Executive summary

Health Council of the Netherlands. Population Screening Act: study of faecal tests within the population based screening programme for colorectal cancer. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/09

In this advisory report the Health Council of the Netherlands' Committee on Population Screening assesses a license application of the Erasmus MC in Rotterdam and the Academic Medical Centre in Amsterdam for a study within the regular population based screening programme for colorectal cancer. The study aims to study if the faecal test FOB-Gold is not inferior to the faecal test OC-Sensor and is therefore safe to use in the national population based screening programme for colorectal cancer in the Netherlands.

The study in the application is divided into two study parts. The first part concerns the clinical validity of the FOB-Gold. The committee advices the minister to grant a license for this study part under some conditions. The cut-off point of the national population based screening programme must be used in this study as well, so that the balance between benefits and harms for the study participants is in agreement with the balance between benefits and harms for participation in the regular population based screening programme. According to the committee the non-inferiority margin and the estimated percentage of discordance for the estimate of the relative sensitivity need to be adapted. If the relative sensitivity of the FOB-Gold indeed proves not to be inferior, within the set margin, to the OC-Sensor, then the specificity must be assessed as well. The specificity must not be lower than the lower level of the 95%-confidence interval of the specificity of the OC-Sensor. Under those conditions the study is

scientifically sound. Also the estimated total number of 20,000 participants for the study sample as calculated by the license applicant, corresponds well with the number as it was calculated by the committee. The balance between benefits and harms for the participants is acceptable (under the recommended condition about the cut-off point). To meet the legal requirements for medical conduct, the information, the informed consent and the complaints procedures should be, as much as possible, in agreement with the population based screening for colorectal cancer. It is important, however, that individuals who are invited for the study are clearly informed about the differences between participation in the scientific study and participation in the regular national population based screening programme.

The second study part concerns the question if participation in population based screening for colorectal cancer with the FOB-Gold is at least as high as participation with the OC-Sensor. According to the committee this research has no scientific significance, because it is not plausible that relevant differences in participation between these two tests will exist. Moreover the results of this study can well be biased without reliable methods to correct for these forms of bias. In that case the study results will not contribute information to the choice between the two tests for the screening programme. Therefore the committee advises not to grant a license for the second study part.