What do the next five years have in store for the European Medicines Agency?

Without resorting to cliché, it has been an unexpected and unprecedented year for the European Medicines Agency (EMA), as well as the rest of the world. At the beginning of 2020 it would have been fair to assume that moving into its new permanent home in Amsterdam was going to be the biggest upheaval for the EMA. Then came COVID-19 and the rush to get a grip on tens of potential treatments and vaccines, with potentially expedited marketing authorisation processes—all with many more eyes on the regulatory body than usual. But as with the rest of the world, COVID-19 is not the only thing going on for the EMA: amidst the crisis they have been developing their strategy for the next five years.

Earlier this month we submitted our response to the strategy, and overall, we were impressed with the agency's plans. Transparency, innovation and collaboration were the buzz words of the document and it was positive to see that these values are critical to how the EMA envisages itself progressing. However, with the position of the EMA more important than ever, we felt there were a handful of concerningly weak promises and missed opportunities that need to be remedied by the time the strategy comes into force.

Three key areas of concern

- **Lack of action on medicines shortages**

The strategy's nuanced understanding of the causes of medicines shortages is one of its strengths. It is deeply concerning, however, to see gathering evidence on shortages remains a priority goal for the EMA given that, as a member of the EMA's Patients and Consumers Working Party (PCWP), we know the agency has repeatedly sought—and been given—plentiful information over the last couples of years. While we applaud evidence-based decision making, we would encourage any further evidence gathering to be undertaken swiftly to allow for timely action on this critical issue. Similarly, we urge the EMA to not shirk responsibility when it comes to addressing the impacts of commercially driven shortages. It is positive that the strategy acknowledges that commercial reasons drive shortages, but the agency must address and sanction organisations causing such shortages; the industry's responsibility for shortages should not be downplayed.

- **Moving towards post-licensing evidence**

The strategy implies that a move towards post-licensing evidence is a foregone conclusion. This is concerning given our understanding of the difficulty in ensuring pharmaceutical companies and research bodies do in fact produce this evidence, and that marketing authorisation decisions based on post-licensing evidence do not undermine medicines safety and public confidence in the process. In some situations, for example for rare diseases,

large-scale, high-quality randomised control trials (RCTs), producing evidence of efficacy pre-authorisation is not feasible. However, we are concerned that the practice of using post-licensing evidence will be extended beyond rare diseases, to treatments for which RCTs are possible. Post-licensing evidence could then be used simply for commercial reasons, for example, to get a COVID-19 vaccine to market before a competitor.

The strategy must include further information on how the agency will ensure post-licensing evidence is gathered in a timely, reliable way, and any products that need to be, are successfully withdrawn. Safety should not be sacrificed for speed or reducing bureaucracy, and we urge the EMA to avoid gradually undermining the value of pre-authorisation clinical trials without sufficient scrutiny of the implications.

- **Revolutionising engagement with civil society stakeholders**

The section on engagement with patient groups and civil society left us disappointed in its lack of detail and ambition. We would very much like to see the EMA revolutionise its CSO engagement, moving towards a much earlier, more two-sided approach where stakeholders have more ownership over how we hold the EMA to account. We also have some concerns about how key groups, like the PCWP, are used as a pro forma engagement in place of more meaningful interaction. Additionally, conflict of interest policies are not effectively enforced for patient groups, meaning too often organisations funded or influenced by the pharmaceutical industry are taking away the space intended for patient representation. However the EMA chooses to move forward, we hope to see early, meaningful engagement with civil society stakeholders become a cornerstone of the agency in the future.

Three missed opportunities?

- **Opportunity to support C-TAP**

Again, it is positive to see information (data and best practice) sharing and global collaboration front and centre in the strategy, and more positive still to see the strategy emphasise the role of collaboration in tackling the COVID-19 crisis. However, the EMA is missing a key opportunity to explicitly support the coordinated international response to COVID-19, such as the World Health Organization’s COVID-19 Technology Access Pool (C-TAP). We hope the stance of the strategy more generally will have positive implications for EU participation in global efforts nonetheless, but it is disappointing, if unsurprising, that the EMA is not taking a braver position.

- **Antimicrobial resistance and pharmaceutical incentives**

The strategy outlines the causes of antimicrobial resistance (AMR) and is strong on the need for new antibiotics, which we support. However, we are concerned that the material content of the strategy remains aspirational rather than practical or realistic. The strategy should take the opportunity to clearly outline the importance of rational use of existing antibiotics, alongside pushing for the creation of new antibiotics. HAI believes the main challenge to overcoming AMR remains the lack of interest in the pharmaceutical industry in developing

new and effective antibiotics due to poor market returns—without a comprehensive look at alternative innovation mechanisms and public-private collaboration, this will not change. The EMA will need to be much bolder if it is to tackle this existential issue.

- **Health Technology Assessment**

The strategy also indicates the value that the EMA places on the proposed joint Health Technology Assessment (HTA) regulation as a tool for increasing affordability and accessibility, which we welcome. That said, we would like to see a more direct and vocal commitment to support HTA. Lack of progress on the HTA dossier remains a challenge to improving and streamlining the regulatory process, and the strategy's stance at the moment is not strong enough to move the dossier out of deadlock at the European Council and up the political agenda across the continent.

We look forward to seeing how the EMA refines its strategy following this period of consultation: we hope that it can build on the positives—transparency, collaboration and innovation–and ameliorate its weaknesses, taking the brave stances that are needed during this crisis and beyond.