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COMMISSION STAFF WORKING DOCUMENT

STAKEHOLDER CONSULTATION - SYNOPSIS REPORT

Accompanying the document

Proposal for a Council Recommendation

on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC

{COM(2022) 474 final}

1. Introduction

This report presents the outcomes of a number of consultations, which were conducted to support the development of a Commission proposal on cancer screening, including namely:

(1) The Scientific Opinion on Cancer Screening in the European Union[1], developed by the Group of Chief Scientific Advisors (GCSA), which builds upon the Evidence Review Report (ERR, SAPEA 2022), additional literature, and expert and stakeholder consultation.

(2) Feedback received from 87 contributors in response to a Call for Evidence on the 'Have your say' platform from 25 January until 22 February 2022[2], by which the Commission invited stakeholders to share their experiences, expectations, evidence and other relevant input to prepare the Council Recommendation. The responders included 40 non-governmental organisations, 20 company and business organisations/associations, 18 citizen/consumer organisations and individual citizens/consumers, 6 public authorities, and 3 academic and research institutions. Contributions were received from 16 EU Member States, and three other countries (Switzerland, United Kingdom, United States).

(3) Inputs from EU/EEA Member States' representatives of health and research ministries participating in the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) Sub-group on Cancer in four meetings organised in the period March-May 2022.

(4) Inputs from stakeholders provided in a public webinar, titled "Cancer Screening – Update of Council recommendation on cancer screening", organised by the Commission on 28 March 2022 with 81 participants), and inputs of 2069 stakeholders who responded to a public online consultation on the Europe's Beating Cancer Plan (February-May 2020). The responders represented all Member States; two thirds were individual stakeholders and one third were representatives of stakeholder organisations, including research (35%), patient associations (25%) and care professional associations (10%).

Results of the consultations are clustered along three questions, which also guided the development of the Scientific Opinion of the GCSA:

(1) How can screening programmes targeting breast, cervical and colorectal cancers be improved throughout the EU?

(2) What is the scientific basis for extending screening to other cancers, e.g. lung, prostate and gastric cancers, and for ensuring their feasibility throughout the EU?

(3) What are the main scientific elements to consider, and best practices to promote, for optimising risk-based cancer screening and early diagnosis throughout the EU?

2. Improving breast, cervical and colorectal cancer screening programmes

2.1 Scientific Opinion

The GCSA Scientific Opinion recommends that the existing screening programmes for breast, cervical and colorectal cancer integrate up-to-date scientific knowledge, are coordinated

[1] European Commission, Directorate-General for Research and Innovation, Group of Chief Scientific Advisors, *Scientific opinion on cancer screening in the European Union*, 2022, https://data.europa.eu/doi/10.2777/14480

[2] Call for Evidence for an initiative Ares(2022) 583417-25/01/2022, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13155-Cancer-Screening-Recommendation-update_en

across the whole cancer pathway, and center around citizens. The report includes the following specific recommendations:

- Improve the participation of citizens in cancer screening programmes by making access easy (e.g. through self-sampling or home-based testing), by offering decision support aids and through shared decision-making between citizens and clinicians.
- Ensure that best practices and quality standards are developed and applied in screening, along with staff training and continuous monitoring and evaluation for quality assurance.
- Extend breast cancer screening for women below the age of 50 with mammography or digital breast tomosynthesis, and for women with dense breasts with magnetic resonance imaging (MRI).
- For cervical cancer, prioritise screening by testing for human papilloma virus (HPV) and support its eradication through the uptake of vaccination against HPV below 15 years of age.
- For colorectal cancer, use fecal immunochemical testing (FIT) as the preferred triage test for referring individuals for follow-up colonoscopy.

2.2 Response on Call for evidence

Almost two thirds of the responses were suggestions to improve the current screening programmes; these were both overarching suggestions or specific for certain types of cancer screening.

Overarching suggestions:

Improve participation

- Improve (digital) communication and awareness campaigns.
- Improve equity within screening programmes.
- Address barriers to cancer screening faced by people with disabilities.
- Pay attention to the realities of trans, non-binary and intersex citizens in access to screening, treatment, and prevention appropriate to their bodies.
- Improve cancer health literacy and awareness through national campaigns.
- Enhance shared decision making.
- Work together with patient organisations.

Improve coordination

- Establish a coordinated action or network of agencies across Member States to prioritise access and allocate adequate funds to cancer screening in their national cancer plans.
- Create a European policy agenda on early detection and diagnosis of all cancers.
- Establish a comprehensive EU-wide monitoring framework, linked to the Cancer Inequalities Registry, to support assessment against predetermined performance indicators.
- Consider differences in implementation when comparing national screening programmes, such as conscious deviation from EU guidelines as to targeted patient populations, scope and methodology, as well as their results.

Improve quality

- Set a minimum standard and promote harmonised screening programmes across the EU, in line with European guidelines with quality assurance, where available.
- Invest in staff, technologies, and diagnostic capacity.
- Train more healthcare professionals, and ensure that healthcare professionals are incentivised to meet quality standards.
- Establish at least one national cancer registry per Member State.
- Support pilot projects that generate evidence.
- Develop, validate and evaluate new screening programmes.
- Monitor adherence and effectiveness of screening programmes at EU level.

Specific suggestions:

- Breast cancer: promote targeted screening; inform women about their breast tissue density; promote earlier access than 45 years; use alternative screening tests (ultrasound, MRI, CEM, DBT).
- Cervical cancer: implement a more common training programme and certification; use alternative screening tests (self-testing, mRNA-based HPV testing, liquid-based cytology).
- Colorectal cancer: better align diagnosis, treatment, and aftercare; build an electronic platform for reporting, acquisition and storage of images and films; build capacity to manage colonoscopies and colorectal cancer surgeries; use alternative screening tests (blood-based screening tests, adenoma detection rate, FIT test).

The suggestions listed were mostly made by company and business organisations when it comes to specific tests, and also by NGOs when it comes to other screening aspects.

2.3 Feedback from EU/EEA Member States' representatives

Overarching suggestions:

- Take a stepwise approach: 1. fully implement the 2003 Council Recommendation (for Member States that have not done this yet); 2. improve the quality and implementation of current cancer screening programmes; 3. expand to other types of cancer screening.
- Build capacity: The EU could support Member States in setting up screening infrastructures and programmes, while taking into account the resources needed to increase and improve cancer screening as well as the implications for the health workforce capacity throughout the entire care pathway, and investing in skill development of healthcare professionals.
- Take a systemwide approach, i.e. link screening with primary prevention; offer screening in close relation with primary care, and ensure continuity of care after a positive screening result.
- Address barriers related to the health system to improve equity and facilitate the exchange of expertise and good practices across Member States and consider twinning programmes.
- Optimise and use validated screening procedures and available tools.
- Pay more attention to risk-based screening protocols and applying other age ranges in case of familial cancers.
- Increase screening participation rates by engaging citizens in designing and implementing information campaigns.
- Improve informed decision-making on participation by paying more attention to citizens' health literacy.

- Collect and exchange quality data for monitoring and evaluation. This would include the development of quality assurance guidelines and a common set of quality indicators/KPIs (including targets), and using digital tools to facilitate data sharing.

Specific suggestions and comments:

- Breast cancer: consider a longer interval between screenings (for the sake of feasibility of population-wide screening); consider an earlier start-age for familial cases; provide more clarity on the definition of 'particularly dense' breasts; consider the implications for the capacity needed for MRI screening; and take into account the chance of allergic reactions to intravenous contrast agents in case of considering MRI.
- Cervical cancer: a discrepancy was noted between the evidence and the proposed draft of the Council Recommendation in the start-age for HPV screening and personalising the screening according to vaccination status. Furthermore, the proposed start-age, stop-age and screening interval are the most intensive ones suggested by European guidelines; this may hamper de-intensification of screening for vaccinated women and in low-risk women (e.g. older women with previous negative HPV tests).
- Colorectal cancer: consider qualitative and quantitative protocols as triage methods; specify the use and evaluation of the FIT test; clarify the role of colonoscopy in the screening process; tackle alignment problems between primary and secondary care in relation to colonoscopies; and consider the option of an endoscopic approach. It was also suggested that Member States conduct systematic evidence-based decision analyses, taking into account the benefit-harm balance, cost-effectiveness and other relevant factors, to finetune their screening approach.

2.4. Feedback from stakeholder groups

The public consultation on the Europe's Beating Cancer Plan resulted in 419 responders (out of 2069) who prioritised improving the participation in breast, cervical and colorectal cancer screening above other actions in the area of screening. The following factors were most frequently mentioned by responders to influence their decision to take part in a cancer screening programme: safety and quality of equipment (31%), information about the usefulness of screening and early diagnosis (21%), expertise and skills of healthcare workers (17%), and costs (12%).

In the more recent stakeholder meeting on cancer screening, stakeholders made some specific suggestions:

- Address the main issues facing LGBTI people in the context of cancer: 1. focus on the body parts that people have, not on the sex marked in their identity documents; and 2. address discrimination.
- Include HPV vaccination for both girls and boys under 15 years of age.

3. Scientific basis for and feasibility of extending screening to other cancers

3.1 Scientific Opinion

The Scientific Opinion recommends to extend population screening to cancers for which scientific evidence demonstrates a good harm-benefit ratio, cost-efficiency, advantages of early detection, and feasibility throughout the EU, while regularly reviewing the scientific

evidence for screening of other cancers. The report includes the following specific recommendations:

- Extend population screening to lung cancer using low dose computed tomography for current and ex-smokers.
- Extend population screening to prostate cancer by Prostate Specific Antigen (PSA)-based screening with additional MRI scanning as follow-up test.
- For gastric cancer, population based screen-and-treat programmes for Helicobacter pylori are only recommended in regions with intermediate to high gastric cancer incidence.
- There is currently no scientific ground for population based endoscopic screening for esophageal cancer, and ultrasound and CA125 screening for ovarian cancer.

3.2 Responses on Call for Evidence

The majority of responders expressed their support to extend screening to other cancers. There were some calls for caution from four NGO's and one academic or research institution, asking to carefully consider cost-effectiveness and the not (yet) established risk-benefit ratio of new screening programme(s) for citizens/patients, also considering unintended harms. One NGO specifically referred to prostate and lung cancer as examples where the risk-benefit ratio was not yet established. Apart from these few cautious reflections, no respondents clearly opposed expansion of cancer screening to specific forms of cancer.

A third of the contributions provided scientific support for extending cancer screening:

- The majority referred to or provided evidence for extending to lung or prostate cancer screening. The positive results of several studies with low dose CT (LDCT) scans as a screening test for lung cancer were mentioned 15 times.
- Targeted screening and risk-based approaches were mentioned as approaches for prostate cancer screening, but also new cancer screening tests such as MRI, biomarking test and PSA home-testing.
- Evidence for extending cancer screening to liver cancer, oral cavity cancer and skin cancer was also provided.

Almost all recommendations were mentioned by company and business organisations and NGO's, except the recommendations regarding skin cancer which were also from academic or research institutions.

3.3 Feedback from EU Member States' representatives

Overarching suggestions:

- Take account of feasibility and cost-effectiveness, in addition to scientific evidence on efficacy, when deciding on new screening programmes. Consider the criteria developed by Wilson & Jungner[3] and recent criteria emerging from this work to decide on new screening programmes.
- Take account of the substantial false-positive rates, and how these could be reduced, in deciding on screening and the approach.
- Approach the implementation of new screening programmes stepwise: include a planning phase; develop EU screening guidelines (and include quality assurance); develop the programme(s); conduct national pilots to identify the optimal strategy, selection criteria and screening intervals; conduct health services research alongside the implementation phase. Clarify the timelines needed for such a stepwise approach.
- Pay more attention to risk-based variants of screening.

[3] Wilson, James Maxwell Glover, Jungner, Gunnar & World Health Organization. (1968). Principles and practice of screening for disease / J. M. G. Wilson, G. Jungner. World Health Organization. https://apps.who.int/iris/handle/10665/37650

- Monitor the benefits and harms, and specify which data are needed.

Specific suggestions and comments:

Lung cancer screening:

- Take account of the health economic perspective in considering the frequency of screening.
- Link screening with smoking cessation support (irrespective of screening result), when screening smokers; and with health education in schools, training institutes, universities.
- Reconsider to be specific on the age range (not backed up with evidence).

Prostate cancer screening:

- Take an earlier start-age in familial cases.
- Discrepancy noted between evidence and recommendations of the GCSA in using the word 'extend' in the screening protocols for risk-adapted screening strategy (in the recommendation to have a baseline PSA at the age of 40-45).
- Define a follow-up pathway for each result of the PSA test.
- Evidence is not conclusive that PSA screening reduces mortality.

3.4. Feedback from stakeholder groups

The public consultation on the Europe's Beating Cancer Plan in 2020 showed broad support (84% of the 2069 responders) for extending cancer screening to other types of cancer, where screening can be effective. Priorities for extending to other cancer types varied: ovarian cancer (mentioned by 28%), prostate cancer (22%), lung cancer (8%), gastric cancer (4%), other types of cancer (37%) and not specified (1%).

In the more recent stakeholder meeting on cancer screening, stakeholders made a specific suggestion on *prostate cancer screening:*

- PSA is reliable as initial test when properly used with risk calculators/ stratification and the use of mpMRI.

4. Scientific elements of risk-based cancer screening and early diagnosis

4.1 Scientific Opinion

The Scientific Opinion recommends to take advantage of the rapidly developing technological possibilities and scientific knowledge to optimise risk-based cancer screening and early diagnosis throughout the EU. Specific recommendation are to:

- Develop a system of "living guidelines" that can be rapidly modified and updated in response to new scientific findings.
- Further develop and implement risk-stratified screening to improve the harm-benefit ratio of screening programmes.
- Ensure preparedness for the introduction of new screening methods, for less invasive and blood-based screening where large-scale clinical trials are expected to yield results for multiple cancer screenings in the coming years.
- Support the establishment of biobanks appropriate for biomarker-based cancer screening research.
- Support the harmonisation of protocols and quality assurance within and between countries.

4.2 Responses to Call for Evidence

A quarter of the responders made recommendations for new screening technologies or approaches:

- *Digital innovation*
  - New imaging in breast cancer (ultrasound, MRI, molecular breast imaging, contrast-enhanced mammography);
  - New non-invasive methods and technologies for prostate cancer screening, also using AI-based computational medicine and network analysis;
  - Exploitation of technical innovations (integrated diagnostics) for prostate cancer screening.
- *Innovative technologies*
  - (High performing) multi-cancer screening test or early detection test;
  - Liquid biopsies (minimally invasive blood/urine tests to detect cancer cells);
  - Genomic testing/Predictive genetic testing (biomarkers).
- *Innovation in the screening programme design*
  - Risk stratification/risk-based screening/targeted or personalised screening in general, and specifically for breast and prostate cancer.
  - Social innovation in programme design, i.e. considering possible behavioural determinants for cancer screening.

Almost all input was from public authorities, company and business organisations and NGO's. Also here some calls for caution were made, among others pointing to the importance of avoiding overdiagnosis and of focusing on high-performing tests only, also to avoid reductions in participation rates over time.

4.3 Feedback from EU Member States' representatives

The recommendation to develop a system of "living guidelines" was supported. It was emphasised that countries should take into account the feasibility, organisational impact and acceptability of such a system. It was also suggested to set up a systematic monitor to assess the quality and impact of (new) cancer screening programmes, and link this with existing cancer monitoring systems, such as cancer registries.

4.4 Feedback from stakeholder groups

Respondents to the public consultation on the Europe's Beating Cancer Plan in 2020 reported that the following elements were areas where screening could be improved: by standard setting, risk categorisation, quality assurance, encouragement of best practices, targeted interventions, monitoring, and research.

5. Discussion

5.1 Improving breast, cervical and colorectal cancer screening programmes

Many recommendations of the GCSA and suggestions from public contributors to the Call for Evidence and Member States' representatives are about improving the participation of citizens in cancer screening programmes. Consensus exist that this could be achieved by better informing citizens (e.g. improving awareness campaigns, improving (digital) communication about risks and benefits, implementing decision tools), but also by facilitating access to screening by implementing self- and home-testing, and alternative testing such as MRI and fecal immunochemical test (FIT).

The GCSA, public contributors and EU Member States' representatives are also unanimous in their recommendation to put more effort in quality improvement and assurance, for example by developing and implementing a minimum set of standards and promoting harmonised screening programmes throughout the EU, in line with European guidelines with quality assurance, where available. and by continuously educating healthcare professionals and training staff operating on equipment. All sources also emphasise the importance of building more screening capacity and training healthcare professionals, including those who are not directly involved in screening, to ensure continuity of care through the cancer pathway.

Coordination of screening programmes at national level or EU level was recommended by the GCSA and the public responders on the Call for Evidence, either to facilitate access and allocate adequate funds to cancer screening in national cancer plans or to ensure optimal communication and integration of screening in the whole cancer pathway. Sources also agree that adherence, efficacy and cost-effectiveness of the screening programmes should be monitored at EU level.

Extending breast cancer screening to women younger than 50 and an additional national vaccination programme against HPV for cervical cancer are specific recommendations supported by all consulted sources.

5.2 Scientific basis for and feasibility of extending screening to other cancers

All sources supported the extension of population screening to cancers for which there is scientific evidence of a good harm-benefit ratio, cost-effectiveness, advantages of early detection, and feasibility throughout the EU. It was also emphasised that the substantial false-positive rates of new screenings need to be reduced.

Screening for lung cancer before symptoms appear can result in earlier diagnosis, reduced mortality, and reduced expenditure. The GCSA, the public contributors to the Call for Evidence and EU countries' representatives all favour lung cancer screening using low dose computed tomography for current and ex-smokers. Screening for lung cancer is recommended by all respondents to be combined with smoking cessation support.

Many sources are also in favour of extending to PSA-based prostate cancer screening, combined with MRI scanning as a follow-up test and follow-up path. Targeted screening and risk-based approaches are mentioned, but further research is needed on the cost-effectiveness, harm-benefit ratio and an earlier start-age in familial cases of prostate cancer screening.

According to the Scientific Opinion of the GCSA, population-based screen-and-treat programmes for Helicobacter pylori are only recommended for gastric cancer in regions with intermediate to high gastric cancer incidence. Population-based screening for H. pylori was not supported by all EU countries, and only minimally supported by public contributors.

5.3 Scientific elements of risk-based cancer screening and early diagnosis

Both the GCSA and the public contributors to the Call for Evidence are aware of the rapidly developing technological possibilities and scientific knowledge to optimise risk-based cancer screening and early detection. Some of these technologies can be used to optimise the selection criteria and the frequency of screening. Digital innovations, such as AI and machine learning, can improve risk models for cancer detection. Several new screening methods, in particular less invasive and blood-based (multiple) cancer screening methods (liquid biopsies, genomic testing, early detection tests, biomarkers etc.), are also promising, but are not yet ready for implementation.

6. How feedback was taken into account

The opinions, suggestions and recommendation of the consulted sources on a new EU Cancer Screening Scheme were taken into account.

With regard to improving the current screening programmes, the Commission recognises the great importance of improving the participation of citizens in cancer screening and of putting more effort in quality improvement and assurance, building more screening capacity and training healthcare professionals. The Commission also emphasises that these screening programmes should be coordinated, and monitored and evaluated systematically.

Regarding extending screening to other cancers, the Commission plans are in line with the recommendation to extend population screening to cancers for which there is scientific evidence of a good harm-benefit ratio, cost-effectiveness, advantages of early detection, and feasibility throughout the EU taking a step-wise approach.

To optimise risk-based cancer screening and early diagnosis the Commission considers the importance of innovative screening technologies and the need for a system of "living guidelines" that can be rapidly updated in response to new scientific findings.

The consultation also revealed a variety of more detailed technical suggestions, which will be taken into consideration during the implementation phase of the new EU Cancer Screening Scheme.