# **Executive summary**

Health Council of the Netherlands. Population Screening Act: mammography in two directions as standard. The Hague: Health Council of the Netherlands, 2013; publication no. 2013/07.

The Netherlands holds five screening organisations charged with population screening for breast cancer. They are requesting permission to make two rather than one images per breast in different directions as standard, from now on, during the biannual follow-up screening. In the context of the Dutch Population Screening Act (WBO), such a change in policy requires a licence from the Minister for Public Health, Welfare and Sport. On 7 January 2013, the Minister requested the Health Council of the Netherlands to provide advice about the licence application. To this end, the Council's Committee on Population Screening assessed the proposed modification to the screening against the requirements the WBO imposes on population screening subject to licence, namely scientific validity, compliance with legal regulations and standards for medical conduct, and a favourable balance between benefits and risks for the people to be screened.

## The proposed screening policy

As screening method, the population screening for breast cancer in the Netherlands uses mammography: the making of X-rays of the breasts. In the initial screening it is standard to make two images per breast: one from the middle to the side of the breast (in the medio-lateral oblique (MLO) direction) and one from top to bottom (in the cranio-caudal (CC) direction). Up till now during the biannual follow-up screening one (MLO) image per breast is standard.

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Additional (CC) images are only made based on medical indication. The licence applicants' request, is to make two images as standard during the follow-up screening.

#### Scientific validity

The Committee has made a positive judgement on the scientific validity of mammography in two directions. Based on the literature, the Committee considers that it is plausible that the discriminating power of the screening is greater if additional images are taken as standard during follow-up screening rather than on indication. The expected modest improvement in test performance is expressed in a reduced risk of missed tumours during the screening, and in a reduced risk of, in retrospect, unnecessary referrals for further diagnosis.

#### Compliance with legal regulations for medical procedures

The information provisions to the potential participants about the modification of the screening, and about its advantages and disadvantages, comply with the requirements.

#### Benefit and risk

A disadvantage for the participants is, that additional images means four compressions of the breasts instead of two. Many women perceive the forceful compressions of the breast as unpleasant or downright painful. The most important risk is the extra radiation exposure. This risk is, however, limited, and less than the added health gain from the better test performance of additional images as standard. The increased sensitivity reduces the risk of unobserved tumours. Additional images as standard also reduce the risk of retrospectively unnecessary referrals to a breast clinic for further diagnosis. In addition, the anxiety some women experience from the interim decision, by the technician, to make an additional image will disappear. The Committee judges favourable about the relationship between the benefit and the risks and other disadvantages to the participants.

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### **Conclusion and recommendations**

The judgement of the Committee is, that the application is in compliance with the statutory criteria of population screening. The Committee recommends the Minister of Health, Welfare and Sport to grant the requested licence.

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