Marijke Eyssen – Interim Director General, Belgian Health Care Knowledge Centre (KCE)

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Marijke Eyssen of the Belgian Health Care Knowledge Centre (KCE) introduces the institution's mission, core values, how it chooses areas of research, and the crucial work the KCE does in non-industry clinical trials.

Could you begin by introducing your background and how you came to head up the KCE?

I am a medical doctor by training, specialized in paediatrics. After several years of clinical practice and research at the university hospitals of Leuven, I became a researcher at KCE in 2005. I was appointed interim deputy director general in January 2018 and I took up my current position as interim director general in January 2020.

Could you give an overview of the KCE's missions, given it seems to have a very large scope?

KCE is an independent federal research centre providing scientific advice on topics related to healthcare and health insurance. Our main mission is to advise policymakers and administrative bodies here in Belgium on the basis of scientific and objective research. Through our research, we aim to highlight the best possible solutions to provide accessible and high-quality healthcare,

taking into account the growing demands on the healthcare system and budgetary constraints. It is important to note that we are not involved in the decision-making process itself.

What are the KCE's core values?

Independence is an important value for KCE. This implies that we aim to formulate advice based on scientific evidence, even when this goes against the interests of one or more stakeholder groups. We are subsidised by the federal authorities, but our specific status guarantees us also scientific independence from them. High scientific quality is also really important to us, as well as transparency in our reporting. This way, we aim to contribute to sustainable, accessible and patient-centric healthcare in which high quality of patient care is guaranteed.

What does transparency mean for the KCE?

Firstly, we are transparent about the methods we use in all of our reports. We try to document those methods as accurately as possible, including how results are gathered and conclusions are drawn. We also document the limitations of the results, why we chose certain methods and not others. Further, in all our reports we mention conflicts of interest declared by the authors, scientific experts and stakeholders.

How does the KCE choose its areas of research?

The area of research for the reports that are published on our website is very broad and is based on a yearly open call for topics. This call is open to anybody who wants to introduce a topic, from public health authorities to universities, professional associations, and patients. We then have a strict procedure for topic selection with several steps so that the most relevant topics which best serve our mission and will have the best impact on healthcare, in general, are selected.

We do not conduct the same kind of research as the pharmaceutical industry. The pharma industry is trying to show the efficacy and safety of newly developed chemicals through trials on patients. However, we look at all potentially relevant questions to healthcare in general such as personalised medicine, for instance.

Since a few years, KCE is also involved in conducting non-commercial comparative effectiveness trials. There is a specific and strict selection procedure in place for these trials.

How is the KCE's research evolving to match the innovative new treatment paradigms being put forward today?

We have experience in health technology assessment (HTA) where we study the relationship between the costs of a specific intervention in relation to its added value. In that sense, we are prepared to take on questions related to high-cost drugs for instance. We are prepared to study the added value of these kinds of drugs and compare them to the costs they have for society. We are not, however, the national decision-making body for drug reimbursement.

How is the fact that some of the KCE's projects originate from patients and patient groups reflected in your work?

Topics introduced by patients get a lot of attention during our topic selection process and have done for a long period of time. Patients are in a unique position to contribute an essential perspective to health policy research as they know what it means to live with the condition. They can inform us on important aspects overlooked by research institutes, health care professionals or policymakers.

One example is our ongoing research on post-intensive care syndrome (PICS). A patient introduced this topic to KCE, and we are now currently conducting research on how to prevent PICS. In the report, we will provide specific measures that should be taken in order to prevent this syndrome occurring.

How does the KCE's criteria for conducting clinical trials differ from that of the industry?

We do not conduct early phase or development clinical research, but there are many other questions in healthcare that are not sufficiently studied in industry-sponsored clinical trials. These questions are very important to patient care and also to more efficient use of public resources. For this reason, in the autumn of 2015, the Belgian Minister of Public Health mandated KCE to provide funding and coordination for large non-commercial pragmatic trials on the comparative

effectiveness of already-existing treatment options. These treatment options may already be in use in the healthcare system but have never been adequately compared directly. It is important that these treatment options are studied in real-life situations. The trials are not limited to drugs or medical devices but can include a broad range of interventions, e.g. diet, psychotherapy, lifestyle interventions, and diagnostic tests.

These trials should have a clear impact on patient health and quality of life, and it should be clear at the start of the trial that they should also have a potential return on investment. We aim to help improve patient care but also eventually to contribute to more efficient use of healthcare resources and budget.

Besides greater uptake of real-world evidence, what other game-changers do you see having a significant impact on the KCE's work?

KCE is contributing a lot in terms of patient involvement in research. For instance, we participate in international networks such as the European Network for Health Technology Assessment (EUnetHTA) and Health Technology Assessment International (HTAi). Through these networks, we participate in large working groups on patient involvement. We work on issues such as how to include patient preferences throughout the development of new medical products, starting from the decision to start with a specific medical product throughout the whole life cycle until it is on the market and even the post-marketing process.

We have also been involved in the National Institute for Health and Disability Insurance (NIDHI)'s program on unmet needs in which specific innovative drugs can get reimbursement from the NIDHI even before they are registered. The aim is to provide faster access to innovative drugs targeting severe or deadly disorders, for which no other treatment option is available. The KCE developed a specific methodology to prioritize those unmet needs and define which needs should get priority in terms of reimbursement by the NIDHI.

Finally, we have also developed a specific procedure on involving patients throughout our own research projects.

Do you have any final comments?

KCE was also involved in the development of the International Horizon Scanning Initiative (IHSI), an initiative to find which new technologies, drugs, and scientific breakthroughs will soon enter the healthcare system. This was initiated by the Beneluxa Initiative on Pharmaceutical Policy, an international collaboration between Belgium, the Netherlands, Luxembourg, Austria and recently Ireland on several areas of HTA-related topics. The purpose is to improve the HTA process by sharing insights internationally and to provide sustainable access to innovative drugs. This also includes making sure that industry is well aware in advance which specific parameters might be required in the process of introducing new products to the market.

Finally, KCE is currently examining a number of recent reimbursement files submitted to NIHDI for innovative medicines and medical devices and looking at the evidence made available by the manufacturer. The strengths and weaknesses of this evidence will be analysed, e.g. regarding effectiveness/cost-effectiveness. Based on this analysis, solutions will be explored, together with the various stakeholders, to complete the lacking evidence and to avoid these evidence gaps in the future.

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