Summary of the advice The Values of Valuable Healthcare Technology - An exploratory advice on the opportunities and risks of artificial intelligence in healthcare

Artificial intelligence, AI, is making its entrance into healthcare. Although this generally occurs outside the regular healthcare system, AI does affect it and will mix with it and ultimately radically change the system.

The Council is of the opinion that AI has much to offer in terms of care. It can increase the quality, accessibility and diversity as well as the affordability and solidarity of care. Nevertheless, there are also risks. AI is not free of value judgement and could undermine these public interests. If the government leaves these developments entirely free from regulation, we run the risk of becoming dependent on dominant private parties.

Taking timely measures is, therefore, important to guide developments in the right direction. This is no easy task. This exploration maps the possible effects of AI in healthcare. The picture is far from complete, however. Whether the identified effects will occur and when, cannot be established in advance.
The Council, therefore, proposes a two-track approach: a track for the long(er) term and a track to start tomorrow.

The first track consists of three parts:

1. *A programmatic approach*, which follows developments closely and brings together experiences. On this basis, the effects on public interests must be regularly examined, as well as what measures are needed to be able to continue to safeguard these interests.
2. *Generating and sharing knowledge, informing citizens*. The government must stimulate substantive knowledge, debate and opinion formation about the role of AI in healthcare and the changes this entails for patients and citizens, employees in the sector, developers, financiers and so on.
3. *Educate*. In the various healthcare study programmes, specific attention to AI is required, both for learning to understand algorithms and for the interaction between people and technology. Healthcare providers and patients of the future should be able to deal with AI. Their role will change, with respect to skills as well as the place that they occupy in the system in which they will work together with technology.

The second track comprises four parts:

1. *Setting quality requirements*. The CE marking for admission to the (European) market for AI applications is inadequate. The government should set further quality requirements for admission to the (Dutch) market. To this end, the government should draw up a set of principles, which can be derived from the so-called Asilomar AI principles 1, with which new AI applications in healthcare must comply. It is important to work together to this end and, where necessary, take initiatives at European level where work is also under way to develop starting points and principles for AI.

2. *Enforce quality requirements.* Providers of AI technology operate largely (initially) outside the collective system. This means that they do not need to apply for admission under the Care Institutions Accreditations Act (WTZi). In that case, they do not have to comply with the resulting rules that aim to guarantee the quality, accessibility and affordability of care.
The government should use a different legal instrument, namely 'Service of general (economic) interest'. This allows the government to set conditions for the quality and reliability of services and the provision of services, the manner in which the agreement is concluded, securities regarding delivery and repair, and pricing (affordable price).

3. *Ensure data continuity.* Companies can go bankrupt. If that happens, patients must have continued access to their data. A mandatory (free) option for patients to download their data in health care systems – possibly combined with a government-imposed 'health data escrow' or recognition for companies that have such an escrow arrangement that allows patients to see that they can always get their data back – can guarantee this and guarantee the continuity of care.

4. *Realise traceability for citizens.* Citizens must be able to see where their medical data is stored and with whom this data is shared: a 'reference index' must be made available to citizens.