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HAI_FY2017

JA2015 - GPSD [705038]

START DATE: 01/01/2017

END DATE: 31/12/2017

DURATION: 12 month(s)

CURRENT STATUS: Finalised

PROGRAMME TITLE: 3rd Health Programme (2014-2020)

PROGRAMME PRIORITY: -

CALL: Financial contribution to the functioning of non-governmental bodies
(Operating grants)

TOPIC: Specific Grant Agreements under HP-FPA-2014

EC CONTRIBUTION: 253000 EUR

KEYWORDS: Civil Society Engagement, Civil Society Engagement.,
Democratisation Of Medicines Policy, Health Security, Increase Access To Needed
Medicines, New Models Of Medical Innovation, Rational Use Of Medicines

PORTFOLIO: Medicinal products for human use

Project abstract

Health Action International's (HAI) work in Europe contributes to EU policy that promotes universal and equitable access to affordable medicines for needed treatment. HAI also supports policies and practices that ensure those medicines respond to societal challenges, are acceptably safe, and appropriately prescribed and used.

HAI's 2017 European work plan focuses on providing technical expertise to policy makers, patient and consumer organisations, health NGOs and other relevant stakeholders. It also focuses on researching the extent of the pharmaceutical industry's promotion of antibiotics to patients and healthcare professionals, as well as on identifying barriers to teaching on promotions in the medical curriculum. HAI will also enable public discussion on affordable access to needed medicines through the organization of public events. HAI will work towards these goals to support EU action that provides responses to gaps in medicines policies and are aligned with HAI's overarching goals on Access to Needed Medicines, Rational Use of Medicines and Democratisation of Medicines Policy projects. Through its European network, HAI provides an independent patient and consumer voice in decisions that affects their health while advocating for high levels of transparency, accountability and impartiality. HAI is a non-profit, independent non-profit organisation. It maintains a European membership network of consumer groups, healthcare professionals, academics and public interest NGOs. The growing European regional network is represented in over half of the EU's Member States. The HAI European office coordinates actions in collaboration with the HAI Europe Association and European civil society organisations.

Summary of context, overall objectives, strategic, relevance and contribution of the action

Health Action International (HAI) envisions a world with safe, effective, affordable and quality-assured medicines for everyone, everywhere. To make this a reality, our staff and global network conduct research and advocacy to advance policies that enable access to medicines and rational medicines use for all people around the world.

In Europe, HAI has grown to become a pre-eminent voice in medicines policy intervention, driven by a strong regional network comprising consumer and patient groups, healthcare professionals, academia and other public health groups. The HAI European office coordinates actions in collaboration with the HAI Europe Association of members and partner European civil society organisations.

Health Action International's work in Europe contributes to EU policy that promotes universal and equitable access to affordable medicines for needed

treatment. HAI also continues to support policies and practices that ensure those medicines respond to public health needs, are acceptably safe, and appropriately prescribed and used. Throughout our various interventions and activities, in 2017 HAI contributed to policy debates in a number of areas, particularly on: mid-term review of Horizon 2020 and FP9; medicines pricing policies and joint cooperation agreements amongst Member States; trade, intellectual property rights and access to medicines, EMA's policy on access to documents, pharmaceutical regulation and health technology assessments. We continued working to raise awareness about the impact of pharmaceutical promotion on prescribing practices and the need to embed education on promotion in the medical curriculum.

The 2017 Operating Grant from CHAFEA enabled HAI to develop and strengthen both the scope and the reach of its activities, which reflect the goals of the Third Health Programme. In particular, HAI contributed to the following Health Programme objectives: 2) Protect Union citizens from serious cross-border health threats – for example by identifying drivers of irrational antibiotic use and developing recommendations to address them; 3) Contribute to innovative, efficient and sustainable health systems – for example, by promoting public-needs driven models of innovation that maximise public return on public investment and enable medicines affordability; 4) Facilitate access to better and safer healthcare for Union citizens – e.g. by participating actively in the European Medicines Agency Patients' and Consumers' Working Party and at the HTA Network Stakeholder Pool.

Methods and means

Depending on the objective and target group of our work HAI deploys a variety of methods and means. These are implemented by HAI directly, (if strategic) in cooperation with members and partner organisations. In our engagements with policy-makers we, for example, make use of policy papers, public consultation responses, and one-on-one meetings. We also organise public conferences, workshops and run public awareness campaigns e.g. 'Our Medicines, Our Right' campaign. We actively engage in civil society coalitions and strategic partnerships to maximise the impact of our work. For media engagement we use press releases and statements as well as social media, which is also used to disseminate our work amongst the general public.

Work performed during the reporting period

- A panel discussion in Brussels (targeting EU-level stakeholders) on R&D and affordable access to needed medicines was organised on 31 January, 2018.
- HAI developed publications on trade and access to medicines, and provided technical expertise to policy-makers and civil society organisations (CSOs).
- HAI was involved in activities of the Transatlantic Consumer Dialogue.
- HAI run a public awareness campaign in The Netherlands and organised a public conference on policy mechanisms that enable transparency of medicines prices and (public share) of R&D costs.
- HAI contributed to raise awareness and enhance technical expertise of policy-makers and civil society groups about policy solutions that support uptake of new R&D models that respond to AMR and improve affordable access to treatment and rational use.
- HAI organised a workshop with medical students and experts to discuss education on pharmaceutical promotion in the medical curriculum, and published a report with recommendations.
- HAI looked into the main drivers of irrational use of antibiotics, including pharmaceutical promotion, and developed a paper with recommendations.
- Throughout 2017 HAI advocated for greater transparency of clinical trial data and stronger requirements for marketing medicines authorisation and HAI supported research into the evidence of the benefit of oncology drugs approved by the European Medicines Agency.
- HAI has developed a variety of communications materials on all its areas of work. Topics included affordable access to medicines, rational medicine use, and democratisation of medicines policy.
- HAI provided technical expertise to relevant stakeholders (policymakers, regulators, CSOs) on all HAI's areas of work through meetings, workshops, and other interventions.

The main output achieved so far and their potential impact and use by target group (including benefits)

Health Action International (HAI) and Commons Network (CN) organised a panel discussion on the opportunities and challenges ahead in the current medical Research and Development (R&D) system. The discussion was attended by over 40 stakeholders, such as representatives from the EU institutions, academia, civil society and industry. The dialogue among these diverse stakeholders focused on the alignment of public funded R&D with societal needs in the context of the mid-term review of Horizon 2020 (H2020) and the drafting of Framework Program 9 (FP9). Concrete recommendations were made to shape the upcoming FP9 in ways that guarantee a fair public return on public investment.

HAI managed to assemble a wide coalition of European and Latin American

CSOs who shared concerns about the potential impact of EU–Mercosur trade negotiations on access to essential medicines. HAI led the process of developing a joint open letter addressed to top EU and Mercosur negotiators with recommendations. The letter was endorsed by over 25 Latin American and European CSOs. HAI also held multiple meetings with the teams of Members of the European Parliament (MEPs) to discuss the Mercosur trade deal.

During the 2017 Dutch election period, HAI launched a public awareness campaign, called 'Our Medicines, Our Right', in The Netherlands to demand increased transparency of medicines prices, R&D costs and public funding of biomedical research. As part of our campaign, in December 2017 HAI organised a public forum in The Netherlands, attended by over 80 people. The event provided the opportunity to discuss different stakeholders' perspectives and potential solutions on key transparency issues.

HAI actively engaged in discussions about the mid-term review of Horizon 2020 and made specific recommendations to the European Commission and Council on alternative models of biomedical innovation. For example, HAI co-authored a response to the public consultation on Horizon 2020 and endorsed a letter calling on the European Commission to increase the social impact of its medical research and innovation (R&I) investments.

In September 2017, HAI organised a workshop on education of pharmaceutical promotion in medical training. The objectives of the workshop were to identify barriers that prevent education on pharmaceutical promotion and conflicts of interest from being adequately addressed in the medical curricula; showcase best practice examples of educational initiatives on pharmaceutical promotion; discuss best ways to structure teaching on promotion and conflicts of interest in the medical curriculum; and identify driving forces that can contribute to policy change.

The workshop was attended by professors from faculties in The Netherlands and abroad, medical student associations and healthcare professionals. HAI received positive feedback from the participants. A report on education on pharmaceutical promotion was published following the workshop.

In May 2017, HAI submitted a joint response to the European Medicines Agency (EMA) public consultation on its access to documents policy. This reinforced HAI's position as an engaged stakeholder with expertise on clinical trial data transparency and public access to regulatory documents.

HAI responded to public consultations from EU institutions and other organisations, such as the Organisation for Economic Co-operation and Development (OECD). We also sent a response to the consultation on the future of HTA in Europe (January). We followed closely the OECD initiative on sustainable access to innovative therapies and responded to its public consultation – HAI delivered an intervention on Strengthening Member State Collaboration on Improving Access to Medicines, and called for greater transparency in areas such as pricing and clinic trials at the WHO EURO RC67 in 2017. Throughout 2017, HAI issued multiple communication materials on all

areas of its work.

Annual General Meeting with the HAI Europe Associ

Achieved outcomes compared to the expected outcomes

Overall our achieved outcomes trumped our expected outcomes, especially in terms of stakeholders reached and credibility of HAI as an expert stakeholder, including its network. Key achieved outcomes are highlighted below:

- Through our activities, we contributed to shape discussions about the need for more transparency on medicines prices and R&D costs. Demands for more transparency are also gaining traction amongst civil society stakeholders (e.g. associations of payers, patients, consumers and healthcare professionals), as well as policy-makers in the EU and at national level. More than 2.000 people have signed on to a petition launched by HAI, which calls for greater transparency.
- Building on previous work, we contributed to raise awareness about the perils of medicines early authorisation procedures and about the need to use expedited approval schemes in exceptional situations, with adequate safeguards. The 2017 Report on EU Options for improving access to medicines approved by the European Parliament calls to “(...) guarantee a thorough assessment of quality, safety and efficacy in any fast-track approval process, and to ensure that such approvals are made possible by means of conditional authorisation, and only in exceptional circumstances where a clear unmet medical need has been identified, and to ensure that a transparent and accountable post-authorisation process to monitor safety, quality and efficacy is in place, as well as sanctions for non-compliance”.
- HAI contributed to bring together a coalition of 25 NGOs from Latin America and Europe that made calls on the need to safeguard access to medicines in the EU & Mercosur trade negotiations.
- We sensitised medical students about the impact of pharmaceutical promotion on clinical practice, and the need for better education on promotion in the medical curriculum. Our evaluation has shown increased demand by universities and medical student associations to discuss and get informed about this topic.
- HAI received a number of invitations to speak at public events and workshops. This shows that HAI is perceived as an expert stakeholder in access to medicines policy debates.

Dissemination and evaluation activities carried out so far and their major results

Dissemination:

To ensure maximum outcomes and transparency, HAI has in place protocols to tailor its dissemination strategy to a given output. The interventions were targeted at the general public, European and national patient and consumer organisations, healthcare professionals, medical students, academia, EU institutions, national governments and regulatory agencies. Distributed materials included policy papers, responses to public consultations, press releases and statements.

Communication materials were successfully distributed to the media and frequently reported by some of the most influential medicines policy outlets. HAI was quoted in several media outlets that publish on nationally and/or broader EU level. In addition to influencing policy, HAI's communication materials helped to increase the visibility of the organisation.

Specific tools were used to inform members about HAI's activities, for example a listserve and an electronic newsletter. The Annual General Meeting provided an additional opportunity to discuss European-based work with the members. It was also an opportunity for members to provide presentations about their work.

Evaluation:

HAI maintains a monitoring and evaluation framework which undergoes continuous improvement. Progress on activities and outputs was reported quarterly by the staff to the Executive Director and PME Officer, as well as presented to the HAI Europe Association Board and to the membership of the organisation at the Annual General Meeting.

We undertook various evaluation activities, the results of which helped inform the formulation of our 2018-2021 Framework Programme. Activities included review sessions (on/offline) with our network members, systemic analysis of the uptake of our (campaign) materials and messaging, and feedback gathering of participants of interventions.

Work package

Work Package 1: Activity 1. Organise conference at EU level on access to medicines

Start month: 1

End month: 11

Work Package Leader: Stichting HAI

(corresponds to Act. 1-3 FPA) Bringing together different HAI projects in 2015-16 work on access to medicines (research, workshops), organise a public conference at EU level on affordable access to needed medicines including transparency demands

Work Package 2: Activity 2. Publications and meetings on TTIP

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

Based on previous work (e.g. Act. 4 SGA 2015 and Act. 3 SGA 2016) publications on TTIP and access to medicines, provide technical expertise to policy makers and CSOs in TTIP negotiations

Work Package 3: Activity 3. Involvement in TACD

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

HAI acts as EU co-chair of TACD's IP Committee by participating and 1) contributing to Steering Committee meetings (2) contributing to annual TACD public meeting and (3) co-drafting TACD resolutions relevant to HAI's work

Work Package 4: Activity 4. Organise a conference in the Netherlands on transparency of R&D costs and medicines prices

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

Act 4: (corresponds to Act. 1-3 FPA) Follow-up on 2016 social media campaign in Netherlands, organise public conference on policy mechanisms that enable transparency of medicines prices and (public share) of R&D costs

Work Package 5: Activity 5. Communication materials and meetings on AMR and new R&D models

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

(corresponds to Act 4 FPA) Use 2016 AMR policy paper to raise awareness and enhance technical expertise about policy solutions that support uptake of new R&D models that respond to AMR and improve affordable access

Work Package 6: Activity 6. Organise a workshop about education on pharmaceutical promotion in medical curriculum

Start month: 1

End month: 11

Work Package Leader: Stichting HAI

(corresponds to Act. 5 FPA): Organise workshop with experts to identify barriers preventing adequate teaching on pharmaceutical promotion in medical school curricula and CME, and issue recommendations for this subject to be formalised in the curriculum

Work Package 7: Activity 7. Briefing paper on pharmaceutical promotion of antibiotics

Start month: 1

End month: 11

Work Package Leader: Stichting HAI

Act. 7 (corresponds to Act. 7 FPA): Research the extent of the pharmaceutical industry's promotion of antibiotics to patients and healthcare professionals and issue policy relations where needed to improve the rational use of antibiotics.

Work Package 8: Activity 8. Communication materials and meetings on clinical trial data transparency and medicines marketing authorisation

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

Act. 8 (corresponds to Act. 6 FPA): Advocate for greater transparency of clinical trial data and stronger requirements for marketing medicines authorisation (addressing concerns on early access schemes such as conditional marketing authorisation, adaptive pathways)

Work Package 9: Activity 9. Develop communication materials on all HAI's areas of work

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

Act. 9 (corresponds to Act 8, 9 FPA): Develop communications materials on all HAI's areas of work: affordable access to medicines; rational use and democratisation of medicines policy

Work Package 10: Activity 10. Provide technical expertise to relevant stakeholders

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

Act. 10 (corresponds to Act 8 and 9 FPA): Provide technical expertise to relevant stakeholders (policymakers, regulators, CSOs) on all HAI's areas of work

Work Package 11: Activity 11. Strengthen HAI Europe's network

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

(corresponds to Act. 10 FPA) Maintain and strengthen HAI Europe network's engagement in EU medicines policy debates; organise Annual General Meeting and

Work Package 12: Activity 12. Contribute to financial sustainability of HAI Europe's network

Start month: 1

End month: 12

Work Package Leader: Stichting HAI

(corresponds to Act. 12 FPA): Contribute to financial sustainability of HAI Europe's network

COORDINATOR



STICHTING HEALTH ACTION INTERNATIONAL (Stichting HAI)

Overtoom
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WEBSITE: <http://www.haieurope.org>

PARTNERS

No partners related to the current project

Event materials for public EU conference

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Organise a public conference at the EU level on affordable access to needed medicines, including transparency demands

Event materials for public conference in the Netherlands

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Organise a public conference on policy mechanisms that enable transparency of medicines prices and (public share) of R&D costs

Report on HAI's contribution at TACD

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Participate in Steering Committee calls and meetings; contributes to organisation of the TACD bi-annual meeting and drafting of TACD resolutions on topics relating to access to pharmaceuticals

Briefing paper about the extent of pharmaceutical industry's promotion of antibiotics to patients and healthcare professionals

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Research the drivers of antibiotic use in Europe, including the role of pharmaceutical promotion vis a vis patients and healthcare professionals

Communication materials on HAI's areas of work

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Press releases, media statements and blogs on all HAI areas of work. Total number (10)

Meeting reports on HAI's areas of work

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Provide technical expertise to policy-makers and other relevant stakeholders (e.g., CSOs) on all work areas through meetings (16)

Report on HAI's contribution to EMA's Patients and Consumers' Working Party

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

HAI participates at 3 meetings of the Patients' and Consumers' Working Party and provides an overview of HAI's active contribution in the PCWP activities in report (1)

Reponses to public consultations

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

HAI responds to 2 public consultations from EU institutions

HAI Europe Association Board meetings and AGM

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Materials for HAI Europe Association Board meetings (2); AGM (1)

Donor reports and funding applications

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 01/06/2018

Map potential donors; draft mid-term and annual reports (3); prepare and send funding applications (3)

Report on workshop about education of pharmaceutical promotion in the medical curricula

Stichting HAI

HAI_FY2017 (HAI_FY2017)

Published on: 23/05/2018

Develop materials for workshop and publish report summarising main outcomes of workshop (including recommendations on way forward)