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Executive Director

Speech EMA Emer Cooke BECA Hearing

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Dear Chair (Dr Arłukowicz), members of the Special Committee on Beating Cancer,

Thank you very much for giving EMA the opportunity to inform you about our activities and views on opportunities to support research and innovation, as well as access for cancer medicines.

The European Medicines Agency has primary responsibility for the scientific evaluation and supervision of medicines. In particular, in the cancer area, all new active substances that are developed for cancer need to be reviewed by EMA via the Centralised Marketing Authorisation procedure. More than 160 new cancer medicines have been approved following assessment by EMA in 26 years of activity.

With this introduction, I would like to outline some of the challenges and possible solutions that we see from our perspective with regard to clinical trials, collaboration with downstream decision-makers and support to innovation for cancer medicines.

First of all, what we see is the need to design clinical trials that address the right questions about meeting the unmet medical need still experienced by the majority of cancer patients. Only with optimally designed trials can we support the innovation and breakthroughs that can address cancer patients' needs, and that will also meet the evidence needs of both regulatory authorities and downstream decision makers.

It is essential that we focus on trials that are fit for purpose from a patient perspective, ensuring that patient views are systematically considered throughout the development process.

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Clinical research in cancer is challenging and especially so for the many rare and paediatric cancers. There is therefore an opportunity here for the EU to optimise the research effort by ensuring access to clinical trials and facilitating participation in trials when considered the best option.

For this, we need to leverage the resources for conducting high quality clinical research in Europe. Also, rare cancers will benefit from facilitating access to clinical trials that would otherwise take prohibitively long time to conduct.

We fully acknowledge patients' expectation to have the option to access clinical trials locally. Currently, we see that the majority of trials are conducted in less than a handful of EU Member States and often in only a few centres. Thus, there is an opportunity to bring trials closer to EU patients by promoting and enlarging the development of competences and trial readiness across Europe.

Planning of such clinical research needs to be refocused on designing quality into clinical trials, which includes applying risk-proportionate approaches and systematically involving patients and a wide range of stakeholders in trial design. We and other regulators are progressing this through the "renovation of the fundamental Good Clinical Practice guidelines" for clinical trials in the context of the International Council for Harmonisation.

Furthermore, we need to encourage and support collaborative clinical trials leveraging collaboration between academia and network scientists to address rapidly emerging regulatory science research questions as well as treatment optimisation.

Indeed, clinical development does not stop with approval or reimbursement. We like to think of evidence generation as a continuum to refine the understanding of what is the optimal use of new cancer medicines in clinical practice. The EU should support clinical research into cancer treatment optimisation, with respect to all important clinical outcomes, real-world effectiveness and safety, and to identify the population that is most likely to benefit. The continuation of generating data is necessary to inform the optimal use of medicine and the choices of doctors and patients.

Here, besides leveraging collaboration with academia, I also see a tremendous opportunity for the EU to develop a "learning health care system" that can maximise data generation in the real-world by federating data from different sources, like electronic health records and cancer registries. As regulators, we can help this effort by describing uncertainties and help design the research questions that need to be addressed. Ultimately though, the challenge is in creating and supporting the right

infrastructure across Europe for systematically collecting, federating, and sharing of key data from different sources. EMA is collaborating with the European Commission to help address these needs in the creation of a European Health Data Space over the next years, contributing in particular through EMA's DARWIN initiative. And we are also reaching out to down-stream decision makers to ensure best utilisation of this wealth of information.

Second, with regard to cooperation with other decision-makers for access, there is a need to maximise transparency of decisions and sharing of information. Building on EMA's work on a structured way to communicate benefit-risk assessment and on EMA's longstanding experience in involving patients in the Agency's work, we need to continue to modernise methodologies to include patient views in the benefit-risk assessment and how we communicate benefit-risk decisions to patients and doctors.

Furthermore, efficient communication is needed to decrease the time lag and differences between authorisation decisions by regulators and access decisions by health technology assessments across Europe, starting already during the phase of clinical research. Multi-stakeholder discussions on development plans is a key component to foster generation of evidence that is needed for different decision making. The recently published European Medicines Authorities Network strategy to 2025 has dedicated a specific chapter on access and availability outlining these perspectives and we have incorporated them in the annual work plans of our scientific committees.

Since 2010, the EMA and EUnetHTA, the European network for Health Technology Assessment, have collaborated to improve the efficiency of the processes and mutual understanding of evidence needs, pursuing the goal of "one evidence generation plan for different decision makers".

The HTA regulation, which was presented by the Commission in 2018 and discussed in this house in 2019, will be instrumental to strengthen the legal basis and procedural rules for EMA to continue its long-standing cooperation with HTA bodies and in that way, help reduce delays and disparities in access to medicines.

To conclude, I would like to stress that, although pricing and reimbursement decisions remain fully within the competence of the Member States, there are many opportunities - as I have highlighted so far - for the EMA, Member States and developers to cooperate more at the EU level in order to increase access to cancer medicines.

EMA is fully committed to delivering on the ambition of creating an enabling environment for the development, evaluation and access to new and repurposed cancer medicines in the EU and we stand ready to support the implementation of the European Beating Cancer Plan that is expected be launched next week.

I look forward to discussing this further with you and the committee members and answer any questions you may have.

Thank you all very much for your attention.