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From:	Presidency
To:	Delegations
Subject:	Final Presidency compromise text on Council Recommendation on cancer screening

Delegations will find in Annex a Presidency compromise proposal for Council recommendations on the above-mentioned subject to be examined at the meeting of the Working Party on Public Health on 11 November 2022.

In comparison to document 13038/22 REV 1, new additions are marked in **bold underline**, new deletions to the Commission Proposal in ~~**bold strikethrough**~~ and other new deletions in ~~**bold strikethrough underline**~~. Changes to the Commission proposal that were already presented at the meetings of the Working Party on Public Health on 11 and 24 October are visible as underline and ~~strikethrough~~.

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 European Commission,

Whereas:

- (1) Pursuant to Article 168(1) of the Treaty on the 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~~. **Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education and monitoring.**
- (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 on the 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 ~~for~~^{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, organisational 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~~^{acquired through} the actions on cancer screening supported under the EU Health Programme¹.
- (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 ~~of~~^{for} the effectiveness of screening is a reduction ~~in~~^{of} ~~incidence and a decrease in~~ disease-specific mortality or in incidence of the invasive cancer.

¹ <https://www.ipaac.eu/>

- (7) Evidence shows the efficacy of screening for breast, colorectal and, cervical, cancer. According to the evidence review report ‘Improving cancer screening in the European Union’ by the consortium Science Advice for Policy by European Academies (SAPEA), there is strong scientific evidence for adding low-dose CT lung cancer screening, good scientific evidence for the benefit of organised, population-based PSA-based prostate cancer screening and (to a lesser extent) prostate cancers, and insufficient evidence on the benefits of introducing screening for gastric cancer. However, the introduction of well-designed screen-and-treat strategies for reducing H. pylori infection (a major cause of gastric cancer) could be considered for countries with high rates of the disease. gastric cancer in certain conditions/circumstances. All of Wilson and Jungner’s criteria² for responsible screening, as well as the additional criteria set out by the WHO³, should be used to assess the feasibility of a screening programme.
- (8) Screening is the process of testing for diseases in people in whom no symptoms have been detected. In addition to its beneficial effect ~~on the incidence and~~ on the disease-specific mortality and on incidence of the invasive cancer, the screening process also 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~~ may pose potential risks/harms, and false -negative results, ~~which that~~ provide false reassurance leading to delays in diagnosis, ~~and overdiagnosis~~, (i.e. detection of cancer-eases not expected to cause symptoms in patients during the patient’s lifetime) and subsequent overtreatment.- 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~~ give informed consent to participate in the screening programmes.
- (9) Ethical, legal, social, medical, organisational, ~~and~~ socio-economic, ~~and~~ gender equity equality, and healthcare capacity and resource aspects ~~have to~~ must be considered before decisions can be made on the implementation of cancer screening programmes.

² Wilson JMG, Jungner G; Principles and Practice of Screening for Disease, World Health Organization, 1968
³ <https://apps.who.int/iris/bitstream/handle/10665/270163/PMC2647421.pdf>

- (10) Due account should be taken of the specific needs of **men and** women, older people, ~~people~~ **persons** with disabilities, and disadvantaged or marginalised groups, like people with a minority racial or ethnic background, and difficult-to-reach persons **and non-responders to screening invitations**, of low-income groups, cancers survivors and of individuals who may be at higher ~~cancer~~ risk of developing cancer or more severe forms thereof for particular reasons, for instance ~~non-responders to screening invitations~~, ~~people~~ persons with a genetic or familial predisposition, people with chronic liver conditions, with genetic or familial predisposition, or people with lifestyle, environmental, and occupational risks.
- (11) Furthermore, **the individual needs of** the needs of ~~people~~ **persons** with disabilities' **need** for **support or** special assistance in order to access cancer screening ~~and~~ or for adapted clinical facilities; should be duly taken into account, as well as the needs of people in remote areas who have major difficulties ~~to~~ reaching the cancer screening services in their regions.
- (12) The public health benefits and ~~cost-efficiency-effectiveness~~ of a screening programme, including the potential impact on ~~cost~~ savings 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; ~~that~~ 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 **and sufficiently high participation of the target group.**
- (14) Systematic implementation requires governance, an organisation with a call/recall system and with quality assurance at all levels, and an effective and appropriate, **accessible and available** 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~~ people to be targeted by the screening programmes and data on all screening tests, assessments and final diagnoses, including ~~the data related to the cancer~~ stage of the cancer 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)⁴. In addition, these procedures should seek alignment and interoperability, as appropriate, with those procedures for collecting, storing and transmitting data ~~with those already developed under~~ 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 ~~out~~ the principles to help ensure interoperability with systems for ~~in~~ collecting, storing and transmitting data ~~with those systems already developed under~~ in other initiatives⁵, 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.

⁴ OJ L 119, 4.5.2016, p. 1.

⁵ For instance, under the scope of ~~that 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.

- (19) This analysis is facilitated if the screening data and appropriate information is linked to and interoperable with cancer registries, and 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~~ European digital infrastructures 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~~ are highly important 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 of participating in the screening programme are well-known and the benefits outweigh the risks, 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~~should only be offered on a population basis if a screening programme satisfies the criteria for responsible screening by Wilson & Jungner, as well as the additional criteria set out by the WHO. Moreover, screening tests should only be offered in organised screening programmes with quality assurance at all levels, and if ~~good~~reliable information about benefits and risks, adequate resources for screening, follow-up with complementary diagnostic procedures and, if necessary, treatment ~~for~~ those with a positive screening test are available.
- (27) Additionally, the screening tests listed in the Annex, and in particular lung, prostate, and gastric cancer screenings, ~~should~~can be implemented in a stepwise approach to ensure the gradual and appropriate planning, piloting, and roll-out of the screening programmes within national priorities. Screening will be implemented with the support of evidence-based European guidelines ~~with~~and quality assurance schemes, to help ensure the roll-out and the monitoring of the screening programmes. It is noted that national contexts, i.e. human and financial resources, affordability, as well as healthcare capacity in Member States, is to be taken into account when implementing new screening programmes.
- (28) The recommended screening tests in the Annex; ~~which have demonstrated their efficacy,~~ should be ~~seriously~~thoroughly considered, the decision ~~of~~by Member States to introduce the recommended screening tests being based on available professional expertise, priority-setting for ~~healthcare~~ human and financial resources as well as for healthcare capacity in each Member State, and the availability of European guidelines ~~with~~and quality assurance schemes 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 as regards the responsibilityies of Member States to ensure the ~~concerned~~ professionals concerned receive adequate training on radiation protection aspects of the technique; the implementation of quality assurance programmes and the quality control of radiological equipment; the evaluation of radiation doses and the establishment of diagnostic reference levels; and ~~to ensure~~ing 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, **systematic** 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 and quality assurance schemes, 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.
- (31a) Through Regulation 2021/2282 on health technology assessment (HTA) the European Union can support voluntary cooperation between Member States with a view to providing real world evidence related to diagnostics used to prevention or screening programmes.**
- (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 **second** ~~Report~~ Report on the implementation of Council Recommendation 2003/878/EC recommended ~~to update~~ the Council Recommendation, as new screening tests and protocols ~~had~~ have been validated and introduced in the EU Member States since 2003, and ~~to include~~ including 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, ~~target~~ focusing in particular on: (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~~ and quality assurance scheme for breast cancer⁶ and presented the European cancer information system⁷ 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~~cancer incidence and survival rates~~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 2021~~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 ~~e~~Cancer sScreening sScheme 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.

⁶ <https://healthcare-quality.jrc.ec.europa.eu/ecibc>

⁷ <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~~updating the methodology and tests for breast, cervical, and colorectal cancer screening, and ~~to~~extending organised cancer screening programmes to lung, prostate, and, in certain ~~conditions~~circumstances, 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~~taking 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~~the 'Resolution on strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy', which also took account of the working document ~~of~~by 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~~two years the results of the ~~e~~C~~ancer s~~Screening s~~S~~cheme in terms of equal access ~~of~~for the target population, in order to keep track of inequalities between Member States and regions, to propose appropriate new measures and to 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 within national priorities, taking into account the basic principles of safety, ethics, public engagement and equity, through systematic population-based programmes and, when appropriate and relevant, 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~~ and quality assurance schemes, where they exist, through a stepwise approach ~~to~~ taking account of available human and financial resources as well as healthcare 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, including potential overdiagnosis and overtreatment, are presented to the people participating in the screening in an understandable way, potentially including on a health professional-to-~~participant~~patients basis, allowing individuals to express informed consent when deciding ~~to~~ participate 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 and, treatments, ~~psychological support and after care to~~ for those individuals with a positive screening test; to offer aftercare and psychological care where it is necessary, possible and relevant, i.e. human and financial resources as well as healthcare capacity in Member States, is to be taken into account;
- (6) to make ~~available~~ human and financial resources available in order to ~~as~~ ensure 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 setting~~ 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 collecting~~, ~~managing~~ and ~~evaluating~~ data on all screening tests, assessments and final diagnoses, including the data related to the ~~cancer~~ stage of the cancer 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 ensuring the appropriate ~~registration, collection, storage and management~~ processing of data and information in 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. The monitoring should be done taking into account the capacity and resources in the Member States and should not impose an unnecessary registration burden on the healthcare systems.

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 **and marginalised** 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 **if they have conclusive scientific evidence of efficacy**;
- (21) to run trials, in addition to those on screening-specific parameters and mortality, on subsequent diagnosis and treatment procedures, clinical outcomes, 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 and organisational aspects 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~~three years of its adoption and, subsequently, every ~~4~~four years to help follow up on this Recommendation in the Union. The reporting should be done without imposing an unnecessary reporting/registration burden on the Member States and their healthcare systems.

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, as appropriate in collaboration with the Member States as appropriate,~~ 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) 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, in particular, on early predictors/tests, scores or algorithms and with the aim of reducing overdiagnosis and overtreatment;

- (3) to support European research on cancer screening, including the rapid development of European guidelines ~~with and~~ quality assurance schemes to help ensuring that the cancer screenings indicated in the ~~a~~ Annex are timely, evidence-based, cost-effective and fully operational and quality-proofed. Additionally, to help ~~showing~~ present the evidence of the social and economic risks and benefits of such programmes;
- (4) to 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~~ European digital infrastructures, 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, if requested, by providing technical support with information activities, **where relevant**, among for the general public and stakeholders about the benefits and the risks of participation in the screening programmes, and that taking into account the principles of health literacy and informed decision-making, to increase participation and equity are taken into account.

Final provisions

~~†~~ The measures included in this Recommendation should be regularly reviewed by the Commission and in collaboration with 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

Technical specifications for the Ccancer screenings listed below, which fulfil the requirements of the rRecommendation, and for which technical specifications will be further specified in European guidelines with quality assurance schemes. The indicated age ranges are to be understood as indicative ranges based oncurrent evidence and subject to national prioritization, smaller age ranges may be appropriate. Member States are invited to assess their national and regional cancer screening governance arrangements to enable timely and effective implementation of **any new or updatedchanges in the** European guidelines.

The aAnnex takes into account the scientific adviceopinion⁸ of the Group of Chief Scientific Advisors on improving cancer screening across the EU, which has been informed by the evidence review report 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 eervical cancer. In addition, taking into account the existing evidence,, tThe scientific advice opinion **advisepropose**– extending 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. However, further evidence is needed on real-life effectiveness, cost-effectiveness and feasibility of particular screening strategies.

Member States are invited to consider implementation of the following cancer screenings, based on conclusive scientific evidence, while assessing and taking decisions on the national or regional level depending on the disease burden and the healthcare resources available, the harm-benefit balance side effects and cost-effectiveness of cancer screening, and experience from scientific trials and pilot projects. For individuals with increased risk of a particular cancer, mMember sStates should consider specific programmes with extended target populations and intensity, considertaking into account scientific evidence and local context.

⁸ Scientific adviceopinion 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>

Breast cancer:

Considering the evidence presented in the European guidelines⁹, ~~B~~breast cancer screening for women ~~starting~~ aged 45~~50~~ to 74~~69~~ with digital mammography as a minimum is recommended. A lower age limit of 45 years, an upper age limit of 74 years, and the use of digital breast tomosynthesis is suggested~~should be considered~~, and for women with particularly dense breasts consider magnetic resonance imaging (MRI), where medically appropriate.

Cervical cancer:

Testing for human papilloma virus (HPV) using only clinically validated assays as the preferred screening tests for women aged 30 to 65 with an interval of ~~five~~ years or more, and ~~e~~Consider adapting ages and intervals to individual risk based on the HPV vaccination history of the individuals, and also consider the possibility of offering kits allowing women to take a self-sample, especially for non-responders to screening invitations.

Colorectal cancer:

~~Quantitative F~~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 ~~t~~for follow-up colonoscopy between 50 and 74 years old. Quantitative information from FIT results might be used to implement risk-tailored strategies, introducing thresholds defined per sex, age and earlier test results. Endoscopy may be adopted as a primary tool to implement combined strategies.

Lung cancer:

Considering the preliminary evidence for screening with use of low-dose computed tomography, and the need for a stepwise approach, countries ~~should begin to test~~should explore the feasibility and effectiveness of this programme, for instance by using implementation studies. The programme should integrate —coupled with planned and organised smoking cessation intervention strategiesprimary and secondary prevention approaches, focusing initially on current heavy smokers and heavy ex-smokers. starting 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) high risk individuals. Special

⁹ [European guidelines on breast cancer screening and diagnosis | ECIBC \(europa.eu\)](#)

Furthermore, attention should be given to the identification and targeting of **other** high risk profiles, ~~inter alia smokers and ex smokers, and~~ Member States should further research how to reach and invite the target group, as there is **for example** no systematic data **documentation (registry)** on smoking behaviour.

Prostate cancer:

Considering the preliminary evidence and the significant amount of ongoing opportunistic screening, countries should ~~take~~consider a stepwise approach, including piloting and further research, to evaluate the feasibility and effectiveness of the implementation of organised programmes¹⁰ aimed at ~~as~~ensuring 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~~Screen-and-treat strategies– for *Helicobacter pylori*, including implementation studies, 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~~ and quality assurance schemes. 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.~~

¹⁰ [cancer-screening-workshop-report-01.pdf \(sapea.info\)](#)