A Year at the Heart of Regulatory Decision Making

by ANCEL.LA SANTOS, Senior Policy Advisor – Europe

It's that time of year when we reflect on our activities and achievements of the last 12 months. It's been a busy year across the organisation, and our European Projects have been no exception! Our Senior Policy Advisor, Ancel.la Santos, looks back at a year of hard work at the heart of regulatory decision making in the European Union (EU), just one of our areas of focus.

One of our main areas of work at the EU level is on pharmaceutical regulation, a cornerstone of ensuring safe and effective medicines for all. This year kicked-off with a legislative proposal by the European Commission on Health Technology Assessments that sought to strengthen cooperation and harmonisation on Health Technology Assessments among Member States. In HAI's view, Health Technology Assessments are crucial to incentivise pharmaceutical innovation with added therapeutic value, and to better inform pricing and reimbursement decisions. For this to happen, however, it is essential that applied methodologies are of the highest standards, and Health Technology Assessment systems are transparent and independent from industry influence. While we welcome efforts to strengthen cooperation on Health Technology Assessments (HTA) at EU level, the Commission's proposal raised some concerns on questions that are essential to HAI and its members. In June, we issued some recommendations about key principles that we think should shape the future system of collaboration, and over the year we put our position forward with Members of the European Parliament and Member State representatives. We were glad to see that the European Parliament adopted a position which improves the Commission's proposal in a number of ways. Now we call for the Council to move the process along in the interest of patients and healthcare systems.

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also essential. The voice of the patient, for example, is crucial to better understand the impact of disease and treatment expectations. At the same time, it is important to give the opportunity to other members of society to participate in HTA processes, like the discussions about the prioritisation of health technologies. After all, HTA is very much linked to the question about how to best distribute public resources. But for the engagement of patient and consumer groups to be optimal, it is important these processes are free of conflicts of interest and are transparent, so as to enhance public accountability. But it doesn't end there. Adequate methods should be in place so preferences and views of individual patients and consumers are captured in ways that a) take account of the scientific process and b) ensure they are representative of groups within the patient community, and society as whole. Any future collaboration on HTA at EU level should take these questions into account.

The current processes for patient and consumer engagement at EUnetHTA, and the HTA Network, have some way to go before they reach their potential. Engagement from Stakeholder Pool patient and consumer groups with the HTA Network should be more meaningful, and more formalised structures of engagement should be in place with EUnetHTA—it is important to enable a more regular and focused dialogue. Right now, it is not always clear to us which criteria and rules on conflicts of interest are applied when stakeholders are consulted in the various projects, although we welcome EUnetHTA's decision to set up task groups to address these questions. This year we had the opportunity to discuss the question of patient and consumer engagement at the EunetHTA Forum organised in May, where we were invited to participate in one of its panel sessions. We also contributed to the Consultation on 'Stakeholders Analysis', performed by EunetHTA's Work Package 2. Earlier in the year, we attended a very fruitful meeting organised by EUnetHTA with the patient and consumer group of the HTA Network Stakeholder Pool and the European Commission. The meeting offered an opportunity to convey some proposals from the group on prioritisation criteria for the selection of health technologies and principles for patient and consumer engagement—which were also presented at the HTA Network Meeting in February.

Our work at the European Medicines Agency (EMA) has also not slowed this year. HAI has been a long-standing member of the Patients' and Consumers' Working Party (PCWP). Membership at the PCWP gives us the opportunity to follow EMA initiatives more closely and bring the consumer voice to the table. All that was going on around Brexit meant that, this year, unfortunately, the number of PCWP meetings were reduced to two. However, we did have interesting discussions at the April and June meetings that we feel are important to engage in, such as on initiatives for electronic product information, the use of observational data(or EMA's concept of 'real world evidence'), clinical trial data transparency, medicines shortages, among other things. We also participated in discussions about patients' input in regulatory processes, commented on the communication of the notion of 'real world evidence/data' and participated in a survey to provide feedback on a patient's video about biosimilar medicines. In November, we participated at the EMA/Heads of Medicines Agencies workshop on medicines availability, where we spoke about ways to improve communication to the public on medicines shortages.

And, like last year, we helped spread the word about the importance of adverse drug reaction reporting by using our social media channels to amplify a campaign launched by medicines regulators.

We can look back, satisfied, at another year of intense engagement at the heart of regulatory decision making. There will be plenty to follow up on in the coming 12 months, not least with the challenges that Brexit may present. But it will also be an exciting year, with the EMA's move to Amsterdam. We look forward to seeing them there!