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Subject:	Proposal for a COUNCIL RECOMMENDATION on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC

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2022/0290 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

on strengthening prevention through early detection: A new EU approach on cancer screening

replacing Council Recommendation 2003/878/EC

{SWD(2022) 296 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Reasons for and objectives of the proposal

The current Council Recommendation 2003/878/EC sets out recommendations for cancer screening. It encourages Member States to implement population-based, quality-assured screening programmes. It has been instrumental in improving cancer screening and ensuring that the vast majority of people in the target age ranges have access to organised screening.

The 2017 implementation report[1] on the Council Recommendation and the European Guide on Quality Improvement in Comprehensive Cancer Control[2] pointed to several ongoing challenges and needs, most importantly that the current Recommendation is not based on the latest evidence. Since 2003, new screening tests and protocols have been validated and introduced in the Member States, and new evidence supports the extension of screening recommendations to other cancers than covered by Recommendation 2003/878/EC. The European Guide on Quality Improvement in Comprehensive Cancer Control, and the Joint action on innovative partnerships for action against cancer[3] launched in 2019 identify prostate, lung, and gastric cancers as potentially suitable for inclusion in future recommendations.

This proposal for a new Council Recommendation replacing Recommendation 2003/878/EC has the following objectives:

- Supporting cancer screening through the whole pathway of cancer care as part of a new Union approach to cancer prevention under Europe's Beating Cancer Plan.
- Supporting the development of the new EU-supported Cancer Screening Scheme to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025;
- Regular systematic monitoring of screening programmes including disparities via the European cancer information system and the Cancer Inequalities Registry;
- Sharing data on cancer screening, including through the planned European Health Data Space[4];
- Updating the breast, cervical and colorectal cancer screening recommendations;
- Extending breast cancer screening from women aged 50 to 69 to include women between 45 and 74 years of age and to consider specific diagnostic measures for women with particularly dense breasts;
- Prioritising cervical cancer screening by testing for human papilloma virus (HPV) for women aged 30-65 instead of pap smear screening between the ages

[1] Cancer Screening in the European Union (2017). Report on the implementation of the Council Recommendation on cancer screening.
[2] https://cancercontrol.eu/archived/uploads/images/Guide/pdf/CanCon_Guide_FINAL_Web.pdf
[3] https://www.ipaac.eu/res/file/outputs/wp5/new-openings-cancer-screening-europe.pdf#page=15
[4] https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

of 20-30 and supporting its eradication through the uptake of vaccination against HPV below 15 years of age;

– Using faecal immunochemical testing for colorectal cancer screening instead of faecal occult blood screening as the preferred triage test for referring individuals aged 50-74 for follow-up colonoscopy ;

– Extending cancer screening programmes to lung and prostate cancer as well as to gastric cancer in those countries or regions with the highest gastric cancer incidence and death rates;

– Taking into account the latest scientific knowledge and innovative technologies, and considering the introduction of novel cancer screening programmes based on minimally invasive methods, for instance liquid biopsies, exhaled breath gas, and other methods.

Consistency with existing policy provisions in the policy area

This proposal for a new Council Recommendation is a key element of the new EU-supported Cancer Screening Scheme. The scheme is one of the flagship initiatives of the Europe's Beating Cancer Plan[5], a key pillar of the European Health Union announced in the 2020 State of the Union address by President Ursula von der Leyen.

The new cancer screening scheme has two main objectives. First, to increase by 2025 the screening rates for breast, colorectal and cervical cancer in the Union, by building on the most recent evidence and methods, and facilitating more targeted and less invasive screenings together with a quality-assured and secured follow-up. Second, the scheme aims to extend organised screening to prostate, lung and gastric cancer (the latter under certain conditions), based on the assessment of validated new screening tests, and on consideration of more general health system parameters, including risk-benefit ratio and cost-effectiveness.

The new EU-supported Cancer Screening Scheme seeks to make the most from digitalisation and health data via the European cancer imaging initiative and the planned European Health Data Space, which aims to develop new diagnostic technologies and to enable cancer patients to securely access and share their health data in an integrated format in the electronic health records between healthcare providers and across borders in the Union.

Consistency with other Union policies

The Mission on Cancer[6] under the Horizon Europe framework programme for research and innovation (2021-2027) is a major component of the Union's investment in cancer research and innovation. Several of the planned actions[7], namely on optimised and improved access to existing screening programmes, developing new methods and technologies for screening and early detection, and developing early predictors/tests will directly support the new EU-supported Cancer Screening Scheme and create an important link between Research and Innovation (R&I) and cancer policies.

5 https://ec.europa.eu/health/system/files/2022-02/eu_cancer-plan_en_0.pdf

6 https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/cancer_en

7 https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/cancer_implementation_plan_for_publication_final_v2.pdf

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

Legal basis

The Treaty on the Functioning of the European Union, and in particular Article 168(6) provides that the Council, on a proposal from the Commission, may adopt recommendations for the purposes set out in that article. This includes the possibility to adopt a recommendation on cancer screening, which complements national policies and contributes to preventing cancer, which is a major health issue in the Union.

Subsidiarity (for non-exclusive competence)

The updated Council Recommendation aims to establish general principles for cancer screening as recommended by the Group of Chief Scientific Advisors and to set out the best practices for cancer screening in the Union.

A Union recommendation based on guiding principles and a joint analysis of the underlying evidence provides added value for Member States, which will not have to embark on individual assessments and can use this as a basis for their national cancer screening policies, while the form of a Council Recommendation allows Member States to adapt their approach to their national needs.

Proportionality

This proposal offers recommendations for evidence-based, patient-centred cancer screening through a systematic population-based approach and, when appropriate, through risk-stratified[8] cancer screenings, supported by European guidelines, with quality assurance at all appropriate levels, in line with the guidelines developed under the European Commission Initiative on Breast Cancer, which have been recently updated[9]. The proposal is suitable for achieving the intended objective and does not go beyond what is necessary and proportionate, as the recommendations help Member States to upgrade their cancer screening programmes leaving ample room for Member States to adapt their approach to national needs and resources.

Choice of the instrument

The Council Recommendation 2003/878/EC on cancer screening is almost 20 years old, and needs to be updated by another Council Recommendation to take into account the increased knowledge about effective cancer screening, while leaving thebasic principles for cancer screening unchanged.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

Ex-post evaluations/fitness checks of existing legislation

N/A

Stakeholder consultations

Stakeholders were consulted on the call for evidence[10] in relation to the update of the Council Recommendation on cancer screening, which was published for feedback from 25 January to 22 February 2022. A total of 87 genuine responses were received,

8 Screening targeted to individuals at higher risk of cancer

9 https://healthcare-quality.jrc.ec.europa.eu/ecibc

10 https://ec.europa.eu/newsroom/sante/items/736795/en

with the majority of replies coming from non-governmental organisations, company/business organisations, consumer organisations/consumers, public authorities, and academic/research institutions. The stakeholders' replies included the need to improve and extend current cancer screening programmes and use of innovative and new technologies, as well as the need for quality assurance and coordination of the screening programmes.

In addition, several meetings of relevant thematic groups of the Cancer Plan's stakeholder contact group and three meetings specifically dedicated to the proposal with the cancer sub-group of the Steering Group on Health Promotion and Disease Prevention and Management of Non-Communicable Diseases took place. Member State experts advised to take into account feasibility, cost-effectiveness and scientific evidence when deciding on new screening programmes and favoured a stepwise approach for the implementation of the new screening programmes.

The opinions, suggestions and recommendations of stakeholders were analysed and taken into account as much as possible. Some of the issues raised were rather detailed and technical and should rather be taken into account during the implementation phase. The outcomes of these consultations and how they were taken into account is described in detail in the synopsis report.

The public had already been consulted in the context of the public consultation on Europe's Beating Cancer Plan[11]. Therefore, no additional public consultation was undertaken.

Collection and use of expertise

The Group of Chief Scientific Advisors published its scientific opinion on cancer screening in the European Union[12] on 2 March 2022. The aim of the opinion was to examine how the Commission can contribute to improving cancer screening across the Union and to inform the Commission's 2022 proposal to update the 2003 Council Recommendation on cancer screening.

The Group's opinion makes three main recommendations:

(1) ensure that existing screening programmes for cervical, colorectal, and breast cancer integrate state-of-the-art scientific knowledge, are coordinated within the whole pathway of cancer management and are centred on the citizens.

(2) extend population-screening programmes to cancers for which scientific evidence demonstrates a good harm-benefit ratio, cost-efficiency, advantages of early detection, and feasibility throughout the Union, whilst regularly reviewing scientific evidence for screening of other cancers.

(3) take advantage of rapidly developing technological possibilities and scientific knowledge to optimise early diagnosis and risk-based cancer screening.

Impact assessments

An impact assessment was not considered necessary as the Commission acted upon the opinion of the Group of Chief Scientific Advisors. The form of a Council

[11] https://health.ec.europa.eu/consultations/public-consultation-europes-beating-cancer-plan_en and https://eurohealthobservatory.who.int/publications/m/europe-s-beating-cancer-plan-consultation-factual-report-from-the-targeted-stakeholder-consultation

[12] https://op.europa.eu/en/publication-detail/-/publication/519a9bf4-9f5b-11ec-83e1-01aa75ed71a1

Recommendation is a non-binding measure and leaves ample room for Member States to adapt their approach to national needs.

4. BUDGETARY IMPLICATIONS

None

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on strengthening prevention through early detection: A new EU approach on cancer screening

replacing Council Recommendation 2003/878/EC

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty- on the Functioning of the European Union, and in particular Article 168(6) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Pursuant to Article 168(1) of the Treaty of Functioning of the European Union, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities. Union action, which is to complement national policies, is to be directed towards improving public health, preventing physical and mental illnesses and diseases, and obviating sources of danger to physical and mental health, including cancer.

(2) Further development of cancer screening programmes should be implemented in accordance with national law and national and regional responsibilities for the organisation and delivery of health services and medical care.

(3) Cancer is a major disease and cause of death throughout Europe. In 2020, an estimated 2.7 million people in the Union were diagnosed with cancer. Extrapolating from the figures for 2020, it is estimated that one in two Union citizens will develop cancer during their lifetime, with long-lasting consequences on their quality of life, and only half of all cancer patients will survive.

(4) Council Recommendation 2003/878/EC sets out recommendations for cancer screening in the Union. It encourages EU Member States to implement population-based, quality-assured screening programmes, and it has been instrumental in improving cancer screening and ensuring that the vast majority of people, in the target age ranges, including from all socio-economic groups and throughout the territory, have access to organised screenings.

(5) Additionally, the governance, organizational requirements, and evaluation of cancer screening have been discussed and information has been shared at Union level, together with the outcomes of experiences gathered under the actions on cancer screening supported under the EU Health Programme[1].

(6) Screening makes it possible to detect cancers at an early stage, or possibly even before they become invasive. Some lesions can then be treated more effectively with a greater

[1] https://www.ipaac.eu/

chance that patients can be cured. The main indicator for the effectiveness of screening is a reduction of incidence and a decrease in disease-specific mortality.

(7) Evidence shows the efficacy of screening for breast, colorectal, cervical, lung and prostate cancers, and gastric cancer in certain conditions.

(8) Screening is the testing for diseases of people in whom no symptoms have been detected. In addition to its beneficial effect on the incidence and on the disease-specific mortality, the screening process has inherent limitations which can in some cases have negative effects for the screened population. These include false positive results, which can cause anxiety and may require additional testing that also has potential harms, and false-negative results that provide false reassurance leading to delays in diagnosis. Healthcare providers should be aware of all the potential benefits and risks of screening for a given type of cancer before embarking on new organised cancer screening programmes. Furthermore, these benefits and risks need to be presented in an understandable way that allows individual citizens to express an informed consent to participate in the screening programmes.

(9) Ethical, legal, social, medical, organisational and socio-economic aspects have to be considered before decisions can be made on the implementation of cancer screening programmes.

(10) Due account should be taken of specific needs of women, older people, persons with disabilities, and disadvantaged or marginalised groups, like people with a minority racial or ethnic background ,and difficult to reach persons, of low-income groups, cancers survivors and of individuals who may be at higher cancer risk for particular reasons, for instance persons with chronic liver conditions, with genetic or familiar predisposition, or with lifestyle, environmental, and occupational risks.

(11) Furthermore, the needs of people with disabilities for special assistance to access cancer screening and/ or for adapted clinical facilities, should be duly taken into account, as well as people in remote areas who have major difficulties to reach the cancer screening services in the regions.

(12) The public health benefits and cost efficiency of a screening programme, including the potential impact on cost saving on health and long-term care systems, are achieved if the programme is implemented according to a stepwise approach, in an organised and systematic way, covering the whole target population and following evidence-based and up-to-date European guidelines with quality assurance, which should ensure the appropriate monitoring of the quality of the screening programmes.

(13) The cost-effectiveness of cancer screening depends on several factors such as epidemiology, and healthcare organisation and delivery.

(14) Systematic implementation requires an organisation with a call/recall system and with quality assurance at all levels, and an effective and appropriate diagnostic, treatment and after-care service following evidence-based guidelines.

(15) Centralised data systems are needed to run organised screening programmes. Those systems should include a list of all categories of persons to be targeted by the screening programmes and data on all screening tests, assessment and final diagnoses, including the data related to the cancer stage when detected through the screening programmes.

(16) All procedures for collecting, storing, transmitting and analysing data in the medical registers and other national and regional official instruments involved must be in full

compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)[2]. In addition, these procedures should seek alignment and interoperability with procedures for collecting, storing and transmitting data with those already developed in other initiatives, including in the European Reference Networks for rare diseases dedicated to cancer.

(17) The Commission Communication on enabling the digital transformation of health and care in the Digital Single Market, empowering citizens and building a healthier society, set the principles to help ensure interoperability in collecting, storing and transmitting data with those systems already developed in other initiatives[3], in full compliance with applicable data protection legislation.

(18) Quality screening includes analysis of the process and outcome of the screening and rapid reporting of these results to the population and screening providers.

(19) This analysis is facilitated if the screening data and appropriate information is linked to and interoperable with cancer registries, incidence and mortality data. Secondary use of data from screening programmes is a valuable resource for cancer research and technological advancement in cancer care, in particular when combined with other data sources such as genomic data. Such secondary data could be obtained under the planned European Health Data Space.

(20) Adequate training of personnel is a prerequisite for high quality screening.

(21) Specific performance indicators have been established for cancer screening tests. These should be monitored regularly.

(22) Adequate human and financial resources should be available in order to ensure the appropriate organisation and quality control in all the Member States. European Funds allocated to Cohesion Policy, notably the Regional Development Fund and European Social Fund Plus, as well as the EU4Health Programme and Horizon Europe might be mobilised to co-finance part of the necessary investments and expenditure, including in research.

(23) Action should be taken to ensure equal access to quality screening, taking due account of the possible need to target particular socioeconomic groups or areas with impaired access to healthcare facilities.

(24) It is an ethical, legal and social prerequisite that cancer screening should only be offered to fully informed people with no symptoms if the screening is proved to decrease disease-specific mortality, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.

(25) The screening methods which presently meet these strict prerequisites are listed in the Annex.

(26) The screening tests listed in the Annex can only be offered on a population basis in organised screening programmes with quality assurance at all levels, and if good information about benefits and risks, adequate resources for screening, follow-up with

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2 OJ L 119, 4.5.2016, p. 1.

3 For instance, under the scope of the present Communication: cancer registries, other national and regional cancer information systems, the European Cancer Information System, the European Reference Networks for rare diseases dedicated to cancer, the planned European Health Data Space, and other relevant data sources and infrastructures.

complementary diagnostic procedures and, if necessary, treatment of those with a positive screening test are available.

(27) Additionally, screening listed in the Annex, and in particular lung, prostate, and gastric cancer screenings, should be implemented in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes. Screening will be implemented with the support of evidence-based European guidelines with quality assurance, to help ensure the roll-out and the monitoring of the screening programmes.

(28) The recommended screening tests in the Annex, which have demonstrated their efficacy, should be seriously considered, the decision of Member States to introduce the recommended screening tests being based on available professional expertise, priority-setting for healthcare human and financial resources in each Member State, and the availability of European guidelines with quality assurance to monitor the quality of the screening programmes.

(29) The introduction of new programmes or techniques for cancer screening involving ionising radiation must be in full compliance with the provisions of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, including the responsibilities of Member States to ensure the concerned professionals receive adequate training on radiation protection aspects of the technique, implementation of quality assurance programmes and quality control of radiological equipment, evaluation of radiation doses and establishment of diagnostic reference levels, and to ensure the involvement of the medical physics expert in optimising imaging procedures.

(30) Screening methodologies are subject to ongoing development. The application of recommended screening methodologies should, therefore, be accompanied by simultaneous assessments of the quality, applicability and cost-effectiveness of new methods if available data justify this. The ongoing and forthcoming work, including the development of European guidelines with quality assurance, may lead to the identification of new screening approaches and new methods, which could ultimately replace or complement the tests listed in the Annex or be applicable to other types of cancer.

(31) International technical cooperation, particularly in the framework of the WHO's International Agency for Research on Cancer, can directly contribute to improving screening programmes and guidelines in the EU and globally.

(32) On 28 May 2008, the Council Conclusions on 'Reducing the burden of cancer' invited the Commission to examine the obstacles to the successful implementation of proven screening methods and to ensure medium- and long-term scientific and professional support to Member States in implementing Council Recommendation 2003/878/EC.

(33) In May 2017, the report on the implementation of Council Recommendation 2003/878/EC recommended to update the Council Recommendation as new screening tests and protocols have been validated and introduced in the EU Member States since 2003, and to include policies for the regular updates of cancer screening guidelines and of the implementation reports.

(34) On 22 April 2021, the Commission gave a mandate, through its Scientific Advice Mechanism, to the Group of Chief Scientific Advisors to prepare scientific advice on

improving cancer screening across the Union, targeting in particular: (i) how to ensure that existing screening programmes for cervical, colorectal, and breast cancers integrate state-of-the-art scientific knowledge; (ii) the scientific basis for extending cancer screening programmes to other cancers, for instance lung, prostate and gastric cancers, and their feasibility throughout the Union; and (iii) the main scientific elements to consider for optimising risk-based cancer screening and early diagnosis throughout the Union.

(35) On 30 June 2021, the Commission launched the new, evidence-based European guidelines with quality assurance for breast cancer[4] and presented the European cancer information system[5] as a key system for monitoring and projecting the burden of cancer.

(36) On 10 December 2021, Council Conclusions on strengthening the European Health Union recalled that the health, economic and social insecurities due to the COVID-19 pandemic had disrupted health promotion and prevention programmes, and negatively impacted access to early diagnosis and treatment of cancer at times of severe pressure on hospital facilities, and that this could have detrimental effects on the incidence and survival of cancer.

(37) Additionally, those Council Conclusions invited the Commission to ensure, as appropriate, effective implementation of the Europe's Beating Cancer Plan, and support Member States in implementing effective cancer control actions, by means of appropriate instruments and tools, including considering submitting a proposal for an update of Council Recommendation 2003/878/EC.

(38) On 3 February 2022, the Commission Communication on 'Europe's Beating Cancer Plan' COM(2021) 44 final, announced the development of a new EU-supported Cancer Screening Scheme to help Member States ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025. The scheme is to be supported by Union funding and to focus on making improvements in three key areas: access, quality and diagnosis.

(39) The new EU-supported cancer screening scheme under the 'Europe's Beating Cancer Plan' also provides for a revision of Council Recommendation 2003/878/EC, including an update of the tests used for breast, cervical and colorectal cancers, and the possible extension of organised screening programmes to additional types of cancers, namely lung, prostate and gastric cancers, taking into account new evidence-based knowledge.

(40) On 2 March 2022, the Commission's Group of Chief Scientific Advisors delivered its scientific opinion 'Cancer screening in the European Union' on improving cancer screening across the Union. This opinion recommended to update the methodology and tests for breast, cervical, and colorectal cancer screening, and to extend organised cancer screening programmes to lung, prostate, and, in certain conditions, gastric cancer, as indicated in the Annex. The opinion was based on the evidence review report 'Improving cancer screening in the European Union' by the consortium Science Advice for Policy by European Academies (SAPEA).

(41) The Commission's Group of Chief Scientific Advisors also advised to take advantage of the rapidly developing technological possibilities and scientific knowledge to optimise early diagnosis and risk-based cancer screening across the Union.

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4 https://healthcare-quality.jrc.ec.europa.eu/ecibc

5 https://ecis.jrc.ec.europa.eu/

(42) On 16 February 2022, the European Parliament adopted a Resolution on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy, which also took account of the working document of its Special Committee on Beating Cancer of 27 October 2020 entitled 'Inputs of the Special Committee on Beating Cancer to influence the future Europe's Beating Cancer Plan'. The Resolution supported the launch of a new EU-supported Cancer Screening Scheme, as announced in the Europe's Beating Cancer Plan. The new EU-supported Cancer Screening Scheme aims to help Member States to ensure that 90% of the EU population who qualify for breast, cervical and colorectal cancer screenings are offered screening by 2025.

(43) The Resolution also called on the Commission to include other cancers in the scheme, based on the latest scientific evidence, with clear targets for each type of cancer, and to evaluate every 2 years the results of the cancer screening scheme in terms of equal access of the target population, to keep track of inequalities between Member States and regions, to propose appropriate new measures and correlate screening programmes with the latest cancer screening research results.

HEREBY RECOMMENDS TO MEMBER STATES:

Implementation of cancer screening programmes

(1) To offer evidence-based and person-centered cancer screening, taking into account the basic principles of safety, ethics, public engagement and equity, through systematic population-based programmes and, when appropriate, offer 'risk-stratified cancer screenings'; the types of cancer and the respective target populations, which should be considered are listed in the Annex;

(2) To implement accessible screening programmes in accordance with European guidelines with quality assurance, where they exist, through a stepwise approach to take account of available human and financial resources.

(3) To facilitate the development of piloting 'risk-stratified cancer screenings' protocols, guidelines, and indicators for high quality and accessible cancer screening programmes on a national and, where appropriate, regional level with adequate territorial coverage including rural and remote areas;

(4) To ensure that benefits and risks are presented to the people participating in the screening in an understandable way, allowing individuals to express informed consent when deciding on participation in the screening programmes, and that the principles of health literacy and informed decision-making to increase participation and equity are taken into account;

(5) To ensure adequate, timely, and complementary diagnostic procedures, treatments, psychological support and after-care to those individuals with a positive screening test;

(6) To make available human and financial resources in order to assure appropriate organisation and quality control;

(7) To assess and take decisions on the national or regional implementation of a cancer screening programme depending on the disease burden and the healthcare resources available, the side effects and cost effects of cancer screening, and experience from scientific trials and pilot projects;

(8) To set up a systematic call/recall system and quality assurance at all appropriate levels, together with an effective and appropriate diagnostic and treatment and after-care service following evidence-based guidelines;

(9) To ensure that due regard is paid to data protection legislation.

Registration and management of screening data

(10) To make available centralised data systems needed to run organised cancer screening programmes;

(11) To ensure by appropriate means that all persons targeted by the cancer screening programme are invited, by means of a call/recall system, to take part in the programme;

(12) To collect, manage and evaluate data on all screening tests, assessment and final diagnoses, including the data related to the cancer stage when detected in the context of the cancer screening programmes;

(13) To collect, manage and evaluate the data, including making the data available for cancer research, including implementation research and development of improved technological possibilities for early cancer diagnosis and prevention, in full compliance with applicable data protection legislation.

Monitoring

(14) To regularly monitor the process and outcome of organised cancer screening and report these results quickly to the public and the personnel providing the screening;

(15) To ensure the appropriate registration, collection, storage and management of data and information using the European cancer information system, to allow the monitoring of cancer screening performance and impact indicators, and other additional information, which can be instrumental to help ensuring the most efficient roll-out of screening programmes, in full compliance with applicable data protection legislation.

Training

(16) To adequately train personnel at all levels to ensure that they are able to deliver high quality screening.

Compliance

(17) To seek a high level of compliance, based on fully informed consent, when organised cancer screening is offered;

(18) To take action to ensure equal access to screening taking due account of the possible need to target particular socioeconomic groups;

(19) To ensure by appropriate means that persons with disabilities, as well as people living in rural or remote areas can access cancer screening services, and that clinical facilities for cancer screening are suitable for persons with disabilities.

Introduction of novel screening tests taking into account international research results

(20) To implement new cancer screening tests in routine healthcare only after they have been evaluated in randomised controlled trials;

(21) To run trials, in addition to those on screening-specific parameters and mortality, on subsequent treatment procedures, clinical outcome, side effects, morbidity and quality of life;

(22) To assess the level of evidence concerning the effects of new methods by pooling trial results from representative settings;

(23) To consider the introduction into routine healthcare of potentially promising new screening tests, which are currently being evaluated in randomised controlled trials, once the evidence is conclusive and other relevant aspects, such as cost-effectiveness in the different healthcare systems, have been taken into account;

(24) To consider the introduction into routine healthcare of potentially promising new modifications of established screening tests once the effectiveness of the modification has been successfully evaluated, possibly using other epidemiologically validated surrogate endpoints.

Implementation report and follow-up

(25) To report and follow up report to the Commission on the implementation of this Recommendation within 3 years of its adoption and, subsequently, every 4 years to help follow up this Recommendation in the Union.

HEREBY WELCOMES THE COMMISSION'S INTENTION:

(1) to report on the implementation of cancer screening programmes, on the basis of the information provided by Member States, not later than the end of the fourth year after the date of adoption of this Recommendation, to consider the extent to which the proposed measures are working effectively, and to consider the need for further action;

(2) to encourage cooperation between Member States in research and the exchange of best practices as regards cancer screening with a view to developing and evaluating new screening methods or improving existing ones;

(3) to support European research on cancer screening, including the rapid development of European guidelines with quality assurance to help ensuring that cancer screenings indicated in the annex are timely, and fully operational and quality-proofed. Additionally, to help showing the evidence of the social and economic benefits of such programmes;

(4) to work in close cooperation with Member States towards overcoming legal and technical barriers impeding the interoperability among cancer and screening registries, other national and regional cancer information systems, the European cancer information system, the European Reference Networks for rare diseases dedicated to cancer, the planned European Health Data Space, and other relevant data sources and infrastructures, in full compliance with applicable data protection legislation .

Final provisions

This Recommendation should be regularly reviewed by the Commission. In addition to the reporting on the implementation of cancer screening programmes (see (1) above), the Commission should report thereon regularly to the Council.

Recommendation (2003/878/EC) is replaced by this Recommendation.

Member States are invited to give effect to this Recommendation by [date].

Done at Brussels,

For the Council
The President