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From:	Presidency
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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

Delegations will find in Annex the Presidency compromise proposal.

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

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 **in line with Article 168(7) of the Treaty of Functioning of the European Union**.

(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 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.

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

(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**, and overdiagnosis, i.e. detection of cancer cases not expected to cause symptoms in patients during their lifetime**. 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 **and gender equity** 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 **genetic or familiar predisposition, 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~~ **effectiveness** 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, **incurred expenses** 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~~ **Appropriate** 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 **as appropriate** 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.

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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.

(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 **and in full compliance with Regulation (EU) 2016/679**.

(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. **This assessment should be an inherent part of the implementation at national level.**

(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 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~~ **may** 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 202**1**~~2~~, 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.

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

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

(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.

(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 **for implementation of the screening programmes, within national priorities**.

(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, **potentially including on a health professional-to-patients basis,** 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**, tailored to needs at national level**;

(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 **aim at** set**ting** 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 **use** ~~make available~~ **appropriate** ~~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 **aim at** collect**ing**, manag**inge** and evaluat**inge** 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~~ **and consider where appropriate,** 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 **aim at** ensur**inge** the appropriate ~~registration, collection, storage and management~~ **processing** 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~~ Participation

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

(18) To take action to ensure ~~equal~~ **equitable** access to screening taking due account of the possible need to target particular socioeconomic groups **or regions in the country**;

(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) ~~t~~**T**o 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 **as appropriate in collaboration with the Member States** the extent to which the proposed measures are working effectively, and **in cooperation with the Member States** to consider the need for further action;

(2) ~~t~~**T**o 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) ~~t~~**T**o 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, **evidence-based, cost-effective** and fully operational and quality-proofed. Additionally, to help showing the evidence of the social and economic **risks and** benefits of such programmes;

(4) ~~t~~**T**o work in close cooperation with Member States towards overcoming legal and technical barriers ~~impeding~~ **in order to improve** 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 **and avoiding duplications of activities and information transmitted**.

(5) To complement national efforts by providing information activities among the general public and stakeholders about the benefits and the risks of 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.

~~**Final provisions**~~

This Recommendation should be regularly reviewed by the Commission **and the Member States**. 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

ANNEX

Cancer screenings, which fulfil the requirements of the recommendation and for which technical specifications will be further specified in European guidelines with quality assurance**. The indicated age ranges are to be understood as indicative ranges based on current evidence and subject to national epidemiological evidence and prioritization, smaller age ranges may be appropriate.**

The annex takes into account the scientific advice[1] of the Group of Chief Scientific Advisors on improving cancer screening across the EU, which has been informed by the evidence review report[2] of the Science Advice for Policy by European Academies consortium entitled 'Cancer screening in the EU'. The evidence review report summarises the results of clinical trials published since 2007, and how to improve the existing cancer screening programmes for breast, colorectal and cervical cancer. In addition, taking into account the existing evidence, the scientific advice is to extend the organised screening programmes to lung and prostate cancer, and to gastric cancer in the countries with the highest gastric cancer incidence and death rates.

Member States are invited to consider implementation of following cancer screenings, while assessing and taking decisions on the national or regional level 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. For individuals with increased risk of a particular cancer, member states should consider specific programmes with extended target populations and intensity, considering scientific evidence and local context.

[1] Scientific advice of the Group of Chief Scientific Advisors on improving cancer screening across the EU https://op.europa.eu/en/publication-detail/-/publication/519a9bf4-9f5b-11ec-83e1-01aa75ed71a1

[2] Cancer screening in the EU https://sapea.info/topic/cancer-screening/

Breast cancer:

Breast cancer screening for women starting aged 45 to 74 with digital mammography or digital breast tomosynthesis[3], and for women with particularly dense breasts consider magnetic resonance imaging (MRI), where medically appropriate.

Cervical cancer:

Testing for human papilloma virus (HPV) for women aged 30 to 65 with an interval of 5 years or more, and consider adapting ages and intervals to individual risk based on the HPV vaccination history of the individuals.

Colorectal cancer:

Faecal immunochemical testing (FIT), quantitative with thresholds defined per sex and age and earlier test result is considered the preferred screening test for referring individuals to follow-up colonoscopy between 50 and 74 years old. Endoscopy may be adopted as a primary tool to implement combined strategies.

Lung cancer:

Considering the evidence for screening with use of low-dose computed tomography, and the need for a stepwise approach, countries should begin to test feasibility of this programme by using implementation studies coupled with planned and organised smoking cessation intervention strategies, start with current and ex-smokers who have quit smoking within the previous 15 years, are aged 50 to 75 years and have a smoking history of 30 pack-years (equivalent to smoking 20 cigarettes per day for 30 years)[4].

[3] European guidelines on breast cancer screening and diagnosis | ECIBC (europa.eu)
[4] Cancer screening – SAPEA

Prostate cancer:

Considering the evidence and the significant amount of ongoing opportunistic screening, countries should take a stepwise approach, including piloting and further research to evaluate the feasibility of implementation of organised programmes[5] aimed at assuring appropriate management and quality on the basis of prostate-specific antigen (PSA) testing for men up to 70, in combination with additional magnetic resonance imaging (MRI) scanning as a follow-up test.

Gastric cancer:

Screening for *Helicobacter pylori* should be considered in those countries or regions inside countries with high gastric cancer incidence and death rates, according to thresholds to be defined in European guidelines with quality assurance. Screening should also address strategies for identification and surveillance of patients with precancerous stomach lesions unrelated to *Helicobacter pylori* infections.

Considering the evidence for screening and the need for a stepwise approach, countries should begin to test the feasibility of this programme, including by using implementation studies.

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[5] cancer-screening-workshop-report-01.pdf (sapea.info)