medicines so that all those that are marketed meet real medical needs, have
therapeutic advantages, are acceptably safe, offer value for money, and are used rationally.

3. Democratisation of Medicines Policy
   Improving democracy and transparency in all aspects of decision making around pharmaceutical policy by
supporting the equal participation of patients and consumers in policy decisions.
Creating positive change in the world is rarely simple. This is particularly true in the field of medicines policy. Yet, in 2012, HAI managed to make tremendous strides in maintaining or increasing access to essential medicines for citizens around the globe, and improving the rational use of medicines amongst prescribers, dispensers and consumers.

Our successes are the result of the generosity of our donors and steadfast commitment and action of our highly knowledgeable and skilled network members, staff and partners. Together, this year, we revealed price, affordability and availability barriers to medicines access in 16 low- and middle-income countries, and successfully opposed the European Union’s Anti-Counterfeiting Trade Agreement, which would have had severe and negative implications for medicines access around the world. We also equipped hundreds of health care professionals, students and consumers with skills to effectively assess pharmaceutical promotion. But we are not content with these achievements.

Every day, one-third of the world’s population continues to suffer and die needlessly because they cannot afford or locate the medicines that they, or their loved ones, need. Others’ lives are forever changed for the worse, or even taken, as a result of adverse drug reactions that are, in part, due to an ongoing and dangerous lack of transparency in clinical trials. And while pharmaceutical companies continue to primarily measure their success based on profits, instead of public health, governments the world over continue to shirk their responsibilities to effectively regulate the industry. Obviously, more must be done.

Because of ongoing struggles, like these, and new challenges, like the rapidly shifting global health and funding landscapes, HAI embarked on an organisational review at the end of 2012. This process, which will continue well into and beyond next year, provides an opportunity for us to explore our key strengths and potential areas for improvement. This process of reflection and introspection will, no doubt, contribute to the dynamism and long-term sustainability of HAI. We are open and receptive to the results and are confident that they will help us push the boundaries of creating positive change in the medicines field in the years to come.

Atze Sybrandy
Access to Essential Medicines

HAI Global continued to be a major source of research, policy analysis and technical expertise regarding medicines pricing, availability and affordability in 2012.

Together with the WHO and a group of international experts, HAI Global published a review series on pharmaceutical pricing policies and interventions. The series contains five working papers on pharmaceutical pricing policies (external reference pricing, regulation of mark-ups in the pharmaceutical supply chain, the role of health insurance in cost-effective use of medicines, competition policy, and sales taxes on medicines) and has a unique focus on low- and middle-income countries. The reviews provide policy makers, in their efforts to improve medicine availability and affordability, with insight into the design and implementation of these policy approaches. HAI Global also commenced reviews on generics policies, health technology assessments and cost-plus pricing, which will, similarly, be used to inform policy development upon their completion in 2013/14.

Additionally, HAI Global provided extensive technical support to 16 medicine price and availability surveys this year. In Ukraine and Moldova, in particular, HAI trained local researchers, supported data collection, analysed the findings, drafted reports and contributed to pricing policy analyses. This assistance is helping Ukraine and Moldova to increase their medicines transparency, both nationally and internationally. Further to this work, HAI used its price and availability data (from its Price Database) to draft the WHO/HAI section on medicine price, availability and affordability in the United Nations’ 2012 Millennium Development Goals Task Force Report, The Global Partnership for Development: Making Rhetoric a Reality. This document has been instrumental in highlighting the need for greater international focus on health issues and the lack of available and affordable medicines for the world’s poor.

Following on from an African consultation in 2011, HAI Global consulted, in 2012, with experts from Cambodia, Lao People’s Democratic Republic, Nepal and Papua New Guinea on developing and implementing pricing policies in resource-constrained settings (supported by the WHO’s Alliance for Health Policy and Systems Research). The outcomes will include a briefing note (to be published in 2013) and journal article (to be published in 2014) to reach a wider audience. HAI Global also participated in the Alliance’s meeting to discuss and set future research priorities.

In addition to disseminating medicines pricing and availability knowledge during meeting presentations, including those at Duke University in the United States and the Quality Medicines Network in Antwerp, Belgium, HAI conducted a situation analysis and drafted a proposal to establish a medicine price and monitoring system in Ghana. In conjunction with the Medicines Transparency Alliance (MeTA) project, HAI assisted the WHO in developing a situation analysis questionnaire to assess the need for, and value of, a medicine pricing and availability monitoring system. Uganda recently used the questionnaire to assess its need, and it is likely that other MeTA countries will also use this tool.
Access to Essential Medicines

HAI Europe, in 2012, continued its efforts to promote policies that support equitable access to medicines and sustainable health systems in Europe. It focused on the implications of intellectual property (IP) enforcement measures on generic competition; in particular, on the negative impact of the Anti-Counterfeiting Trade Agreement (ACTA) on internal market policies. With its partners, HAI Europe co-organised advocacy activities amongst health NGOs to oppose ACTA. This included the development of a policy brief based on a technical analysis of ACTA’s potential harms to public health, as well as numerous other advocacy publications. These materials, which targeted key decision makers in the European Council and European Parliament, were covered in 12 news reports in six European countries. HAI Europe’s recognised technical expertise in IP and medicines also earned invitations to provide advice to European parliamentarians and the broader NGO community, as well as an opportunity to present concerns about access to medicines during a European Parliament event hosted by the Liberals (ALDE) and Socialists (S&D). These activities contributed to the success of the campaign; in July, the European Parliament voted to reject ACTA.

Related to this work, and to inform its position on the European Union (EU) Customs Regulation, which was reviewed in 2012 by the European Commission, European Parliament and Member States in the European Council, the Dutch government requested technical analysis and input from HAI Europe. This input helped the government raise concerns within the European Council about the potential impact of the Regulation, particularly on the trade of generics. Additional advocacy activities by HAI Europe and its partners resulted in the adoption of an important amendment to the report that was eventually selected by the Council: limiting the scope of customs enforcement of in-transit medicines to cases where there is a risk of diversion. HAI Europe, along with Oxfam, also drafted an advocacy document, which provided policy decision-makers with an overview of which amendments to support and reject to protect access to medicines.

HAI Europe also conducted awareness raising activities and research with partners regarding the potentially negative effects of EU-wide austerity measures on access to medicines in Europe. Staff began the development of a literature survey outline and collection of documented examples that highlight inequitable access to medicines in the EU. They also partnered with the European Public Health Alliance and other stakeholder organisations to strengthen pro-health policies in response to the financial crisis and maintained its relationship with European Commission officials active on pharmaceutical dossiers at the Directorate General Competition and Directorate General Health and Consumers. As a result, HAI Europe was successful in drawing attention to the negative impact of stronger IP enforcement measures on generic competition and lack of transparency in medicines prices and procurement.

Furthermore, to advance EU actions on the exploration of new models of medical innovation, HAI Europe advocated on the national, EU and multilateral levels for open access to research publications and increased data-sharing of research results, particularly for publicly-funded research. This included the development of a policy paper, *Time for the EU to Lead on Innovation*, in collaboration with the Trans-Atlantic Consumers Dialogue. HAI Europe also encouraged governments to
explore new models of biomedical innovation that delink the cost of innovation from the price of the product. The success of providing technical expertise into future research and development (R&D) funding under Horizon 2020 and co-organising two successful meetings in the European Parliament with policy makers was realised in November; the Parliament voted in favour of mandatory open access to research publications in Horizon 2020 and supported increased access to data and non-exclusive licensing of results in major societal challenges, such as health.

Finally, HAI Europe co-organised and co-hosted a successful three-day meeting in December with Alianza LAC-Global, its regional network in Latin America, of which it is a member. The meeting resulted in the revitalisation of the Alianza, including the addition of new members from Argentina and Costa Rica, as well as an ambitious work plan for 2013-2015.
Rational Use of Medicines

HAI Global and HAI Europe staff and members continued to promote, distribute and teach Understanding and responding to pharmaceutical promotion: A practical guide to a wide global audience in 2012. More than 300 copies of the guide were distributed at conferences, including the International Pharmaceutical Federation Centennial Congress in Amsterdam, the annual PharmOut Conference in Washington, D.C., and the Third People’s Health Assembly in Cape Town. Opportunities to teach the manual at events, including a day-long medical student symposium at the University of Groningen, workshops for Health Projects for Latvia and the Agency for Medicines and Medical Devices of Montenegro, and numerous guest lectures at universities in Amsterdam, also proved beneficial. They enabled HAI staff and members to directly inform hundreds of health care students and professionals, regulatory officials, civil society leaders and ministries of health staff about the negative impact of pharmaceutical promotion and best practices for dealing with it.

Throughout the year, over 3000 printed copies of the manual were also distributed through HAI’s regional offices and partners, such as the WHO Eastern Mediterranean Regional Office and PharmAware United Kingdom, or directly to university faculties. In addition, almost 200 electronic copies of the guide were downloaded from the HAI Global and Europe websites. It is now estimated that at least 20 universities worldwide teach at least some part of the guide to their students.

In addition to these activities, HAI Europe continued its efforts to promote health security by highlighting the link between data transparency and safe medicines use in 2012. In particular, it capitalised on a unique opportunity to provide technical advice to inform European Medicines Agency (EMA) policy revisions on access to clinical trials data, while a number of HAI Europe members participated in several relevant working groups. HAI Europe also sought the implementation of new commitments on access to clinical trials data in the proposed Clinical Trials Regulation from the European Commission by providing in-depth advice to Members of the European Parliament (MEPs), including the rapporteur and shadows, as well as policy advisors from political groups, in the lead-up to the Parliament's review of the Regulation. This important activity, and others, resulted in the tabling of numerous pro-transparency amendments by MEPs in the legislative process, which is expected to conclude next year.

Further to this, HAI Europe participated in a closed meeting with the Heads of Medicines Agencies in Copenhagen to discuss policy revisions for clinical trials data disclosure and the handling of commercial confidentiality, as well as numerous other EMA stakeholder consultation processes. It also conducted a joint analysis of the EMA’s policy and used the results to pressure EU medicines regulators to make data more accessible for democratic and empowered decision making about therapies. The results of these consultations and other activities are still to be determined.
Democratisation of Medicines Policy

Throughout 2012, HAI Global continued its role as the International Secretariat of the Medicines Transparency Alliance (MeTA), together with the WHO. It provided administrative and civil society support to the seven participating MeTA countries: Ghana, Jordan, Kyrgyz Republic, Peru, Philippines, Uganda and Zambia. With the programmatic aim of increasing access to essential medicines by improving transparency and accountability, HAI Global primarily focused its work on helping each country to re-establish a well-functioning MeTA council and to finalise a rolling annual work plan. To this end, HAI Global held in-country meetings with each MeTA council to confirm that broad multi-stakeholder representation existed, and to discuss the important role and capacity that civil society organisations offer the councils in supporting improvements in transparency and accountability of the pharmaceutical sector. Each country’s work plan, prior to commencing project funding, was also assessed. Following that, three countries began implementing activities, which are highlighted in the box below.

Advancing Medicines Policy through MeTA in 2012

Uganda: Engaging multi-stakeholders
The national MeTA Council in Uganda became the first group within the pharmaceutical sector to represent all key national stakeholder groups: the national government, represented by the Ugandan Ministry of Health; the private sector, including wholesalers, manufacturers and faith-based institutions; civil society, represented by the Coalition for Health Promotion and Social Development (HEPS Uganda); the WHO Country Office; and Danida (the Ministry of Foreign Affairs of Denmark), which supports in-country development programmes. In the past, collaboration was limited to the Ugandan Ministry of Health, WHO and HAI (represented by HEPS Uganda). The recent expansion of members has fostered and enhanced dialogue and information sharing across and within the sectors. And, for the first time ever, both the private and civil society sectors were invited by the Ministry of Health to participate in the development of the National Pharmaceutical Sector Strategic Plan (NPSSP II 2009/10 to 2013/14).

Jordan: Ensuring civil society representation in policy reform
MeTA Jordan became the first forum in the country to bring together stakeholders from the public, private and civil society sectors to discuss medicines supply chain issues and solutions. The inclusion of civil society into the medicines policy debate was a critical achievement; previously the sector had been fragmented—mainly comprised of fundraising patient groups with little advocacy and campaign experience—and without a strong voice to influence policy.

MeTA helped unify Jordanian civil society, in part, by assisting with the development of a database containing civil society and patient organisations. Today, the civil society sector contributes to, and is unified under, one group: the Jordanian Civil Society Organisation (CSO). The CSO defends patients’ rights by calling for, and using, high-quality data to press for evidence-based reforms in Jordan’s medicines sector.

Kyrgyz Republic: Promoting regulatory transparency
Regulatory transparency has long been a concern in the Kyrgyz Republic. To address this issue, MeTA Kyrgyz Republic collaborated with the Drug and Regulation Authority (DRA) to increase the availability of medicines information. As a result, the DRA launched a new website and has begun to routinely publish legal framework documents, update information on registered and rejected medicines, and monitor and publish medicines prices.

Changing medicines procurement practices to reduce costs
A MeTA study found that drug prices procured in the capital city of Bishkek were significantly higher (median price ratio: 1.42) than in the regions (e.g., median price ratio Chui region: 0.98). Drug procurement for municipal hospitals was centralised in Bishkek, while regional hospitals procured medicines themselves. The MeTA Kyrgyz Republic NGO coalition sent the study results to Bishkek’s office of the mayor, city council and the health ministry. As a result of this action, the mayor ended the practice of centralised medicines procurement for municipal hospitals. They now get a better price for the medicines they procure independently.
Democratisation of Medicines Policy

Meanwhile, in its efforts to ensure that EU policies are responsive and accountable to public health needs, HAI Europe, in partnership with the Corporate Europe Observatory, undertook novel research to quantify the size of the pharmaceutical industry and gain insight into its potential influence on EU policy making. Moreover, it monitored broader EU policy debates and took action on those that can have indirect, but meaningful, effects on medicines on the market and their use. This work has contributed to the balance of stakeholders advising the EMA and ensured that genuine public interest representatives are consulted in medicines safety issues.

HAI Europe also participated in several meetings of the Patients’ and Consumers’ Working Party at the EMA. Through many interventions, it aimed to strengthen the transparency, accountability and independence of the Agency.

Further to this, HAI Europe continued supporting the next generation of civil society voices that aim to align EU policies and decision making with wider public health and societal interests. It focused specifically on ensuring the smooth functioning and sustainability of the HAI Europe network, including reaching out to potential new members and developing HAI Europe’s field of expertise. This included publishing numerous newsletters, which resulted in member requests to distribute information on their behalf, holding an annual general meeting in Amsterdam, which was attended by 25 members, and expanding its social media activities and audiences.
Governance
The HAI Foundation Board (2012-2013)

Atze Sybrandy
Chair
Atze has an extensive background in human resources management and international development. Currently based in the Republic of South Sudan, he is the Director of Human Resources and Administration with Save the Children International.

Prem Chandran John
Deputy chair
Prem is the chair of the Global People’s Health Movement and a physician in the public sector. He has a long history of participation in the Asian Community Health Action Network and HAI.

Paul Lindgreen
Treasurer
Paul has a vast career in financial controlling and management with organisations including the Dutch Authority for Workers Insurance (UWV), CARE Netherlands and Oxfam Novib. He joined the Board in June 2013.

Eva M. Ombaka
Member
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Financials

For the 2012 financial year, HAI received a total of €1,124,400 from donors to support activities. This represents a considerable funding increase in comparison to 2011 (€786,100). Since 2011, the United Kingdom Government’s Department for International Development (DFID) has become HAI’s main donor. Its other major donor is the European Commission, through the Executive Agency for Health and Consumers.

As shown in the graph below, programme expenses for 2012 totaled €943,710 (2011: €786,350). Of this amount, overhead costs represented 5.8% (2011: 6.5%).

Complete 2012 financial statements are available on the HAI Global website.